Clinical Preventive Services in **Substance Abuse** and **Mental Health Update:**

From Science to Services

U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES
Substance Abuse and Mental Health Services Administration
Center for Mental Health Services
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Clinical Preventive Services in **Substance Abuse** and **Mental Health Update:** From Science to Services

Joel L. Nitzkin, MD, MPH
Shelagh A. Smith, MPH, CHES

U.S. Department of Health and Human Services
Substance Abuse and Mental Health
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Office of the Associate Director for Organization and Financing, Center for Mental Health Services, Substance Abuse and Mental Health Services Administration, 5600 Fishers Lane, Rockville, MD 20857.

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Table of Contents

Figures

Tables

1. Executive Summary

This report has been prepared to summarize the most promising preventive interventions of a behavioral nature intended to impact mental and substance use disorders, or in some cases, medical outcomes. This review focuses on prevention interventions that are primarily delivered by health care systems. Interventions provided in schools, worksites, communities, and criminal justice systems were excluded, as were population-based interventions.

The information provided here increases the rigor of a previous literature review published by SAMHSA in 2000 by Dorfman and updates it. That report was a first of its kind in that it reviewed the literature to identify preventive interventions in mental health and substance abuse that offer evidence for a positive effect on individuals, while imposing no additional cost to health plans, based on rigorous research studies. However, that report confined its discussion to only those studies with positive effects.

This newer report fills in the previous gaps by including all studies, regardless of outcome—even those with negative or no effects—and based on the literature, describes the optimal circumstances for implementing services and tracking costs. The descriptions may be most useful to health care organizations and providers in determining what preventive services to offer and how to implement them. The report may also be helpful to employee benefits designers and advisors, managed care organizations, employers, researchers, financial managers of health plans, and decisionmakers for benefit package services. A common barrier is that although rigorous research exists, often there is a lag time in applying research findings to practice.

The literature included in this monograph was published in English between 1964 and mid-2003. More than 3,000 papers and related documents were reviewed, and of those, approximately 530 were appropriate to be included in this report. Most of the literature items reviewed are research studies summarizing randomized or other controlled trials, as well as other governmental recommendations that were based on rigorous research studies, such as the precedent-setting universal recommendation in 2002 by the Agency for Healthcare Quality Research that adults be screened for depression.

Because the field of prevention of mental or substance use disorders has not yet uncovered a "magic bullet" equivalent to a vaccine in clinical medicine, we must rely on associated indicators to identify individuals who are at risk for developing disorders. For example, we may target known risk factors, such as those associated with disadvantaged first-time young mothers, or increase

protective factors that promote resilience. Based on the rigor of the research presented here, the breadth of applicability among interventions, and their potential cost-effectiveness for health plans, effective behavioral preventive interventions can be classified as basic or "general," or less widely applicable but "targeted" to certain groups at risk or within specific conditions.

The following interventions discussed here in detail have shown the greatest promise, based on the research reviewed, to diminish or prevent the development of a mental or substance use disorder. They can be categorized as "general" (universally applicable) or "targeted" to specific subgroups with certain risk factors.

- Universal screening of pregnant women for use of tobacco, alcohol, and illicit drugs.
- Home visitation for selected pregnant women, and some children up to age 5.
- Supplemental educational services for vulnerable infants from disadvantaged families.
- Screening children and adolescents for behavioral disorders.
- Screening adolescents for tobacco, alcohol, depression, and anxiety.
- Screening adults for depression and anxiety, and use of tobacco and/or alcohol.
- Psychoeducation to increase early ambulation of surgical patients, adherence to prescribed regimens of care for patients with chronic diseases, and to decrease somatization of other patients. Psychoeducation refers to counseling integrated with health education to address emotional, perceptual, and psychological barriers to compliance with prescribed regimens of care. Somatization refers to true physical symptoms and true physical illnesses that are initially psychogenic in nature.

According to the literature, services exhibiting the greatest potential to reduce costs include screening pregnant women for use of tobacco, alcohol, or drugs, with follow-up services; screening and follow-up for depression or other major mental illnesses in persons with major, chronic medical illness; and psychoeducation for heavy users of health care services, persons with chronic diseases, or persons scheduled to undergo surgery. This publication presents an analysis of the research basis for providing these services and guidelines for implementation, data collection, and management.

I. Introduction

The Substance Abuse and Mental Health Services Administration (SAMHSA) is a component of the Federal Government's Department of Health and Human Services (DHHS). In 2003, DHHS launched a campaign called *Steps to a Healthier U.S.* under the direction of DHHS Secretary Tommy Thompson. This initiative focuses on chronic disease prevention and health promotion. The connection between the health of the mind and the body is generally accepted, with a plethora of literature documenting that individuals with conditions such as cancer, heart disease, and hip fracture improve and survive longer when mental disorders such as depression are prevented or treated successfully.

This monograph explores the need for and value of preventive services for mental health and substance use disorders in health care settings. These disorders are widespread and costly, and they exact a high toll on our Nation and around the world. The World Health Organization (WHO) determined the "burden of disability" associated with one major mental illness, unipolar depression, ranked fourth among all leading causes of disability worldwide. By the year 2020, the disease burden from depression will rank number two, surpassed only by heart disease (Murray & Lopez, 1996). The disability and disease burden of various medical conditions were estimated by "disability-adjusted life years," or DALYs. This global burden has been underrecognized in economic cost and the impact on social structure.

In the United States, who has not been touched by a family member or a relative suffering from an emotional disorder or drug problem? In this country, in any given year, about 5–7 percent of adults have a serious mental illness, according to several national studies (New Freedom Commission, 2003). If milder mental disorders are included, about 40 million adults aged 18–64 years, or 22 percent of the population, had a diagnosis of a mental disorder (Kessler, McGonagle, Zhao, et al., 1994). About 20 percent of children are estimated to have mental disorders with at least mild functional impairment (DHHS, 1999), and those with serious emotional disorders make up approximately 5–9 percent of all children ages 9–17 (New Freedom Commission, 2003).

In 2002, an estimated 22 million Americans aged 12 or older were classified with substance dependence or abuse (9.4 percent of the total population) (SAMHSA, 2002). Of these, 3.2 million were classified with dependence on or abuse of both alcohol and illicit drugs; 3.9 million were dependent on or abused illicit drugs, but not alcohol; and 14.9 million were dependent on or abused alcohol, but not illicit drugs (SAMHSA, 2002). An estimated 3.5 million

people aged 12 or older (1.5 percent of the population) received some kind of treatment for a problem related to the use of alcohol or illicit drugs in the 12 months prior to being interviewed for the 2002 National Survey on Drug Use and Health (SAMHSA, 2002).

Why try to prevent these disabling disorders? While the social and psychological effects are enormous, the economic costs to society to treat these illnesses are staggering. National expenditures for mental health and substance abuse in 1997 were estimated to be $82.2 billion (Coffey et al., 2000). Mental health care is the largest component of that estimate, as 86 percent ($70.8 billion) was for treatment of mental illness and 14 percent ($11.4 billion) was for treatment of substance abuse (Coffey et al., 2000). Compared with other spending on retail trade, Americans spent more on mental health and substance abuse treatment in 1997 than they did on computer software. In 1995, they spent more for these disorders than the amount for treatment of most other types of disease, including cancer, injuries, respiratory diseases, and musculoskeletal diseases, respectively (Coffey et al., 2000).

The following information addresses screening procedures for emotional disorders, depression, tobacco, alcohol, and illicit drugs. It also identifies behavioral health services that may prevent or ameliorate mental (behavioral) illness or otherwise reduce health care costs.

Clinical Preventive Behavioral Services

Clinical preventive services for behavioral disorders usually start with the primary care provider taking 30 seconds to 2 minutes to screen for depression and the various substance-use topics. This screening is followed by a diagnostic interview and counseling for those showing evidence of high-risk or early-stage behavioral illness. Then, either the primary care provider or a specialized mental health professional provides follow-up management. These interventions require skill, consistency, and special training of the primary care providers as well as the capacity of the health care delivery system to connect selected patients with specialized mental health professionals. There is little value to such screening procedures if the health care delivery system lacks the means to follow up with definitive diagnoses and management. Some health care systems opt for increased training of primary care practitioners to reduce reliance on mental health professionals.

