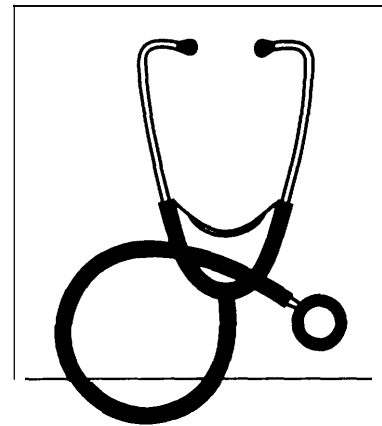


Evidence on the Effectiveness of a Select Group of Clinical Preventive Services

3

There is a vast literature on the effectiveness of preventive health care services. The purpose of this chapter is to present a general overview of the current state of knowledge about the effectiveness of a select group of clinical preventive services in order to address the issue of whether effectiveness criteria can and should be used to design insurance benefits for preventive services. The review relies heavily on previous reviews, particularly those that used a systematic and explicit approach to evaluating the evidence. Organizations which have reviewed the evidence on the effectiveness of clinical preventive services include the U.S. Preventive Services Task Force (USPSTF), the Canadian Task Force on the Periodic Health Examination (CTFPHE), and the Centers for Disease Control and Prevention's (CDC) Immunization Practices Advisory Committee (ACIP) (see appendix F for a description of these groups and the methods they used to determine effectiveness). Because research has progressed since these organizations completed their reviews, subsequent studies which may have altered previous conclusions about effectiveness are identified. Conclusions of other groups, such as specialty societies and other government agencies, are also presented in order to provide a sense of the degree of consensus about the effectiveness of a particular intervention. However, most of the specialty societies, and some of the government agencies, did not base their conclusions on comprehensive reviews of the evidence, nor clearly link their recommendations to the research evidence. Therefore, although the recommendations of these organizations are presented, they are not used to draw conclusions about effectiveness.

This chapter reviews the evidence on effectiveness of most of the services recommended by the USPSTF for asymptomatic



individuals on the basis of individuals' sex and age, as opposed to other indications of risk such as family history (see table 3-1 for a list of the preventive interventions recommended by the USPSTF and appendix G for the periodic health examinations recommended by the USPSTF). In addition, some of the clinical preventive services which the USPSTF did not recommend for routine use are also reviewed (table 3-2 lists some of the interventions which the USPSTF did not recommend as appropriate for routine use in asymptomatic populations). Finally, all of the services included in major congressional health care reform proposals introduced in the 102d Congress are reviewed (see appendix H for a description of these proposals).

REVIEW OF THE EVIDENCE

Annual General Physical Examination

In the 1920s, the American Medical Association (AMA) and the Metropolitan Life Insurance Company first endorsed the annual physical examination as conferring long-term benefits (128). However, over the years the wisdom of this approach has been questioned. In 1979, the CTFPHE recommended that annual checkups for adults be abandoned and that primary care prevention be selectively provided according to age- and sex-specific packages of health services (29).

The CTFPHE criticized annual physical examinations on several grounds. First, they argued that the content and frequency of the examinations bore little relation to the needs of different age groups. Second, they found that there was little evidence that the tests and procedures typically included in the checkup examination were effective. Third, they found that procedures were repeated once a year even though many could have been performed equally effectively at longer intervals. In sum, they found that "the

routine general annual check-up is nonspecific and casts a searching net far too broadly, particularly in the adult, is inefficient and, at times, is potentially harmful" (29).

Although the annual physical examination is no longer recommended, both the USPSTF and CTFPHE recommend periodic health examinations. The difference between the periodic health examination and the annual physical examination is that the former: 1) is provided less frequently; 2) more specifically details the interventions which should be included; 3) places a greater emphasis on tailoring interventions to individual circumstances; and 4) is limited primarily to those services which have been shown to be effective. In large part, the rest of this chapter describes the evidence on the effectiveness of services which might be included in the periodic health examination.

Breast Cancer Screening

In 1993, an estimated 183,000 new cases of breast cancer will be diagnosed and 46,300 people will die from breast cancer (20). Breast cancer is the most frequently occurring cancer in women in the United States and the second most common cause of cancer death among women (20).

There is good evidence from randomized clinical trials and case-control studies that a combination of clinical breast examinations and mammography reduce breast cancer mortality in women aged 50 and older (63,101,187,224). Most studies, however, have not shown a clear benefit of mammography and clinical breast examination for women aged 40 to 49 (see Hurley and Kaldor for a review of these studies, [101])¹ and the optimal onset for screening is controversial. Questions also remain about the optimal periodicity of screening and about the independent effects

¹ The randomized clinical trials are cited in the references at the end of this report and include refs. 168, 174, 9, 158, 76, 140, 141. The case-control studies are also cited and include 226, 47, 156.

Table 3-I-Preventive Interventions Recommended By the U.S. Preventive Services Task Force for Nonpregnant, Asymptomatic Persons, 1989^a**SCREENING**

- History
- Height and weight
- Blood pressure
- Breast examination by clinician
- Mammogram
- Papanicolaou smear
- Screening for visual acuity
- Eye exam for amblyopia and strabismus
- Glaucoma testing by an eye specialist
- Screening for hearing loss
- Screening for anemia using hemoglobin and hematocrit tests
- Screening for phenylketonuria (PKU)
- Screening for congenital hypothyroidism
- Nonfasting total blood cholesterol
- Thyroid function tests
- Urinalysis for asymptomatic bacteriuria, hematuria, and proteinuria

For high-risk groups only^b

- Complete skin exam for skin cancer
- Clinical testicular exam
- Auscultation for carotid bruits
- Palpation for thyroid nodules
- Complete oral cavity exam for oral cancer
- Screening for sickle cell disease
- Screening for diabetes using blood glucose measurement
- Fecal occult blood test/sigmoidoscopy
- Fecal occult blood test/colonoscopy
- Screening for lead toxicity
- Tuberculin skin test
- Rubella antibodies
- Syphilis testing
- Chlamydia testing
- Gonorrhea testing
- Counseling and testing for human immunodeficiency virus (HIV)
- Resting electrocardiogram
- Exercise stress test
- Radiologic screening to detect low bone mineral content

COUNSELING

- Counseling about diet, exercise, injury prevention, dental health, smoking cessation, substance use, sexual practices

CHEMOPROPHYLAXIS^c AND IMMUNIZATIONS

- Immunizations (Diphtheria-Tetanus- Pertussis [DTP], Oral poliovirus [OPV] Measles-mumps-rubella [MM R], Haemophilus influenza type b [Hib], Hepatitis B [HBV], Tetanus-diphtheria [Td] booster, Pneumococcal vaccine, influenza vaccine)
- Fluoride supplements
- Aspirin prophylaxis to prevent myocardial infarction
- Chemoprophylaxis with estrogen therapy

^a The frequency of these interventions vary substantially by age and gender.