Most clinical preventive services require the same infrastructure elements as those commonly used for quality assurance, accreditation, and in some States, licensure and Medicaid reimbursement:

- Policies and procedures, with committee oversight and annual review
- Provider training
- Patient outreach and communications
- Data systems—often including dummy billing codes (codes for services that are not individually reimbursed), chart review, and/or limited patient and provider surveys

These preventive services differ from those usually classified as “disease management” or “demand management” in that patients needing these preventive services usually are identified through clinical screening, not through review of the claims database.

Models of Preventive Services

Two well-known models of preventive services are used when referring to behavioral programming for public health or mental health promotion and substance use prevention. They are reviewed briefly here.

The Public Health Model

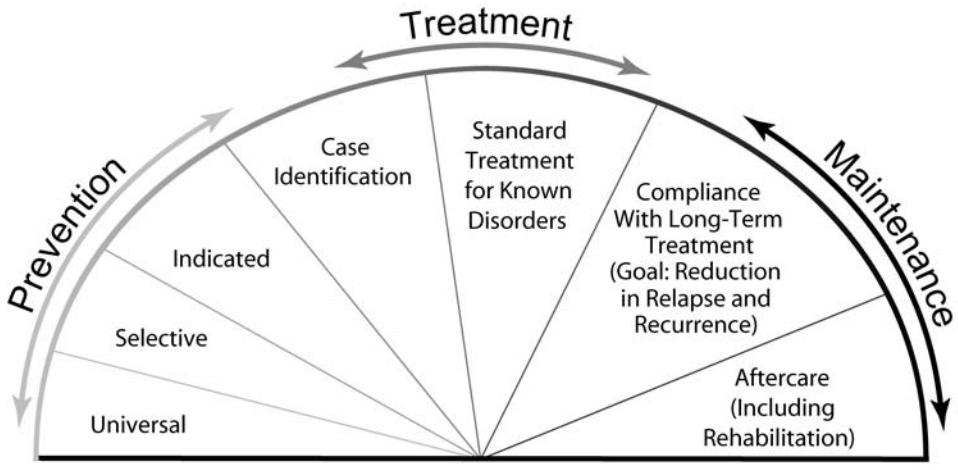
Public health traditionally defines preventive services as "primary," "secondary," or "tertiary." Primary preventive services, such as immunizations and programs related to tobacco, diet, and exercise, are intended to intervene before the onset of illness to prevent biologic onset of illness. Secondary preventive services include screening to detect disease before it becomes symptomatic, coupled with follow-up to arrest or eliminate the disease. The Pap test and mammography are medical examples of secondary prevention. Tertiary prevention refers to prevention of complications in persons known to be ill. Prevention of stroke through effective treatment of hypertension is an example of tertiary prevention. Much of disease management is tertiary prevention. In the public health model, the three levels of prevention are separate and distinct.

The Continuum of Health Care Model According to the Institute of Medicine (IOM)

When dealing with substance use and other behavioral disorders in clinical settings, the levels of prevention are less distinct than with physical illnesses. The tasks of identifying risk factors and detecting early-stage disease are usually accomplished by patient or family interview. Initial management of both risk and early stage disease is often conducted via patient and family counseling by the primary care provider. Thus, the continuum of the health care model is more practical than the public health model when dealing with preventive behavioral health services.

The continuum of health care model is

Figure 1. Continuum of Health Care



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drawn from a 1994 report of the Institute of Medicine (IOM) (Mrazek & Haggerty, eds., 1994), as originally proposed by Gordon (1983). It differs from the public health model in that it covers the full range of preventive, treatment, and maintenance services. There are three types of preventive services in the IOM model—universal, selective, and indicated. These do not correspond to the primary, secondary, and tertiary services in the public health model. Screening and follow-up preventive behavioral services correspond to secondary prevention within the public health model. Other preventive behavioral services, including most community-based services, correspond to primary or tertiary prevention.

In the IOM model, a "universal" preventive measure is an intervention that is applicable to or useful for everyone in the general population, such as all enrollees in a managed care organization. A "selective" preventive measure is desirable only when an individual is a member of a subgroup with above-average risk. An "indicated" preventive measure applies to persons who are found to manifest a risk factor that puts them at high risk (Mrazek & Haggerty, eds., 1994). All these categories describe individuals who have not been diagnosed with a disease.

Universal interventions, on a per-client basis, are relatively inexpensive services offered to the entire population of a life-stage group. They are conducted as a primary prevention or screening to identify sub-populations and individuals who need more intensive screening, preventive, or therapeutic services. A clinical example would be the provision of prenatal care as a universal service for all pregnant women. A behavioral health example would be the use of a simple screening protocol to identify depression in all adult patients at all primary care visits.

Selective interventions are more intensive services offered to subpopulations identified as having more risk factors than the general population, based on their age, gender, genetic history, condition, or situation. For example, more intensive breast cancer screening is provided for women with a family history of breast cancer. A behavioral health example would be offering smoking cessation programming to all smokers.

Indicated interventions are based on higher probability of developing a disease. They provide an intensive level of service to persons at extremely high risk or who already show asymptomatic, clinical, or demonstrable abnormality, but do not meet diagnostic criteria levels yet. Case management and intensive in-home assessment, health education, and counseling are examples of indicated interventions (Mrazek & Haggerty, eds., 1994).

Sometimes a universal service is a screening procedure provided to all, or a primary prevention procedure such as vaccinations for children. The selective service involves diagnostic procedures to confirm or deny a diagnosis, and the indicated service involves much more intensive, individualized services for those at highest risk.

The efficacy and cost-efficiency of preventive services depend on the entire array of universal, selective, and indicated service components. They also depend on the ability of the health care system to target and limit the more costly indicated interventions to those who could most benefit from them.

Appendix C to this report provides a more detailed presentation of the following policy, management, planning, and evaluation issues:

- Translation of preventive behavioral research into health care practice
- Assessment of the need for preventive services
- Assessment of the efficacy of preventive services
- Infrastructure and service components for preventive services

"General" vs. "Targeted" Services

Within this monograph, services are also classified into one of two categories, "general" and "targeted," depending on the evidence base and the nature of the service. Those designated as "general" are supported by the evidence base as being appropriate for universal implementation by all health care systems. Services that are classified here as "targeted" appear to be appropriate for selected populations (e.g., selective or indicated populations if applying the IOM model), or they have a developing research base that is promising. "Targeted" services might also be social or educational interventions that could be provided by nonmedical staff to secure educational and social benefits.

Clinical vs. Community Preventive Services

Most preventive behavioral services are delivered in school and community settings, not health care settings (Schinke, Brounstein, & Gardner, 2002; DHHS, 1999). In a 1998 review of indicated preventive behavioral services for children and adolescents, Durlak and Wells (1997) used meta-analysis to review 177 programs—73 percent were in a school setting, compared with 23 percent that were mainly in medical settings. In a similar review published 1 year later by the same authors (Durlak & Wells, 1998), none of the programs was in a medical setting.

This report has been prepared to summarize and analyze the most promising preventive interventions (based on rigorous research studies) for consideration by health care organizations. Only interventions deliverable by health care systems are reviewed in this report. Most community preventive services are oriented toward school-age children, adolescents, and young adults—age groups with relatively low exposure to health care delivery settings. Such services generally are provided by and through schools and community organizations.

Health care settings, however, are effective in reaching pregnant women, infants, adults with major chronic medical illnesses, and those in need of surgical procedures. For example, these settings provide a place to address the behavioral needs of these patients through behavioral screening and preventive services, with follow-up in prescribed regimens of care. In this way, clinical preventive services for depression and substance abuse can reduce emergency room use and hospitalization (Olfson, Sing, & Schlesinger, 1999). Psychoeducational services also can speed recovery of postsurgical patients (Egbert, Battit, Welch, & Bartlett, 1964; Mumford, Schlesinger, & Glass, 1982).

It may not be incumbent upon health care delivery systems to provide highly specialized social and educational support services (Devine, O'Connor, Cook, Wenk, & Curtin, 1988), but health care delivery systems do have a role to play. Through their mental health and social work staff, they maintain working relationships with community-based, social service, educational, and even correctional agencies to ensure they meet the needs of members of the health care delivery system.

Health Care Delivery System Provision of Preventive Behavioral Services

The need for behavioral services is substantial. Many who could benefit from treatment for these disorders do not receive care (Woodward et al., 1997; Harwood, Sullivan, & Malhorta, 2001).

Some of the lack of development of behavioral health services within health care delivery systems may be owing to the perception that mental health and substance use disorder services may be "softer" and therefore less effective than conventional medical therapy. However, the efficacy and cost-efficiency of these services is well established and has been recommended by multiple national organizations since at least the early 1990s (U.S. Preventive Services Task Force [USPSTF], 1996, 2002a, 2003).

The 1994 IOM report was titled *Reducing Risks for Mental Disorders—Frontiers for Preventive Intervention Research* (Mrazek & Haggerty, eds., 1994). A 1998 follow-up report, *Preventing Mental Health and Substance Abuse Problems in Managed Care Settings* (Mrazek, 1998), was completed in collaboration with the National Mental Health Association (NMHA). This report recommended widespread implementation of primary preventive programming to address five problem areas within health care systems:

1. Prevention of initial onset of unipolar major depression across the life span
2. Prevention of low birthweight and prevention of child maltreatment in children from birth to 2 years of age whose mothers are identified as being at high risk
3. Prevention of alcohol or drug abuse in children who have an alcohol- or drug-abusing parent
4. Prevention of mental health problems in physically ill patients (comorbidity prevention)
5. Prevention of conduct disorders in young children

The 1999 Surgeon General Report was titled *Mental Health: A Report of the Surgeon General* (DHHS, 1999). Although the major focus of this report was care and management of mental disorders, all major preventive services were included.

SAMHSA published two recent prevention-related health care reports. The 2000 literature review titled *Preventive Interventions Under Managed Care* (Dorfman, 2000) used broader definitions of "prevention" and "mental health services" and recommended six interventions for managed care plans:

1. Prenatal and infancy home visits
2. Targeted cessation education and counseling for smokers—especially those who are pregnant
3. Targeted short-term mental health therapy
4. Self-care education for adults
5. Presurgical educational intervention with adults
6. Brief counseling and advice to reduce alcohol use

This new literature review retains four of the above services and omits numbers three and four on short-term mental health therapy and self-care. The companion document published in 2002 was titled *Estimating the Cost of Preventive Services in Mental Health and Substance Abuse Under Managed Care* (Broskowski & Smith, 2002). This report provided cost data for each of the services recommended in the 2000 literature review. It also featured, for each set

of recommended services, a range of costs and options based on case mix and private versus public insurance coverage. It estimated the cost to managed care organizations (MCOs) to implement recommendations for four possible scenarios ranging from most expensive to least expensive, given drivers such as enrollment mix, staffing, staff salaries, and fixed and variable expenses. This report did not consider savings in other health care expenses. Even with the most expensive of cost profiles, the report did conclude that all six services could be fully implemented at a marginal cost of less than a 1 percent increase in cost, per member per month.

During this period, SAMHSA and the National Committee on Quality Assurance (NCQA)–sponsored Health Employer Data Information Set (HEDIS) program have attempted to bring preventive behavioral services to the attention of the managed care community. In response to market pressures to demonstrate high scores on HEDIS measures, the managed care community has taken giant strides to improve the care of patients with depression and has taken steps to enhance member adherence to prescribed regimens of care for diabetes.

In 1998, SAMHSA's Center for Substance Abuse Prevention created the National Registry of Effective Programs (NREP) as a resource to help professionals in the field become better consumers of prevention programs (Schinke et al., 2002). NREP reviews and screens evidence-based programs (conceptually sound and/or theoretically driven by risk and protective factors) that, through an expert consensus review of research, demonstrate scientifically defensible evidence. NREP initially focused on substance use prevention but has expanded to include mental health; co-occurring mental health and substance use disorders; adolescent substance use treatment; mental health promotion; and adult mental health treatment. Many programs focus on school and family, but increasingly, programs from community coalitions and environmental programs are being identified as well implemented, well evaluated, and effective.

NREP evaluates programs for substance abuse prevention and treatment, co-occuring disorders, and mental health treatment, promotion, and prevention. After receiving published and unpublished program materials from candidates, NREP reviewers, drawn from 80 experts in relevant fields, rate each program according to 18 criteria for methodological rigor, and they also score programs for adoptability and usefulness to communities (Schinke et al., 2002). Based on the overall scoring, NREP categorizes programs as Model Programs, Effective Programs, Promising Programs, or Programs with Insufficient Current Support. Those wishing to learn more about Model Programs can visit www.modelprograms.samhsa.gov. At this site, there is also a link providing detailed information about NREP and the process for submitting a program for NREP review.

Despite these efforts, behavioral services—both preventive and therapeutic—still are not adequately identified, provided, or arranged by primary care practitioners. They also are not adequately promoted by health care systems. Brief screening instruments for alcohol and drug problems, for example, have been available for a number of years but are not widely used by practicing physicians (Duszynski, Nieto, & Vanente, 1995; National Center on Addiction and Substance Abuse at Columbia University, 2000). In a 2002 review, Garnick et al. (2002) conducted a telephone survey covering 434 MCOs in 60

market areas nationwide and secured useful responses from 92 percent of them. Only 14.9 percent of MCOs required any alcohol, drug, or mental health screening by primary care practitioners. Slightly more than half distributed practice guidelines that addressed mental illness, and approximately one third distributed substance use disorder practice guidelines.

DHHS's 2003 campaign, *Steps to a Healthier U.S.*, focuses on chronic disease prevention and health promotion with the goals of decreasing both the prevalence of certain chronic diseases and the risk factors that allow conditions to develop. This initiative aims to bring together local coalitions to establish model programs and policies that foster health behavior changes, encourage healthier lifestyle choices, and reduce disparities in health care.

In early 2003, SAMHSA published a review of the delivery of behavioral services by managed care organizations, based on 1999 data. This report, *The Provision of Mental Health Services in Managed Care Organizations* (Horgan et al., 2003), showed substantial variability from plan to plan, as well as substantial variability among health maintenance organizations (HMOs), point-of-service (POS) plans, and preferred provider organizations (PPOs). All MCOs provided behavioral services, but these services usually had limits and copayments that were more restrictive than for comparable medical services. Fewer than 10 percent required screening for behavioral disorders in primary care settings (Horgan et al., 2003).

Another SAMHSA report, also published early in 2003, offers some insight into discrepancies in coverage, comparing medical to behavioral services and discrepancies in policy and coverage, comparing therapeutic to preventive services. This report, titled *Medical Necessity in Private Health Plans: Implications for Behavioral Health Care* (Rosenbaum, Kamoie, Mauery, & Walitt, 2003), noted that services are covered by health insurance plans only if they are considered a "medical necessity." The term medical necessity was defined differently for different services within each health plan, with due consideration given for each of the following five domains:

1. Contractual scope—whether the contract provides any coverage for certain procedures and treatments, such as preventive and maintenance treatments that are not necessary to restore a patient to "normal functioning." This dimension preempts any other coverage decision.
2. Standards of practice—whether the treatment (as judged by the health plan) accords with professional standards of practice.
3. Patient safety and setting—whether the treatment will be delivered in the safest and least intrusive manner.
4. Medical service—whether the treatment is considered medical as opposed to social or nonmedical.
5. Cost—whether the treatment is considered cost-effective by the insurer (Rosenbaum et al., 2003).