^b Factors defining someone as "high risk" are factors other than age and gender, such as family history or behavioral characteristics.

^c Chemoprophylaxis is the use of chemical agents (e.g., aspirin, fluoride) to prevent disease.

SOURCE: U.S. Congress, Office of Technology Assessment, 1993, adapted from U.S. Preventive Services Task Force, *Guide to Clinical Preventive Services* (Baltimore, MD: Williams and Wilkins, 1989).

Table 3-2—Preventive Interventions Not Recommended By the U.S. Preventive Services Task Force for Use on Asymptomatic Persons, 1989

-
- Routine measurement of blood pressure using intra-arterial catheters
 - Routine screening for peripheral arterial disease in asymptomatic persons
 - Screening for prostate cancer using transrectal ultrasound and serum tumor markers (e.g., PSA)
 - Screening asymptomatic persons for lung cancer by performing routine chest radiography or sputum cytology
 - Screening of asymptomatic women for ovarian cancer
 - Routine screening for pancreatic cancer in asymptomatic persons
 - Screening of asymptomatic persons for risk of low back injury
 - Routine spinal radiographs of asymptomatic persons to screen for low back injury
 - Routine prenatal screening for maternal phenylketonuria (PKU)
 - Routine ultrasound screening of pregnant women at low risk for intrauterine growth retardation
 - Routine electronic fetal monitoring during labor for women not at increased risk for fetal distress
 - Screening for cognitive impairment among asymptomatic Persons^a
 - Performance of routine screening tests for depression in asymptomatic persons^b
 - Routine screening for suicidal intent^c
 - Routine screening interviews or examinations for evidence of violent injuries^d
 - Screening for alcohol or drug abuse using biochemical markers and drug testing
-

a The USPSTF recommends, however, that clinicians “remain alert for” changes in cognitive function in patients ages 65 and over.

b The USPSTF recommends, however, that clinicians “remain alert for” depressive Symptoms.

c The USPSTF recommends, however, that clinicians “remain alert for” suicidal risk factors.

d The USPSTF recommends, however, that clinicians “remain alert for” signs of physical abuse or neglect.

SOURCE: U.S. Congress, Office of Technology Assessment, 1993, adapted from U.S. Preventive Services Task Force *Guide to Clinical Preventive Services* (Baltimore, MD: Williams and Wilkins, 1989).

of mammography and clinical breast examination in reducing breast cancer mortality.

The Canadian National Breast Cancer Screening study was specifically designed to prospectively examine the efficacy of screening with yearly mammography and clinical breast examination as compared to no screening in women aged 40 to 49 years old at entry (140,141). The Canadian National Breast Cancer Screening study also examined the separate effects of mammography and clinical breast examination. The study concluded that at 7 years from entry “screening with yearly mammography and physical examination of the breasts detected considerably more node-negative, small tumors than the control group, but it had no impact on the rate of death from breast cancer” for the 40 to 49 year old age group (140). Similarly, the study found that screening women aged 50 to 59 with yearly mammography in addition to physical examination of the breasts detected considerably more node-negative, small tumors than screening with

physical examination alone, but it had no impact on the rate of death from breast cancer (141). The results of the Canadian trial are still being debated in the research community (16,160) and the study will follow patients for at least another three years (140,141).

The screening recommendations of different organizations reflect the uncertainties about the optimal protocols for breast cancer screening for average-risk women under 50 years old. The USPSTF recommended mammography screening and clinical breast examination for women age 50 and older every one or two years, concluding at approximately age 75 unless pathology has been detected. The USPSTF notes that it maybe ‘prudent’ to begin mammography at an earlier age for women at high risk for breast cancer. Most other groups also endorse periodic mammography screening and clinical breast examination of asymptomatic women for breast cancer; however, many recommend that screen-

ing begin at age 35 or 40.² These recommendations were published previous to the recent results of the Canadian National Breast Cancer Screening study and could change in light of these results.

Colorectal Cancer Screening

In 1993, an estimated 152,000 new cases of colorectal cancer will be diagnosed and 57,000 people will die from colorectal cancer in the United States (20). The detection of neoplasms (cancers and adenomatous polyps) in the colon or rectum involves either direct inspection of the colon and rectum or indirect measurement of biochemical markers for the presence of cancers or polyps (193). Today, the most common screening technologies are the fecal occult blood test (FOBT) and flexible sigmoidoscopy (193).³

The effectiveness of FOBT in reducing colorectal cancer morbidity is still being investigated and debated. Concerns center on the test's sensitivity, specificity and predictive capability (2). Although some medical organizations have recommended FOBT screening of asymptomatic adults (e.g., American College of Physicians, 1991 [63]; National Cancer Institute, 1991 [219]; American Cancer Society, 1991 [5]; and the American College Obstetricians and Gynecologists, 1988 [7]), the USPSTF and the CTFPHE concluded that there is insufficient evidence to recommend for, or against, FOBT in adults without risk factors for colorectal cancer (33,224). OTA concluded that FOBT screening improves the stage distribution of cancers detected, which may translate into decreases in cancer mortality; however, even in the very large trials ongoing at the time of OTA's 1990 review, no such mortality effect had been identified (193).