The medical necessity report noted that Federal or State regulation is limited in covering how health insurance plans define medical necessity (Rosenbaum et al., 2003). This SAMHSA update is intended to build upon the reports noted above to further enhance implementation of preventive behavioral services in health care settings.

Organization of This Report

This report is organized in the following manner: After the Executive Summary and Introduction, the Methods follow as Chapter III. (Additional details about methodology and the outcomes of the literature searches are included in Appendix A.) Chapter IV provides an overview of interventions.

Chapters V to IX address specific interventions based on age and life-cycle groups. These chapters include an abstract; a narrative introduction; a review and synthesis of the literature relating to the intervention's evidence of need, efficacy, cost-efficiency, data needs, and implementation-related issues. Summaries of all proposed interventions for each life-cycle group are also presented.

Chapter X focuses on a single intervention, psychoeducation, for three categories of adult patients. Chapter XI presents overall Conclusions, followed by the References section with more than 530 entries, and four Appendices that provide details of methods, management, billing codes, and procedures for implementation and evaluation.

III. Methods

The purpose of this literature review was to update, increase the rigor, and supercede a preliminary literature review published by SAMHSA in 2000 (Dorfman, 2000). This report includes a review of literature pertinent to the preventive interventions highlighted in the 2000 review, as well as the addition of other preventive interventions pertinent to health care delivery systems.

Scope of Review

Articles published between 1964 and 2003 were included in three separate searches, using different techniques for different time frames:

- Stage One: 1998–2002: Advanced Search on PubMed using nine specific search terms. (See details below.)
- Stage Two: 1964–2002: Search PubMed using articles listed in previous SAMHSA literature review (Dorfman, 2000) and PubMed's "related articles." (See Appendix A.)
- Stage Three: July 2002–October 2003: Ad hoc inclusion of selected recent, highly pertinent articles.

Stage One

First, a PubMed review was conducted for the period from January 1, 1998, to July 20, 2002, to identify new preventive interventions not discussed in the 2000 report. The specific terms used in the advanced search for the period from January 1998 to July 2002 are listed here:

1. Preventive health services OR preventive medicine OR preventive psychiatry OR primary prevention AND mental disorders NOT specific topics listed in items 2–9 below
2. Mass screening and mental disorders NOT in topics 3–9 below
3. Health education OR health promotion OR patient education AND mental disorders NOT topics 2, or 4–9
4. Home care services or home nursing AND mental disorders
5. Self-care and mental disorders (Note: there was no way to search separately on health risk appraisal in PubMed.)
6. Prenatal care OR perinatal care AND mental disorders
7. Disease management AND managed care AND mental disorders
8. Case management AND mental disorders
9. Psychoeducational (any reference where this term was used in title, abstract, or text; there is no MeSH term on this topic)

Because preliminary searching yielded more than 20,000 references by simple search techniques—with enormous numbers of duplicates and inappropriate references—advanced search techniques with the following criteria were used:

- Limits: All fields, 1998–July 20, 2002, English Human
- The term "mental disorders" was used to include all mental and behavioral disorder-related topics, including but not limited to substance use disorders, tobacco, alcohol, drug dependence, depression, schizophrenia, psychosis, anxiety state, adjustment reaction, hysteria, phobic disorder, obsessive-compulsive disorder, neurosis, hypochondriasis, somatization, malingering, personality disorder, disordered behavior
- Management of behavioral disorders to prevent onset or complications of major medical illnesses was considered in this literature review, as was psychoeducation to reduce postsurgical convalescence

The results of this advanced search are summarized in Appendix A.

Stage Two

In the second stage, a more focused literature review was conducted for the period January 1964–July 2002 using PubMed to search for potentially omitted neutral or "negative studies" relative to the topics in the 2000 SAMHSA report and other items that may have been missed in the original literature search. This was accomplished using an alternative PubMed search technique; that is, listing the key studies used by Dorfman in the SAMHSA 2000 report, and then searching what Pub Med lists as "Related Articles." The results of this search are listed in Appendix A.

Stage Three

Finally, selected additional references were added for publications published between July 2002 and October 2003. These studies were those so recent but so relevant to the objectives of this review that they were included, although a methodical review of this time period was not included.

The literature review also included an extensive set of publications provided by the SAMHSA office, various sets of national recommendations, and an extensive subsidiary set of literature searches, primarily based on the works cited in the documents noted above.

More than 3,000 papers, reports, recommendations, and Internet sites were reviewed, including 528 that are included in this report. Most represent randomized controlled trials, while the remainder provide background information and guidance relative to planning, implementation, and program evaluation.

Exclusions

This literature review was limited to preventive behavioral services best provided by health care systems. This excluded community, social, economic, general-population education, and school-based and criminal justice interventions. Although worksite interventions (such as employee assistance programs) were not addressed in this monograph, worksite and productivity gains were included as benefits of some of the proposed interventions.

Because of the enormity of the literature, a number of topics were excluded from this review: AIDS-related issues; Alzheimer's disease; attention deficit hyperactivity disorder; autism; delirium; dementia; eating disorders; encopresis; gambling; genetic testing and screening; homelessness; jet lag; mental retardation and developmental disorders (other than prenatal services and early childhood education); prison/jail; sexual issues and problems. Also excluded

were adult misuse and abuse of prescription medications, care facilitation, and provision of support services to caregivers.

PubMed

The literature review conducted for this monograph used PubMed, a service of the National Library of Medicine. PubMed includes more than 14 million citations for biomedical articles, back to 1950. These citations are from MEDLINE and additional life science journals.

PubMed was used to cover the previous Grateful Med 11 databases used to prepare the 2000 SAMHSA report (Dorfman, 2000). (The previous 2000 SAMHSA report included 11 databases located on Grateful Med: MEDLINE, HealthSTAR, PREMEDLINE, AIDSLINE, AIDSDRUGS, AIDSTRIALS, DIRLINE, HISTLINE, HSRPROJ, OLDMEDLINE, and SDILINE [Dorfman, 2000].) It should be noted that Grateful Med was phased out in 2001 and replaced with PubMed. See www.nlm.nih.gov/pubs/techbull/jf01/jf01_igm_phaseout.html for details. Questions may be directed to custserv@nlm.nih.gov, or call 888-FIND-NLM.)

Synthesis of Literature Review Findings for Development of Monograph

The data synthesis was conducted as a multistep procedure. The first step concentrated on randomized and other controlled studies, the 2000 SAMHSA report (Dorfman, 2000), and the second and third editions of the *Guide to Clinical Preventive Services*, a report of the U.S. Preventive Services Task Force, as published in 1996 (USPSTF, 1996; USPSTF, 2003). The second step was taken to assess the rigor of the research studies and to gather as much data as possible to address cost, feasibility, time delay, and implementation-related issues. The final step was to format and organize the material in a manner that will help ease implementation in health care delivery systems.

The national guidance document most directly pertinent to this report is the third edition of the *Guide to Clinical Preventive Services*, a report of the U.S. Preventive Services Task Force, as published in 2003 (USPSTF, 2003). This third edition, which updates the second with newer scientific studies, is still evolving as new recommendations are posted on the Internet. Using literature review procedures more elaborate and more rigorous than feasible for this report, the *Guide* covers many but not all of the mental or substance abuse topics reviewed herein. For topics well covered in both reports, the findings and recommendations of the *Guide* are extensively duplicated, and then supplemented with findings in more recent literature and pertinent findings from older literature not included within the *Guide*. The newer guideline on depression is used in this SAMHSA report.

Quality and Types of Evidence

The following criteria are based on the 1996 second edition of the U.S. Preventive Services Task Force's *Guide to Clinical Preventive Services* (USPSTF, 1996)—

I: Evidence obtained from at least one properly designed, randomized controlled trial

II-1: Evidence obtained from well-designed controlled trials without randomization

II-2: Evidence obtained from well-designed cohort or case-control analytic studies, preferably from more than one center or research group

II-3: Evidence obtained from multiple time series with or without the intervention, or dramatic results in uncontrolled experiments

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

This literature review focused on category I and II-1 studies for proof of efficacy. Special attention was given to studies showing no effect to determine whether the strength of these studies is sufficient to nullify those showing positive results, and to studies in other categories for the guidance they provide relative to program implementation issues. All readily available studies were reviewed, regardless of study design, to identify and address the program implementation issues of importance to translate results of the controlled studies into day-to-day health care practice. The discussion for the evidence base for each guideline addresses the strength of the most important studies and the strength of the overall evidence base.

Additional details on the methods used in development of this monograph are presented in Appendix A.

Synthesis of Findings

The first stage of searches yielded more than 20,000 articles; advanced searching narrowed that number to 3,436. Of those, 76 studies were randomized controlled trials (RCT), and of those RCT, only 49 were relevant. The second stage of searching, based on nine anchor studies from the previous SAMHSA report by Dorfman (2000), yielded 1,132 references, of which 340 were RCTs or meta-analyses. Analysis of those 340 articles revealed 58 were positive studies, while 11 were neutral or showed no effect of the intervention. The last stage encompassed about 38 recent articles, published in late 2002 through part of 2003, that were recent and relevant to the interventions under consideration.

Intervention topics were considered for inclusion in this report if they were preventive (i.e., not purely therapeutic; intended to prevent the occurrence or progression of a risk factor or illness), and behavioral in nature (involving substance misuse or a mental health condition, intended to impact medical or behavioral outcome), and appropriate for provision by health care delivery systems. Studies that were included for consideration met the USPSTF design criteria I through II-2 (see definitions above), and in one case, II-3, explained below.

After analysis of all the peer-reviewed, published studies generated through the search mechanism, most topics selected for "general" interventions to be delivered universally were required to have at least one or more RCTs. For interventions where no RCT existed, less rigorous literature was reviewed for consideration as a suggested service, and if used, targeted to selected patient groups, based on their risk factors. For example, the inclusion of screening for illicit drug use by pregnant women was based on less rigorous observational studies (classified as II-3) because no RCTs can be performed with this group due to ethical considerations. Similarly, since there were no RCTs for screening children for behavioral disorders or screening adolescents for the interventions, other well-designed, peer-reviewed studies were considered.

If the literature was strong and the potential benefits outweighed the potential harmful effects, the intervention was included as a suggested guideline. Once the

evidence was established that a screening procedure (for tobacco, alcohol, illicit drugs, depression, or behavioral disorders) was justified for one age-specific life cycle group, it was also considered for other age groups. For example, randomized trials exist for screening adults for depression, but not adolescents. The established basis for the service in adults encouraged a review of intervention literature on screening adolescents for depression as well.

After consideration of meta-analyses, randomized trials, and well-designed, nonrandomized controlled trials, studies with negative or neutral results were analyzed. This was followed by consideration of all other available literature on the intervention. These steps were taken to identify determinants of success and failure of implementations. While many studies were synthesized into a balanced review of each intervention, only those studies that qualified as a major trial, large meta-analysis, or published research that provided specific guidance about implementation were included as references.

IV. Overview of Interventions

A health care system could initiate a screening program for one disorder, or for a single age cohort, or for a life cycle group, and use the policy, management, and evaluation procedures as templates for other preventive behavioral services to other age and life-cycle groups. Two tabular summaries of screening topics based on age and life cycle groups addressed in this monograph follow:

Table 1: Summary of Universal Preventive Service Guidelines

	Tobacco	Alcohol	Illicit Drugs	Child/Adolescent Behavioral Disorders	Depression
Pregnant Women	General	General	General		
Children and Adolescents (5–18 years)				Targeted	
All Adolescents (12–18 years)	General	General	General		Targeted
Adults (19 years and older)	General	General			General

Table 1 summarizes the screening and follow-up guidelines for all patients within the life cycle group. Those designated as "general" are intended for all patients within that group. Pregnant women and adolescents should be screened for use of tobacco, alcohol, and illicit drugs. All adults should be screened for depression, as well as selected adolescents who are at unusually high risk. The use of the term "targeted," relative to children and adolescents, reflects literature that shows the utility of a standardized questionnaire, the Pediatric Symptom Checklist, but the absence of published studies that demonstrate improved patient outcomes. All adults aged 19 and older are grouped into a single life cycle group. For the preventive behavioral services covered in this report, the guidelines are identical for seniors.

The robust literature search supports "general" services for implementation by all health care delivery systems. "Targeted" services can be considered by health care delivery systems, but they will only be appropriate for providers serving highly vulnerable populations or those with the staff expertise to effectively use guidelines and tools. They are either less well documented or are not to be universally applied.

Screening pregnant women, adolescents, and adults and providing follow-up for

Table 2: Summary of Selective Preventive Service Guidelines

Pregnant Women; Children to Age 5	Targeted: Intensive case management, outreach, and home visitation services for selected families handicapped by social and economic dependency
	Targeted: Supplemental educational services for selected infants and preschool children born to mothers with mental retardation or selected other problems
Adults (19 years and older)	General: Psychoeducation and related services for patients with chronic disease
	General: Psychoeducation for patients scheduled for surgical procedures
	Targeted: Psychoeducation for patients with somatization

Table 2 summarizes the preventive behavioral interventions suggested for specific groups of patients. The first service with home visitation is targeted to high-risk pregnant women and their children through age 5. The second service is for children born to mothers with mental retardation or other limitation. The last three interventions on psychoeducation are for adults who fall into one of three categories.

tobacco use, inappropriate use of alcohol, illicit drug use, and depression may be regarded as "general" services, supported by rigorous replicated research studies, as are psychoeducational services for patients with chronic diseases and those scheduled for surgical procedures.

The following are exceptions to the general guidance above:

- There is no evidence that screening pregnant women for depression will reduce the prevalence or severity of postpartum depression, and the research is not yet sufficient to demonstrate that all adolescents and children should be screened for depression.
- Community programs that address tobacco, alcohol, illicit drugs, behavioral disorders, and depression are all important preventive measures. In clinical settings, there appears to be no specific need for physicians and nurses to screen children for these disorders, as is suggested for adolescents and adults. Screening children and adults for other behavioral disorders may be considered a "targeted" service, as noted below.
- Depression is a common and serious problem in adolescence. The screening modalities used in adults appear somewhat less specific for adolescents, and too few substantive studies exist on screening adolescents for depression to assert a robust evidence base. The USPSTF found insufficient evidence in 2002 to make a recommendation for universal depression screening of adolescents, similar to the one they made for adults.
- Adults using illicit drugs should be treated vigorously for both the physical and psychological aspects of their addiction. That having been noted, the literature does not support screening all adults for use of illicit drugs.

Screening for child and adolescent behavioral disorders using the Pediatric Symptom Checklist (PSC) is widely used in many medical practices and Medicaid programs. The current literature documents the ability of this brief, one-page instrument to identify children in need of further behavioral evaluation. Unfortunately, there are no randomized controlled studies that compare outcomes on screened individuals with unscreened populations. Despite the fact that no randomized, controlled trials have been conducted, PSC screening is still classified here as "general" because of its low burden, ease of use, wide applicability, and potential cost-effectiveness.

The "targeted" services for pregnant women and infants handicapped by social and economic disadvantage can be considered under the general category for health care delivery systems serving Medicaid and "safety net" populations, but this designation may not be appropriate for other systems.

The supplemental educational services for infants and preschool children born to mothers with mental retardation or selected other problems are nonmedical services needed by infants and preschool children whose risk profiles are most obvious to their primary care providers. Health care delivery systems can identify the infants and children in need of these supplemental services and either provide the services or otherwise connect these infants and children to needed educational programming.