Results from one large randomized trial, the Minnesota Cancer Control Study, have recently been reported (135). The study randomly assigned more than 46,000 participants, 50 to 80 years of age, to either annual FOBT screening, biennial FOBT screening, or a no-screening control group. Those with a positive test were evaluated with colonoscopy. After 13 years, annual FOBT testing decreased the 13 year cumulative mortality from cancer by 33 percent. This trial may alter the previous conclusions of the USPSTF and other organizations. In addition, there are several other ongoing randomized control trials of FOBT screening of asymptomatic adults that should provide more evidence about its effectiveness (72,90,114,123).

The benefits of screening asymptomatic adults for colorectal cancer using sigmoidoscopy are also uncertain. The USPSTF concluded that "there is insufficient evidence to recommend either for or against fecal occult blood testing with sigmoidoscopy as effective screening tests for colorectal cancer in asymptomatic persons" (224), although they went on to state that "[it] may be clinically prudent to offer screening to persons age 50 and older with known risk factors for colorectal cancer" (224). Similarly, the CTFPHE concluded that there is not enough evidence on the effectiveness of sigmoidoscopy in reducing mortality to recommend it as a screening procedure in people who have no risk factors for colorectal cancer (33). In 1990, OTA concluded that there was inadequate evidence that sigmoidoscopy reduces cancer mortality rates over time; however, OTA noted that there had never been a good trial to determine the effect of screening with the flexible fiberoptic sigmoidoscopy on cancer mortality, so the lack of evidence on

²The American College of Physicians, 1991 (63), the American Academy of Family Physicians, 1993 (3), and the CTFPHE, 1979 (29) also recommend screening with mammography and breast physical examination beginning at age 50. The American Cancer Society, 1991 (5), National Cancer Institute, 1991 (219), and the American College of Obstetricians and Gynecologists, 1989 (7), recommend mammography beginning at age 35 or 40.

³Colonoscopy has also been recommended as a primary screening technique in people at increased risk of colorectal cancer based on family history (224).

outcomes should not be equated with the existence of negative evidence (193). Despite the paucity of direct evidence, some organizations have recommended regular screening with sigmoidoscopy, in conjunction with FOBT, for asymptomatic individuals who are over 50 years old (e.g., American College of Physicians, 1991 [63]; National Cancer Institute, 1991 [219]; American College of Obstetricians and Gynecologists, 1989 [7]; and American Cancer Society, 1991 [5]).

Two recent case-control studies concluded that screening by sigmoidoscopy can reduce mortality from cancer of the rectum and distal colon (149,167). Additional evidence about the efficacy of colorectal cancer screening may be provided by a large randomized trial being planned by the National Cancer Institute; however, the results from this trial will not be available for at least eight years (80).

Cervical Cancer Screening

In 1993, an estimated 13,500 new cases of cervical cancer will be diagnosed and 4,400 women will die from cervical cancer in the United States (20). The principal screening test for cervical cancer is the Papanicolaou (Pap) smear.

Although there have been no randomized clinical trials examining the effectiveness of cervical cancer screening in reducing mortality, the evidence from many case-control and observational studies over time suggest that screening is protective (62,193,224).⁴

Based on its review of the evidence, the USPSTF recommends regular Pap smears every one to three years (at the physician's discretion) for all women who are or have been sexually active, until age 65, at which age they may be discontinued if previous smears have been contin-

uously normal (224). Pap smears have also been recommended by a number of other organizations.⁵

Prostate Cancer Screening⁶

Among men, prostate cancer is the second most common cancer and the second most common cause of death from cancer in the United States (6). During 1993, it is estimated that 165,000 new cases of prostate cancer and 35,000 prostate cancer related deaths will occur in the United States (20). Screening tests for prostate cancer which are currently in clinical use include digital rectal examination (DRE), measurement of prostate-specific antigen (PSA), and transrectal ultrasound (TRUS) (95).

None of the screening methods have been assessed in randomized clinical trials in which the control group received no screening. This lack of demonstrated efficacy, in addition to the potential for false positives, uncertainty about the natural history of the disease, and treatment of clinically insignificant disease, has led reviewers to conclude that there is currently insufficient evidence that detection and treatment of prostate cancer in its early stages, using any of the three techniques mentioned, will improve survival (41,95,224).

DRE has not been shown to be effective in clinical trials and the USPSTF and CTFPHE made no recommendation either for or against routine DRE for prostate cancer (38,224). In contrast, other organizations have advocated its use for routine screening (e.g., the National Cancer Institute recommends annual DRE beginning at age 40 [219]).

Most organizations do not recommend serum tumor markers (e.g., PSA) or transrectal ultrasound for routine screening (e.g., 219). In fact the

⁴The studies reviewed by the USPSTF include the following references: 8, 11, 14, 43, 51, 89, 106, 124, 125, 142.

⁵The organizations which recommend Pap smears include: American Cancer Society, 1991 (5); the National Cancer Institute, 1991 (219); the American College of Obstetricians and Gynecologists, 1989 (7); the American Academy of Family Physicians, 1993 (3); and the American College of Physicians, 1991 (63).

⁶In a separate study, OTA is examining the effectiveness, safety, and costs of screening for prostate cancer in the Medicare population. The screening technologies to be considered are the digital rectal examination and prostate-specific antigen (PSA) technologies.

USPSTF and the CTFPHE recommended against using PSA and transrectal ultrasound for routine screening (38,224).⁷ However, the American Cancer Society recently recommended that PSA screening be done annually in conjunction with DRE on men 50 years of age and older (22). The National Cancer Institute is currently conducting a multicenter randomized trial of the value of TRUS, DRE and PSA screening, but the results from this trial will not be available for at least eight years (80,218).⁸

Cholesterol Screening

Despite the decline in the death rate from cardiovascular diseases over the past 15 years, cardiovascular diseases remain the number one cause of death in the United States (216). The association between elevated serum cholesterol level (hypercholesterolemia) and the risk of contracting and dying from cardiovascular disease is supported by a large body of evidence from epidemiologic, pathologic, animal, genetic, and metabolic studies (87,190).