When dealing with patients who have heart disease, asthma, diabetes, or other major chronic illnesses, the term psychoeducation, as defined earlier, refers to counseling integrated with health education to address emotional, perceptual, and psychological barriers to compliance with prescribed regimens of care. The value and efficacy of psychoeducation for chronic disease patients is well established in the published literature (Spiegel, Kraemer, Bloom, & Gottheil, 1989; Roter et al., 1998; Hammerlid, Persson, Sullivan, & Westin, 1999; Dusseldorp, van Elderen, Maes, Meulman, & Kraaij, 1999; Von Korff et al., 1998; Winkler et al., 1989; Parcel et al., 1994; Mishel et al., 2002). Similar psychoeducational services have been shown to be of substantial value for both children and adults scheduled to undergo surgical procedures (Egbert et al., 1964; Mumford et al., 1982; Devine & Cook, 1983; Devine et al., 1988; Jay, Elliott, Fitzgibbons, Woody, & Siegel, 1995).

As previously defined, somatization describes true physical symptoms and true physical illnesses that are initially psychogenic in nature. Those who experience somatization use substantial medical resources but do not display physical illness adequate to explain their high use. Recent reviews have estimated the prevalence of somatoform disorders in the range of 10–15 percent of primary care patients (Kroenke, Spitzer, deGruy, & Swindle, 1998; Kirmayer & Robbins, 1991; Spitzer, Williams, et al., 1994; Kellner, Lin, Von Korff, et al., 1985) and documented the impact of these disorders on both quality of life and health care utilization (Kroenke et al., 1998; Katon, Lin, Von Korff, et al., 1991; Smith, Monson, & Ray, 1986; Swartz, Landerman, George, et al., 1991; Kroenke, Spitzer, deGruy, et al., 1997; Smith, 1994; Escobar, Rubio-Stipec, Canino, et al., 1989; Deighton & Nicol, 1985; Hiller, Rief, & Fichter, 1995). Although there are several studies suggesting that screening for somatization, followed by psychoeducational interventions is of value (Smith, Rost, & Kashner, 1995; Fifer et al.,

2003), specification of exact screening and follow-up procedures is insufficient to suggest implementing psychoeducational services for somatization as a general clinical preventive service.

V. Pregnant Women

The literature provides strong evidence that substance use disorder (tobacco, alcohol, and use of illicit drugs) services for pregnant women can substantially reduce premature births, neonatal deaths, birth defects, and the need for neonatal intensive care. Alcohol use that would not be considered physically problematic for nonpregnant women is medically contraindicated during pregnancy. Effective interventions to address tobacco and alcohol use in pregnancy yield benefits in excess of program costs within 12 months of program initiation. Preventing use of illicit drugs during pregnancy may generate similar benefits, but studies have not been done to definitively confirm or deny this impression. The health care cost savings achieved within 12 months of program initiation will be due to reduction in use of newborn intensive care unit (NICU) services.

The evidence base for the recommended tobacco-related and alcohol-related universal interventions for pregnant women is very strong and includes well-designed, randomized controlled trials. The evidence base for services related to illicit drugs does not include randomized controlled trials because ethical and practical considerations preclude such studies. (Randomized studies would require purposely denying care for substance abuse to half the women in the study.) Despite this limitation, the data from currently available nonrandomized studies fully justify vigorous efforts to identify and address illicit drug use by pregnant women.

The literature specific to depression during pregnancy was insufficient to justify pregnancy-specific depression screening because it does not seem to be of value in preventing postpartum depression (Hayes, Muller, & Bradley, 2001).

Screening pregnant women for use of tobacco, alcohol, and illicit drugs during pregnancy may be considered in the context of similar interventions for all adolescents and all adults. Special emphasis is given to pregnant women in this section of this monograph because such screening usually can be relied upon to be cost-effective by offsetting reductions in health care costs within 12 months of providing the screening service.

Yet another factor is the well-documented increased responsiveness to such screening and counseling during pregnancy, when women appear more sensitive to such screening. After delivery of the infant, they are likely to relapse into previously established patterns of substance use disorder. This relapse, although undesirable, does not negate the value of their abstinence from substance use disorder during pregnancy.

Tobacco

Robust research suggests that tobacco screening and follow-up be classified as essential for all pregnant women in all health care settings. The immediate benefit (direct outcome) is reduction of tobacco use for the duration of pregnancy. The indirect but definitive benefit is reduction in the percentage of women delivering low-birthweight infants who are at high risk of requiring neonatal intensive care (NICU) services and reduction of infant mortality.

Tobacco-related programming for pregnant women has a very high probability of being cost-effective by reducing the need for NICU and other hospital services. This is true even with very low quit rates because of the extremely high cost of NICU and other hospital services.

Within the doctor-patient interface, tobacco control for pregnant women is perhaps best delivered in the context of tobacco and alcohol screening and related services for pregnant women. The primary intervention takes place at the first prenatal visit, when a full history is taken and substantial counseling is provided.

From the perspective of the health care system, the initial screening and follow-up services are best developed in the context of a well-established array of related services for all life-cycle groups, with links to community-based support services.

Interventions

General information on screening, follow-up, and data gathering are presented in Appendix D of this monograph.

The literature provides evidence that every pregnant woman should be asked whether she smokes or uses any other form of tobacco. If so, she may be counseled to quit—at least for the duration of the pregnancy—for the benefit of the unborn child. This may be reinforced at every outpatient visit.

Intervention issues specific to tobacco and pregnancy are as follows:

- Research studies indicate that more intensive smoking cessation programming for pregnant women has not been shown to be more effective than less intense interventions (unlike studies for nonpregnant adult smokers).
- Adequate data are not available to recommend for or against the use of nicotine-replacement products in pregnant women.

Review of Literature

A more general review of the tobacco and health literature is presented in the discussion of tobacco in the Adults (19 Years and Older) section of this report. The following review is limited to literature specific to pregnant women.

Evidence of Need

According to the 1996 Second Edition of the U.S. Preventive Services Task Force's *Guide to Clinical Preventive Services* (USPSTF, 1996)—

> … Smoking during pregnancy causes about 5 percent to 6 percent of perinatal deaths, 17 percent to 26 percent of low-birthweight births, and 7 percent to 10 percent of preterm deliveries (DHHS, 1989; Centers for Disease Control and Prevention [CDC], 1990), and it increases the risk of miscarriage and fetal growth retardation. It may also increase the risk for sudden infant death syndrome (SIDS) (Mitchell, Ford, Steward, et al., 1993; Schoendorf & Kiely, 1992)… .

> Pregnant women who stop smoking by the 30th week of gestation have infants with higher birthweights than infants born to women who smoke throughout pregnancy (CDC, 1990).

Effectiveness: Evidence Base for Intervention

In two of the earlier randomized clinical trials, tobacco cessation counseling with self-help materials increased mean birthweight and decreased the incidence of intrauterine growth retardation (Ershoff, Quinn, Mullen, & Lairson, 1990; Sexto & Hebel, 1984).

Studies indicate that asking pregnant women about tobacco use, combined with physician counseling and supplementary smoking cessation programming can increase tobacco-abstinence rates 5–23 percent, comparing intervention to control groups (Ershoff et al., 1990; Sexto & Hebel, 1984; Hjalmarson, Hahn, & Svanberg, 1991; Windsor, Lowe, Perkins, et al., 1993; Mayer, Hawkins, & Todd, 1990).

Since the mid-1980s, every major health-related organization that has addressed this issue has recommended routine clinician counseling of adults, pregnant women, parents, and adolescents to avoid or discontinue smoking and use of smokeless tobacco (USPSTF, 1996; American College of Physicians Health and Public Policy Committee, 1986; American Academy of Family Physicians [AAFP], 1994; American Academy of Pediatrics [AAP], 1994, 1988; American College of Obstetricians and Gynecologists [ACOG], 1993; Manley, Epps, Husten, et al., 1991; American Medical Association [AMA], 1993, 1994a; American Dental Association [ADA], 1992; Canadian Task Force on the Periodic Health Examination, 1994b; National Institutes of Health [NIH], 1989, 1994; American Academy of Otolaryngology—Head and Neck Surgery, 1992; Green, ed., 1994).