Clinical interventions for preventing diseases associated with elevated cholesterol involve measuring blood cholesterol levels and, in patients with hypercholesterolemia, establishing a protocol for lowering cholesterol, either through diet or medication. Randomized clinical trials reveal a decrease in the incidence of coronary heart disease in middle-aged men with high blood cholesterol who are assigned to cholesterol-lowering drugs (48,75,130,131). There is also some evidence from clinical trials, albeit weaker, that lowering cholesterol through diet reduces the incidence of coronary heart disease in men (57,96,147,224).

Published clinical trials of the effects of lowering cholesterol offer little or no information about the effects of treatment on women of any

age, men with borderline cholesterol elevations, children, young adults, and the elderly (39,77). Similarly, although there is indirect evidence that high blood cholesterol during childhood may increase the risk of developing coronary heart disease in adulthood, the relationship between lowering cholesterol during childhood and decreased incidence of coronary heart disease during later life has not been demonstrated in controlled studies, in part due to the difficulty of performing such studies (224). The lack of direct evidence about whether routinely screening children, women, young men, and men older than age 65 would lower their mortality must be weighed against the potential cost and adverse effects of widespread cholesterol screening of these populations. Therefore, routine cholesterol measurement in these populations is controversial (77, 78,151).

Questions also remain about the association between reducing cholesterol levels and total mortality (i.e., mortality for all causes, including coronary heart disease). None of the randomized clinical trials of the effectiveness of lowering cholesterol on health outcomes found a significant effect on total mortality (190). In part, the failure to affect total mortality was due to a trend in several studies toward higher rates of death from noncardiovascular mortality, such as from violence, accidents, trauma, suicide, and cancer, in the groups receiving treatment to lower cholesterol (98,143,151,153).

Clinical practice guidelines regarding the detection and treatment of hypercholesterolemia are controversial (122). The USPSTF concluded that while there is evidence to support screening for hypercholesterolemia in high-risk groups, such as middle-aged males, there is no direct evidence from clinical studies that a policy of routine screening of the general population would achieve

⁷ A recent updated review by the USPSTF, not yet published, did not change its previous recommendation concerning DRE, PSA, and TRUS screening (59).

⁸ The trial will consist of 74,000 subjects aged 60 to 74 at entry. Each participant will undergo digital rectal examination and PSA screening every three years. Those with either a positive DRE or PSA test will then be screened using ultrasound (218).

significant reductions in mortality and morbidity (224). In their recommendations, the USPSTF stated that periodic measurement of total cholesterol was most important for middle-aged men and it may also be clinically prudent in young men, women, and the elderly. They noted that the optimal frequency for cholesterol measurement in asymptomatic persons has not been determined on the basis of scientific evidence and they recommended leaving the decision regarding frequency to clinical discretion (224).

In 1985, the National Heart, Lung, and Blood Institute (NHLBI) organized the National Cholesterol Education Program (NCEP) with the goal of developing a national policy for cholesterol reduction in the United States. In 1987, the NCEP issued their guidelines and stated that all adults age 20 and older should have their blood cholesterol level measured at least once every 5 years (more often for those with total cholesterol levels greater than 200 mg/dL). The NCEP recommended that low density lipoprotein (LDL) cholesterol be measured in persons who are candidates for intensive interventions (65,84) and also issued specific treatment recommendations (65). The NCEP recommended screening blood cholesterol levels only in those children and adolescents whose risk of developing coronary vascular disease as adults could be identified by family history or by the coexistence of several risk factors.⁹

The chief differences between the USPSTF and the NCEP guidelines are that the USPSTF recommended intensive treatment based primarily on

total cholesterol rather than LDL cholesterol, made less aggressive recommendations for screening women, and made no specific recommendations for children.

Hypertension Screening

Hypertension is a leading risk factor for coronary artery disease, congestive heart failure, stroke, renal disease, and retinopathy. As noted above, heart disease is the leading cause of death for both men and women in the United States (216), and in 1989, 733,867 people died from diseases of the heart (216). Sphygmomanometry (the blood pressure cuff) remains the most appropriate screening test for hypertension in the asymptomatic population (224).

After reviewing the evidence on the effectiveness of early detection of hypertension, the USPSTF concluded that “it is clear from several large clinical trials that lowering blood pressure is beneficial and that the population incidence of several leading causes of death can be reduced through the detection and treatment of high blood pressure” (224).

The USPSTF recommends “regular” blood pressure measurement in all persons age 3 and above (224). They note that the optimal frequency has not been determined and leave the determination to clinical discretion (224). Most expert groups recommend blood pressure measurement in asymptomatic populations, although the recommended frequency of measurement differs among organizations.¹⁰

⁹ The American Academy of Family Physicians recommends that healthy **asymptomatic** adults with no known risk factors have serum total cholesterol, fasting or nonfasting, at least every five years starting at age 20 (3). The American College of Physicians recommends total serum cholesterol measurement at least once during early adulthood and at intervals of 5 or more years up to age 70 (63).

¹⁰ The Canadian Task Force recommends blood pressure measurement for men and women ages 16 to 64 at least every 5 years and at every visit for other reasons (29). They recommend blood pressure measurement every two years in males and females aged 65 and older (29). In contrast, the American College of Physicians recommends blood pressure measurement for all adults ages 18 and older every one to two years (63). The American Academy of Family Physicians recommends that all adult patients ages 18 and older have their blood pressure **checked** at every physician visit with a minimum of once every two years (3). The Joint National Committee on **Detection**, Evaluation, and Treatment of High Blood pressure (**JNCV**) recommends blood pressure measurement every 2 years for people 18 years of age and older with systolic blood pressure less than 130 mm Hg and diastolic blood pressure less than 85 mm Hg (109). The **JNCV** recommends more frequent blood pressure measurement if the initial measurement was shown to be higher than 130 mm Hg and diastolic blood pressure less than 85 mm Hg. For children age 3 through adolescence, the **JNVC** recommends that blood pressure be measured once a year.