Strong evidence for the efficacy and cost-efficiency of tobacco-related interventions for pregnant women can be found in multiple randomized controlled trials and meta-analyses. Four are briefly reviewed below.

The first set of randomized controlled trials was published by Ershoff et al., from Kaiser Permanente, in Los Angeles (Ershoff et al., 1990; Ershoff, Mullen, & Quinn, 1989). These studies explored the benefits of various intensities of smoking cessation programming for pregnant women in an HMO, representing a wide range of socioeconomic classes and racial and ethnic diversity. Women who were welfare clientele or who did not speak English were not included in these studies.

The first trial included 126 cases and 116 controls. The experimental intervention consisted of one-time counseling and a set of eight short self-help booklets distributed by mail at weekly intervals, with the women committed to completion of activity assignments within the booklets. The control group received the initial counseling, a two-page brochure, and usual physician counseling. No attempt was made to modify the physician counseling or to provide other health education to the intervention group. This intervention resulted in a 22.2 percent quit rate in the study group, compared with an 8.6 percent quit rate in controls. Compared with the control group, the self-help groups were 45 percent less likely to deliver a low-birthweight infant. Within the studied population, mean cost per full-term birth, without intrauterine growth retardation, was $695. Mean cost per preterm birth was $6,213. Benefit-cost ratio, based on data limited to the infants' initial hospitalization, was estimated at about 3:1.

In 1995, Ershoff et al. published data from 171 pregnant women who quit smoking

prior to pregnancy, then relapsed during pregnancy (Ershoff, Quinn, & Mullen, 1995). These women were provided the same interventions noted above (simultaneous with the study noted above). In the intervention group, 16 percent relapsed, compared with 20 percent in the control group—a difference too small to be of statistical significance.

In 1996 and 1997, the Ershoff team ran another smoking cessation trial among pregnant women. This study, published in 1999 (Ershoff et al., 1999), randomized 390 English-speaking women, 18 years of age and older, into three groups. The first received usual physician counseling and a self-help book. The second also was given telephone access to a computerized telephone cessation program based on interactive voice response technology. The third received the booklet, usual counseling, plus proactive telephone counseling from nurse educators using motivational interviewing techniques and strategies. All three groups achieved the approximate 20 percent quit rate achieved in the earlier study, but the more intensive interventions provided no additional benefit. In all three groups, cessation rates among initially heavy smokers were strikingly low. Within each of the groups, approximately two thirds of the women made at least one serious attempt to quit smoking, at least for the duration of pregnancy. Most were unable to do so. Mean reductions in cigarette smoking among those who continued to smoke were modest, averaging a reduction from 8.3 cigarettes per day to 7.8 cigarettes per day.

Windsor et al. reported on a preliminary and more definitive trial conducted in a public health clinic population in Birmingham, Alabama (Windsor, Warner, & Cutter, 1988; Windsor et al., 1993). The initial study randomized 309 pregnant smokers into three groups. Group 1, the control, received information in a nonfocused interaction on smoking and pregnancy requiring approximately 5 minutes at the first prenatal visit. Group 2 received the standard clinic information plus a copy of *Freedom From Smoking in 20 Days*, a self-help manual published by the American Lung Association (ALA). They also received an ALA informational packet entitled "Because You Love Your Baby" and a 10-minute educational session by a baccalaureate-trained health education specialist at the initial prenatal visit. The third group received the Group 2 intervention, but with a pregnancy-specific self-help manual, *A Pregnant Woman's Self-Help Guide To Quit Smoking*. No smoking cessation interventions were used in any of the three groups after the first prenatal visit. Smoking status was confirmed midpregnancy and at the end of pregnancy using patient self-reports and saliva thiocyanate tests. The quit rates were 2 percent, 6 percent, and 14 percent for the three groups, respectively.

In the follow-up study, published in 1993 (Windsor et al., 1993), the Windsor team randomized 814 pregnant smokers from the same clinic setting to case and control groups. The control group received an intervention similar to that of Group 2 from the earlier study. The experimental group received more extensive written materials and counseling, with follow-up and reinforcement at each subsequent clinic visit. Quit rates in the two groups were approximately the same as the quit rates in the earlier study—8.5 percent and 14.3 percent in the two groups, respectively. Quit rates were higher for African Americans than for Whites in both control and experimental groups (10.7 percent and 18.7 percent for African Americans, compared with 5.2

percent and 10.0 percent for Whites).

In a study similar to the second Windsor study but conducted in a Women, Infants, and Children (WIC) clinic in Grand Rapids, Michigan, Mayer et al. (1990) demonstrated quit rates of 11 percent among the experimental group and 3 percent among the controls. When measured 4.7 weeks postpartum, the quit rates within the two groups were 7 percent and 0 percent, respectively.

The strength of this evidence base and benefits of such screening were reaffirmed in a 2002 meta-analysis by Melvin et al. (Melvin, Dolan-Mullen, Windsor, Whiteside, & Goldenberg, 2000). Another extensive literature review published that same year (Lumley, Olver, & Waters, 2000) noted that smoking cessation programs in pregnancy appeared to reduce smoking, low-birthweight and preterm birth, but no effect was detected for very low birthweight or perinatal mortality. Five trials of (postpartum) smoking relapse prevention showed no significant benefit (Lumley et al., 2000).

Efficacy and Program Implementation Issues

A meta-analysis by Mullen (1999) provides a summary of the available literature and implementation-related issues to be considered by individual managed care plans. Important program implementation points include the following:

- Smoking during pregnancy is a substantial health hazard to the fetus/infant and mother.
- These hazards appear to be best avoided by having the woman quit smoking prior to pregnancy; but if that has not been achieved, substantial benefits may be secured by having her quit, or at least substantially reduce cigarette consumption during pregnancy.
- Available interventions only offer limited quit rates (5–23 percent).
- Prevalence of smoking is higher and response to smoking-cessation programming is less substantial in low-income and otherwise economically and socially vulnerable women.
- Estimating both current smoking rates and quit rates in a given population can be problematic because smokers who know they should not smoke often lie. The better studies (such as all those referenced above) supplement the women's statements with laboratory measures of tobacco exposure. Laboratory confirmable quit rates tend to run much lower than the rates suggested by interviews of smokers. (Editorial note: such laboratory confirmation, measuring cotinine or thiocyanate used in research studies, is not suggested for routine clinical practice.)
- Studies show that pregnant women seem to respond differently to smoking-cessation programming, compared with other adults who smoke. In other adults, more intensive programming with more frequent personal contact increases quit rates, as does use of nicotine replacement products. With pregnant women, basic physician counseling, supplemented by limited interventions, such as self-help materials, appears to generate maximal benefit, while more intensive programming does not increase quit rates.
- High-quality data on the efficacy of nicotine replacement products are not available for pregnant women.

The one issue of greatest concern not addressed by Mullen is the level of benefit, according to quit rate, that is needed to

generate cost-effectiveness within 12 months of program initiation. This issue is addressed in a cost-benefit/cost-effectiveness analysis of such programming published by Marks and his team at the Centers for Disease Control and Prevention (CDC) in 1990 (Marks, Koplan, Hogue, & Dalmat, 1990). This analysis, based on the studies referenced previously in this report and a number of similar studies by other authors, demonstrates an average savings of $3.31 for each dollar spent on effective smoking cessation programming. This estimate assumes a quit rate of approximately 15 percent, with the cost calculations limited to prenatal care and the initial hospitalization at time of birth of the infant. Considering the cost of care for the infant in subsequent years, the benefit exceeds $6 per dollar spent on smoking cessation programming for pregnant women. According to these limited calculations, a program with a quit rate of only 5 percent could pay for itself within a year. These cost-benefit calculations do not include costs averted relative to respiratory illness in mother and infant or any of the other smoking-related costs, some of which can be substantial.

One other study of note is that of Latts et al. (Latts, Prochaska, Salas, & Young, 2002) in a Denver, Colorado, managed care plan. In this study, the sponsoring plan staff from participating physician offices were trained and paid $150 for each pregnant woman counseled. This study, reported as an uncontrolled pilot study, failed to increase the number of smokers counseled.