Smoking Cessation Interventions

In 1990, approximately 46 million adults in the United States smoked (212). Smoking is the leading preventable cause of death in the United States, and it is estimated to account for about 390,000 deaths annually (206). These include 30 percent of all cancer deaths, 21 percent of deaths from coronary heart disease, 18 percent of stroke deaths, and 82 percent of deaths from chronic obstructive pulmonary disease (214).¹¹ In addition, smoking during pregnancy contributes to low birthweight and fetal and infant mortality (214). Many of the risks associated with smoking have been found to diminish after quitting (214).¹²

Smoking cessation methods fall into two broad categories: self-help strategies (e.g., quitting on one's own) and assisted strategies (e.g., provider-initiated smoking cessation counseling, smoking-cessation clinics, nicotine chewing gum or nicotine patch) (213). Ninety percent of successful quitters used a self-help strategy, most by quitting abruptly (70). Only ten percent of those who quit use assisted strategies (70); however, these may be people who are more severely addicted. Insurance could cover all or some of the assisted methods. For example, benefits could cover physician advice about smoking cessation, smoking cessation classes, or prescriptions for nicotine patches or nicotine chewing gum.

A meta-analysis of 39 clinical trials of several different types of smoking cessation interventions (e.g., counseling, nicotine gum, written self-help materials) found that the average difference in the cessation rates between the intervention and the control group was 8.4 percent after 6 months and 5.8 percent after 1 year (119).¹³ Meta-analyses were also done for specific types of smoking

cessation intervention. Programs based on face-to-face advice had the best results, followed by programs based on nicotine chewing gum and self-help books. However, the main conclusion from the overall review was that reinforcement—by increasing the number of contacts, the types of contacts, and the number of people making the contacts—rather than a particular intervention or delivery system for the smoking cessation method, produces results (119).

The nicotine patch is a relatively new method of smoking cessation which delivers nicotine through the skin to prevent nicotine withdrawal symptoms. The efficacy of the nicotine patch was not evaluated in the meta-analysis by Kottke and colleagues described above, but is now widely used and has been studied in several clinical trials (1,27,53,73,102,111,144,146,159,177,178). Both nicotine gum and patches are recommended by their manufacturers only for use in conjunction with behavior modification programs (12,129,136,157). Other nicotine delivery forms which may become more widely used are nasal spray. At this time nicotine containing nasal spray for smoking cessation has not been approved by the Food and Drug Administration (54).

Although the average success rates associated with smoking cessation interventions are low, smoking cessation programs can result in a large absolute reduction in the number of smokers. For example, each year about 28 million of the 46 million smokers visit a physician (i.e., assuming 60 percent of the U.S. population has a physician office visit each year [216]). If all physicians counseled their smoking patients to quit and 3 percent of those counseled were able to quit, then physician-based efforts would potentially result

¹¹ The relative risk calculations for these estimates are based on the results of a prospective study sponsored by the American Cancer Society during the period 1982 to 1986 (79).

¹² For example, several prospective and retrospective epidemiologic studies have demonstrated the reduction in lung cancer risk over time following smoking cessation (214). After 10 years of abstinence, the risk of lung cancer is about 30 percent to 50 percent of the risk in continuing smokers (206). Smoking cessation for 5 or 10 years also reduces the risk of cancers of the larynx, oral cavity, esophagus, pancreas, and bladder (214).

¹³ The 95 percent confidence interval of the studies was plus or minus 2.8 and 2.6 percent, respectively.

in about 800,000 additional smokers quitting each year. Therefore, the overall effectiveness of smoking cessation programs, in terms of the potential to reduce mortality, may be large.

In 1989, the USPSTF recommended that smoking cessation counseling be offered on a regular basis to all patients who smoke, or use smokeless tobacco, although they left the frequency of smoking cessation counseling to clinical discretion (224). The USPSTF also outlined strategies that can increase the effectiveness of counseling regarding tobacco use, including: direct, face-to-face advice and suggestions; scheduled reinforcement; self-help materials; referral to community programs; and prescription of nicotine gum (224).

Adult Immunizations

Although the widespread implementation of childhood vaccination programs has substantially reduced the occurrence of many preventable diseases, the CDC has concluded that ‘successful childhood vaccination alone will not eliminate specific disease problems’ and that ‘a substantial proportion of the remaining morbidity and mortality from vaccine-preventable diseases presently occurs among older adults and adolescents’ (210).

The Immunization Practices Advisory Committee (ACIP) of the CDC issues recommendations for adult vaccination. The ACIP’s definition of the populations who should receive vaccinations varies. Some vaccinations are indicated for persons who escaped natural infection or were not previously vaccinated (e.g., vaccines against diphtheria, tetanus, measles, mumps, rubella, and poliomyelitis). Other vaccines are recommended for all older adolescents and adults (e.g., the ACIP recommends that all adults receive tetanus and diphtheria

boosters every 10 years). The use of other vaccines is indicated on the basis of age (e.g., all persons 65 and older should be immunized once for pneumococcal pneumonia and should receive influenza vaccinations). Finally, other vaccines are indicated according to individuals’ occupation, environmental situations, lifestyles, immigration status, and travel to some countries.

Prenatal Care

The five leading causes of infant death in 1989 were: 1) congenital anomalies, 2) sudden infant death, 3) disorders relating to short gestation and unspecified low birthweight, 4) respiratory distress syndrome, and 5) newborns affected by maternal complications of pregnancy (216). Prenatal care encompasses a wide range of preventive, diagnostic, and therapeutic services which may include screening for potentially harmful conditions in the mother and fetus, education and counseling, and nutritional supplements (188).

Evidence suggests that earlier and more comprehensive prenatal care can reduce infant mortality and prevent low birthweight and other perinatal complications, particularly in high-risk groups (188). However, review groups have concluded that more information is needed about which specific components of prenatal care are effective (188,205).

The USPSTF recommends that the following preventive interventions be provided to all pregnant women: blood pressure measurement; hemoglobin and hematocrit; ABO/Rh typing; Rh(D) antibody testing; syphilis screening; hepatitis B surface antigen (HBsAg); urinalysis for bacteriuria; gonorrhea culture; counseling about nutrition, tobacco use, alcohol and other drug use, and safety belts; maternal serum alpha-fetoprotein

¹⁴ The glucose tolerance test is used to test for gestational diabetes. The USPSTF found that the effectiveness of treatment for gestational diabetes in preventing most of the health risks associated with gestational diabetes (perinatal mortality, neonatal metabolic derangements, congenital anomalies) had not been demonstrated in well designed clinical trials. The USPSTF argued, however, that since treatment is unlikely to result in significant maternal or fetal harm, routine screening for gestational diabetes may be a reasonable measure. In contrast, other reviewers have concluded that the test is not reliable and because of the lack of demonstrated treatment efficacy, screening of pregnant women is unlikely to make a significant impact on perinatal mortality (100). Moreover, these authors argue that a positive test may provoke unwarranted and expensive testing and anxiety.

(MSAFP), and the oral glucose tolerance test.¹⁴ For women with selective risk factors they also recommend the following additional interventions: hemoglobin electrophoresis; rubella antibodies; chlamydia testing; counseling and testing for human immunodeficiency (HIV); ultrasound cephalometry; and ultrasound examination. The USPSTF notes, however, that their list is not exhaustive and reflects only the topics reviewed by the USPSTF.

A useful source of information about the effectiveness of prenatal care is the Cochrane Collaboration Pregnancy and Childbirth database (previously called the Oxford Database of Perinatal Trials) which comprises a register of most, if not all, of the reports of controlled trials in perinatal medicine. Very complete and systematic reviews of the efficacy of specific components of prenatal care, based on this database, were published in 1988 (40) and in 1992 (170). The Cochrane Collaboration Pregnancy and Childbirth database is being continuously updated and reviews and meta-analyses of perinatal research are published electronically, every six months, by the Cochrane Collaboration (24).

Newborn Screening for Congenital Disorders

About 4,500 cases of detectable diseases causing death or mental retardation occur in newborns each year (188). Newborn screening seeks to identify biochemical abnormalities that suggest the presence of disease in affected but as yet asymptomatic infants (188).

In most States, newborn screening is mandated by law, except in the case of parental refusal on religious or other grounds (188). In some States, the laws specify what types of testing will be done; in others, the range of tests included is determined by the health department, a government official, or a commission (10). The number of States that screen for various newborn congenital disorders is shown in table 3-3. Recently, some researchers have raised concerns about the

Table 3-3-The Number of States Screening for Specific Types of Newborn Congenital Disorders and Number of Cases Confirmed with the Diagnosis, 1990

Disorder	Number of States (and the District of Number of Columbia, Puerto Rico, confirmed and the Virgin Islands) cases, 1990	
Phenylketonuria (PKU)	52	337
Congenital hypothyroidism	52	1,190
Galactosemia	38	86
Hemoglobinopathy	42	N/A
Maple Syrup Urine Disease	22	3
Homocystinuria	21	9
Biotinidase deficiency	14	15
Congenital Adrenal Hyperplasia	8	51
Tyrosinemia	5	1
Cystic Fibrosis	2	14

SOURCE: Council of Regional Networks for Genetic Services (CORN), New York, NY, "Newborn Screening Report: 1990," supported in part by project #MCJ-361011-01-0 from the Maternal and Child Health Program (Title V, Social Security Act), Maternal and Child Health Bureau, Health Resources and Services Administration, United States Department of Health and Human Services, Rockville, MD, February 1992.

process by which States decide what diseases to require for screening (44,99).

The USPSTF recommends screening all newborns for phenylketonuria (PKU) and congenital hypothyroidism (224), as does the CTFPHE (29,36). The USPSTF recommends screening newborns of Caribbean, Latin American, Asian, Mediterranean, or African descent for sickle cell diseases. However, a NIH consensus conference has recommended universal screening for sickle cell diseases (49,220). In addition, a panel convened by the Public Health Service's Agency for Health Care Policy and Research recently recommended universal sickle cell testing, arguing that a baby race or ethnic ancestry cannot be inferred by name or appearance (26). Many of the tests currently part of State newborn screening programs have not been reviewed by the USPSTF.

Childhood Immunizations

All vaccines must undergo a structured approval process before being licensed for public use, and the efficacy of most childhood vaccines

in reducing mortality and morbidity has been well established on the basis of randomized controlled trials (126). The ACIP recommends that all children receive nine different vaccines (many in combination form and all requiring more than one dose). The nine vaccines are for measles, mumps, rubella (German measles), diphtheria, tetanus toxoids, pertussis (whooping cough), polio, haemophilus influenza Type b, and hepatitis B. Recommendations are also issued by the Committee on Infectious Diseases of the American Academy of Pediatrics (AAP), and the American Academy of Family Physicians (AAFP). In contrast to many other recommendations related to clinical preventive services, these groups attempt to keep their recommendations consistent with each other and there are only slight differences among their recommendations.¹⁵

Well-Child Care

When included in health reform proposals, specific services for children and adolescents are usually not individually identified, but rather are covered as a package of services termed “well child” or “well baby” care which are offered at various points in a child’s life. The components of well-child care include developmental screening, physical examinations, parent counseling, and immunizations and chemoprophylaxis (224). In its extensive 1988 review, OTA concluded that, when evaluated as a whole, there is no evidence to support the contention that well-child care (other than immunization) significantly influences mortality or morbidity among children (188), OTA noted, however, that the sample sizes, follow-up periods, and outcome measures in these studies were consistently poor, thus leaving open

the possibility that some medical benefits do exist. Several individuals and organizations have reviewed evidence on specific components of well-child care. Their findings are summarized below.

General Physical Examination

Physical examination involves a series of diagnostic procedures intended to detect a variety of medical conditions (188). In its 1988 report, OTA found that “all but one of the studies examining the effectiveness of the general physical examination concluded the exam has little merit” (188).

Some specific physical diagnostic procedures are the Ortalan maneuver for identification of congenital dysplasia of the hip, forward bending for detection of scoliosis, and abdominal palpation for detection of tumors. Reviews of specific physical examination procedures have been completed by the CTFPHE and USPSTF. The CTFPHE concluded that there was good evidence to recommend screening for congenital dislocation of the hip (37), but did not recommend screening for scoliosis (29). The USPSTF recently reviewed the evidence for screening for adolescent scoliosis and concluded that there was insufficient evidence to recommend for or against routine screening of asymptomatic adolescents (225). Given the lack of evidence, the USPSTF did not recommend routine visits to clinicians for the specific purpose of screening adolescents for scoliosis.¹⁶

Screening For Iron-Deficiency For Anemia

Anemia is a condition that exists when hemoglobin levels drop below the normal range of values for the population (224). In unselected

¹⁵ For example, the American Academy of Pediatrics recommends that a second dose of **MMR** vaccine be given at **approximately 12 years** of age, whereas the **ACIP** recommends that it be given at school entry, at ages 4 through 6, along with DTP and OPV. The second dose at 4-6 years may have two advantages: **primary** vaccine failures are corrected sooner and individuals may be easier to reach when they are entering school. The different recommendations may be a result of different views on the prevalence of primary vaccine failure and on the best way to reach the population.

¹⁶ The **AAP** recommends that a physical **examination** be performed on all children at regular intervals up to age 20 and possibly beyond (4).

populations of children, the overwhelmingly predominant **cause** of anemia is iron deficiency (74), and in childhood, screening for anemia is recommended largely as a screen for iron deficiency (188),

Hemoglobin concentration and hematocrit are the principal tests for detecting anemia. In their review, the USPSTF concluded that there was evidence from prospective studies to support screening for anemia in infants, and some evidence, although weak, to support screening in pregnant women. They found no evidence to support screening in other populations. Therefore, the USPSTF did not recommend routine testing for anemia for asymptomatic persons, except for pregnant women and infants (224). Other groups have found evidence only to support selective screening of high-risk groups. Based on their 1988 review, the OTA concluded that "... early identification of high-risk infants (e.g., those of low socioeconomic status) with either a capillary hemoglobin/hematocrit or free erythrocyte protoporphyrin (FEP) appears reasonable, with a liberal threshold for institution of a trial of iron therapy" (188). The CTFPHE suggests hemoglobin measurement of infants who are premature, those born of a multiple pregnancy or of an iron-deficient woman, and those of low socioeconomic status (29).¹⁷

Screening for Amblyopia and Strabismus

Amblyopia is subnormal visual acuity. The term specifically denotes a developmental disorder of visual function arising from either sensory stimulation deprivation or abnormal binocular interaction. In the latter sense amblyopia is familiarly known as "lazy eye" (137). Strabismus is a misalignment of the eye that the patient cannot overcome without aid. The condition is a lack of parallelism of the visual axes of the eyes,

which can result from neuromuscular or visual disturbances.

The USPSTF review of the literature revealed only one cohort study that addressed the effects of preschool screening for vision disorders (68). The study found that children who had been routinely screened prior to school entry had less vision impairment than did those who had not been screened. The USPSTF also indicated that there is evidence that interventions for amblyopia and strabismus are significantly less effective if started after age 5 and increase the risk of irreversible amblyopia, ocular misalignment, and other visual deficits.

The USPSTF recommends testing for amblyopia and strabismus for all children once before entering school, preferably at age 3 or 4. Screening for amblyopia and strabismus was also recommended by the CTFPHE (37).

Screening for Hearing Impairment

The USPSTF concluded that although the detection of hearing loss during infancy appears to be worthwhile, the screening tests currently available are too inaccurate for routine screening of children under age 3 (224). The USPSTF recommended hearing screening only for neonates at high risk for hearing impairment (e.g., family history of hearing impairment, congenital perinatal infections, low birthweight). In contrast, a NIH Consensus Development Conference recently recommended universal screening for hearing impairment of all infants shortly after birth (221).

The USPSTF found insufficient evidence of benefit to recommend hearing screening of asymptomatic children older than age 3 or in adolescents. Based on their review, OTA concluded in 1988 that the efficacy of screening preschool children for hearing impairment is unknown

¹⁷The AAP guidelines state "[p]resent medical evidence suggests the need for reevaluation of the frequency and timing of hemoglobin and hematocrit tests" (4). The AAP recommends a hematocrit or hemoglobin test once during infancy, early childhood, late childhood, and adolescence (4).

given the uncertain impact of hearing deficiency and treatment efficacy (188).

Developmental Screening

OTA reviewed the efficacy of the Denver Developmental Screening Test (DDST), which is the developmental screening tool most widely used and recommended for use by child health personnel (188). OTA concluded that while the evidence suggests that the DDST, when administered immediately prior to school entry, has a fair ability to predict developmental abnormalities accurately, there is limited evidence that the detection of a problem will result in improved school performance. In a 1989 review, the CTFPHE found only one randomized controlled trial that examined the effectiveness of the DDST (28,34). The study found no statistically significant differences in outcome between the control and screened groups, for example, in terms of their use of specialized educational services, academic achievement, cognitive and perceptual motor tests, and assessment of behavioral, social and emotional well-being. However, there was a statistically significant increase in worry about schoolwork among the parents of children in the intervention group. The CTFPHE recommended that the DDST not be included in the periodic health examination.

Urinalysis

Several conditions, including pyelonephritis (kidney infection) and renal scarring, are associated with asymptomatic urinary tract infection. Urinalysis is a common method of screening for urinary tract infection and is widely performed on asymptomatic children as apart of routine examinations (1 13). The USPSTF concluded that urine dipstick to detect the presence of bacteria maybe beneficial in preschool children, but further studies are needed to establish its effectiveness (224). A recent review of the effectiveness of urinalysis

found that the test had limited accuracy (113). Moreover, the reviewers found no evidence of benefit from early treatment and emphasized the risks associated with treatment. The reviewers concluded that periodic screening for the presence of bacteria should not be part of routine well-child care.¹⁸

Frequency of Well-Child Care Services

Scientific evidence about the optimal frequency of childhood preventive interventions is lacking (224). The CTFPHE recommended that healthy term infants have six well-baby visits within the first two years of life (37). The USPSTF recommended five visits from birth to 18 months, but stated that clinicians should exercise discretion in selecting an appropriate schedule (224). The American Academy of Pediatrics recommends nine visits from birth to age 2, yearly visits from age two to age six, and biennial visits from age 6 to age 20 (4).

Summary

In Summary, at present well-child care may include procedures which have been found effective, ineffective, or whose effectiveness has not been evaluated. Immunizations are highly effective and are universally recommended as a component of well-child care. There is some evidence to support screening for vision impairment (for amblyopia and strabismus), hearing impairment, congenital dysplasia of the hip, and hematocrit or hemoglobin testing for anemia in infants, particularly those at high risk. More research is needed to confirm the effectiveness of routine urinalysis, other types of physical examinations (e.g., for scoliosis), developmental behavioral assessments, and to determine the frequency of well-child care visits. The efficacy of screening for cholesterol and hypertension was reviewed elsewhere. Blood pressure measurement in children is recommended by a number of groups,

¹⁸ The AAP has written that "[p]resent medical evidence suggests the need for reevaluation of the frequency and timing of urinalysis" (4). In the interim, the AAP recommends that urinalysis be done once during infancy, early childhood, late childhood and adolescence (4).

although screening for cholesterol is controversial.¹⁹

Contraceptive Services

Contraceptive services include counseling and the provision of contraception. Contraceptive methods **that are** highly efficacious include: oral contraception (birth control pills), intrauterine devices (IUDs), condoms, diaphragms, and sterilization (224). The effectiveness of contraception depends largely on its correct use (196). Counseling is one way to increase the effectiveness of methods to prevent pregnancy. Counseling can be provided in several clinical settings, including physicians' offices and family planning clinics.

No direct evidence indicates that physician counseling can lead to more effective contraceptive use or lower pregnancy rates. Despite this acknowledged lack of evidence, the USPSTF recommends that clinicians obtain a detailed sexual history from all adolescents and adult patients, and based on this information, that clinicians provide counseling on the level of risk associated with the patient's current contraceptive techniques and, when indicated, available contraceptive methods. The CTFPHE also recommends the inclusion of counseling to prevent unwanted pregnancy in the periodic health examination of adolescents (32).

Sexually Transmitted Diseases

In the United States, the most prevalent sexually transmitted diseases (STDs) include HIV infection, genital herpes, genital warts, syphilis, gonorrhea, and chlamydia. It has been estimated that, in the United States, 1 million persons are infected with HIV (208), 20 to 30 million with

genital herpes (108), and 12 to 24 million with human papillomavirus which causes genital warts (120).²⁰ In addition, more than 55,000 cases of syphilis in the infectious stage, the highest number in 40 years, were reported in 1990 (112). In 1990, 700,000 cases of gonorrhea were reported by local health departments. Finally, an estimated 3 to 4 million men, women, and infants acquire chlamydia each year (207). While these prevalence statistics provide an indication of the enormity of the problem, they may underestimate the magnitude of the problem and must be viewed cautiously. Many STDs are not required to be reported, many are not easily diagnosed, and many are asymptomatic and unapparent (108,112).

Complications of STDs vary. The most serious complications from STDs include death, pelvic inflammatory disease (PID), sterility, ectopic pregnancy, chronic pelvic pain, gonococcal arthritis, blindness, cancer associated with human papillomavirus, fetal and infant death, birth defects, and mental retardation (196,206). The incidence of these complications is not trivial. For example, AIDS is the third leading cause of death in persons aged 25-44 (216), and an estimated 1 million cases of symptomatic PID occur annually in the United States (209).

The most efficacious way of preventing STDs and their complications is abstinence from sexual intercourse or maintenance of a mutually monogamous sexual relationship with an uninfected partner (196,224). For individuals who do engage in sexual intercourse, the most effective way to prevent transmission is to prevent the exchange of blood, semen or vaginal fluid (e.g., by use of a condom) (224).

Complications associated with STDs may be prevented and transmission reduced through early

¹⁹ The American Academy of Pediatrics recommends the following components for well-child care at various points in a child's life: height and weight measurement, head circumference measurement, blood pressure, vision and hearing screening for those at high risk, developmental and behavioral assessment (by history and appropriate physical examination and, if suspicious, by specific objective developmental testing), physical examination, hereditary and metabolic screening according to State law, immunization, tuberculin testing for high risk groups, hematoctrit or hemoglobin, urinalysis, anticipatory guidance, and initial dental referral (4).

²⁰ More recent studies using advanced screening technologies (i.e., the polymerase chain reaction [pCR] technique) suggest that the level of prevalence of subclinical cases of papillomavirus infections is substantially greater (13).

detection and treatment. Recommendations for STD screening have been balanced by concerns about the cost of screening, low yield of positive results due to relative low prevalence, and a high probability of false-positive results in low prevalence populations (23). The USPSTF recommends screening at-risk individuals for syphilis, chlamydia, gonorrhea, and HIV. The USPSTF and most other organizations that issue guidelines for STD screening (e.g., CDC, CTFPHE) have not recommended universal screening, but rather a strategy of assessing patient risk factors, by taking a history of sexual practices, and then selectively screening. Criteria identified as risk factors for certain STDs include the following: multiple sexual partners, sexual contact with a proven case, a sexual partner with multiple sexual contacts, a history of repeated STDs, being a resident of a high prevalence area, asymptomatic persons who attend clinics for STDs, asymptomatic persons who attend other high-risk health care facilities, homosexual or bisexual man or partner of same, IV drug abuser or partner of the same, or one who received a blood transfusion between 1978 and 1985.

SUMMARY

This chapter provides an overview of the current state of knowledge about a select group of

clinical preventive interventions some of which may be able to prevent or forestall a considerable amount of mortality and morbidity. The clinical preventive interventions identified in this chapter as effective for some asymptomatic individuals, include breast cancer screening, cervical cancer screening, smoking cessation interventions, cholesterol screening, hypertension screening, immunizations for adults and children, some components of prenatal care, screening for some newborn congenital disorders, some components of well-child care, contraceptive services, and screening for sexually transmitted diseases. Other services have been found to be effective, but only appropriate for persons at high risk (see table 3-1 for a list of some of these services). Not all clinical preventive interventions have been found to be effective. Moreover, even when preventive interventions are found to be effective for certain populations and applications, questions remain about their effectiveness when applied to other populations or in ways not directly studied.