Program implementation issues deal with the social and cultural milieu of the pregnant woman, her educational and socioeconomic status, and the dedication of both the physician and health care system to tobacco control. The Ershoff (Ershoff et al., 1999), Windsor (Windsor et al., 1988, 1993), and Mullen (1999) studies referenced above provide information on providing effective and cost-efficient smoking-cessation services to pregnant women in conventional HMO settings (Ershoff et al., 1999) and indigent care clinics (Windsor et al., 1988, 1993). The Mullen study (Mullen, 1999) provides excellent guidance on issues to be addressed in the design of such programs.

In the studies where this has been documented, more than half the women who quit smoking during pregnancy resume smoking after the birth of the infant (CDC, 2002). Thus, screening of pregnant women for tobacco use and provision of antismoking programming does not eliminate the need for the pediatrician to address these same issues after birth of the infant, for the benefit of both mother and child.

Data Needs Specific to Tobacco and Pregnancy

Refer to Appendix D, Procedures for Implementation and Evaluation of Preventive Services, for a discussion of issues related to screening, follow-up, and data gathering.

Assessment of Need for Programming and Assessment of Program Efficacy

Collecting the following data would help health plans track and evaluate the impact of tobacco interventions:

- Medical records data showing use or suspicion of use of tobacco before and during pregnancy
- The number and percentage of these women who quit prior to the first prenatal visit
- Rates of NICU utilization and other hospital services during the first 30 days of life
- Perinatal death rates (infant death rates

during the first 30 days of life)
- Comparison of fetal/infant illness, death, and health care utilization through the first 30 days of life, comparing mothers who quit, those who did not, and nonusers (as ascertained by interview and recorded in the medical record)

Summary of Tobacco Use and Pregnancy

Tobacco use during pregnancy is a major cause of prematurity, low birthweight, and neonatal death. The robust literature indicates that all pregnant women—and those comtemplating becoming pregnant—should be screened for use of tobacco and advised to quit. In response to such screening and follow-up, quit rates from 5 to 30 percent can be expected. Even a 5 percent quit rate is likely to pay for itself in reduced utilization of intensive care for premature infants within 12 months of program initiation.

Alcohol

Screening pregnant women for alcohol use is classified as "general." This means that extensive research suggests programming is beneficial to all pregnant women in all health care settings. The direct outcome is reduced alcohol use during pregnancy. The immediate benefit is a dramatic reduction in Fetal Alcohol Spectrum Disorders (FASD), including the most debilitating form, Fetal Alcohol Syndrome (FAS), and a modest reduction in prematurity. Given the relative rarity of FAS and FASD in most health care settings, and the nature and quality of the literature available, the primary measurable benefit to reducing alcohol use in pregnancy relates to the reduction in prematurity and low birthweight. The absence of claims for FAS and FAE does not suggest a lack of need for alcohol control programming for pregnant women.

Alcohol-related programming for pregnant women has a very high probability of being cost-effective by reducing the need for NICU services. This is true even with very low abstinence rates because of the extremely high cost of premature births and underweight newborns.

At the doctor-patient interface, alcohol-control programming for pregnant women is probably best delivered in the context of tobacco and illicit drug screening and related services for pregnant women. The primary intervention takes place at the first prenatal visit, when a full history is taken and substantial counseling is provided.

From the perspective of the health care system, the initial screening and the follow-up services may be best developed in the context of a well-established array of such services for all life-cycle groups, with links to community-based support services.

Interventions

A general discussion of factors related to screening, follow-up, and data gathering appears in Appendix D, Procedures for Implementation and Evaluation of Preventive Services. The literature provides strong evidence that every pregnant woman should be asked about alcohol consumption and should be urged to abstain, at least for the duration of the pregnancy for the benefit of the unborn child. Similarly, research suggests that those who historically have consumed alcohol would benefit from having this message reinforced at every outpatient visit.

Intervention-Related Issues Specific to Alcohol and Pregnancy

Information adapted from the 1996 Second Edition of the U.S. Preventive Services Task Force's *Guide to Clinical Preventive Services* (USPSTF, 1996) suggests that—

- All pregnant women be screened for

evidence of problem drinking or risk drinking (two drinks or more per day or binge drinking), especially during the first trimester of pregnancy.

- All pregnant women and all women contemplating pregnancy be informed of the harmful effects of alcohol on the fetus and be advised to cease drinking.
- Women who both smoke and drink be advised that their risk of low-birthweight infants is greatest.
- Patients with evidence of alcohol abuse or hazardous drinking be offered brief advice and counseling.
- Patients with evidence of alcohol dependence be referred to appropriate clinical specialists or community programs.
- Physician education: Because of the difficulty in ascertaining alcohol use in many women, use of facilitators, as suggested later in this report, or use of videotape-augmented training of obstetric care practitioners may be considered. A group in New Mexico has demonstrated the value of the videotape-augmented training in a randomized controlled trial (Handmaker, Hester, & Delaney, 1999).

In a 2002 review of alcohol problem-related screening questionnaires, the National Institute on Alcohol Abuse and Alcoholism (NIAAA, 2002) stated—

> … Two questionnaires are available that are appropriate for pregnant women, both derived in part from CAGE (Cut Down/Annoyed/Guilty/Eye opener) (Chan et al., 1994), T-ACE Tolerance-Annoyed/Cut down/Eye Opener (Sokol, Martier, & Ager, 1989) takes approximately 1 minute to complete and is more accurate than AUDIT (Alcohol Use Disorder Identification Test) for detecting current alcohol consumption and risky drinking, as well as history of past alcoholism; however, it is less specific (Chang, 2001). The five-item TWEAK (Tolerance/Worried/Eye opener/Amnesia/K(c)ut down) (Russell, Martier, & Sokol, 1991) performs similarly to T-ACE (Chang, 2001) and can be used to detect a range of drinking levels from moderate to high-risk consumption (Dawson, Das, Faden, et al., 2001).

Details on these and other alcohol-related screening tests can be found on the NIAAA Web site at www.niaaa.nih.gov. Additional information and sample questionnaires for CAGE and AUDIT are provided in the discussion about alcohol in this monograph.

Literature Review

More substantial reviews of the alcohol-and-health literature can be found in the sections of this monograph related to selected children, adolescents, and adults. The discussion on adults and alcohol includes presentation and discussion of the most important alcohol screening questionnaires.

Evidence of Need

According to further information in the 1996 Second Edition of the U.S. Preventive Services Task Force's *Guide to Clinical Preventive Services* (USPSTF 1996)—

> The proportion of pregnant women who report drinking has declined steadily in the U.S. (Serdula, Williamson, Kendrick, et al., 1991). Recent surveys indicated 12–14 percent of pregnant women continue to consume some alcohol (Goodwin, Bruce, Zahniser, et al., 1994; CDC,

1994b), with most reporting only occasional, light drinking (median: four drinks per month) (Serdula et al., 1991). Binge drinking or daily risk drinking (usually defined as two drinks per day or greater) is reported by 1–2 percent of pregnant women (Goodwin et al., 1994; CDC, 1994b, 1995a), but higher rates (4–6 percent) have been reported in some screening studies (Sokol et al., 1989; Russell, Martier, Sokol et al., 1994).

Excessive use of alcohol during pregnancy can produce fetal alcohol syndrome (FAS), a constellation of growth retardation, facial deformities, and central nervous system dysfunction (microcephaly, mental retardation, or behavioral abnormalities) (Rosett, Weiner, & Edelin, 1983). Other infants display growth retardation or neurologic involvement in the absence of full FAS (i.e., fetal alcohol effects [FAE]) (NIAAA, 1993). FAS has been estimated to affect approximately one in 3,000 births in the U.S. (1,200 children annually), making it a leading treatable cause of birth defects and mental retardation (Abel & Sokol, 1991; CDC, 1993b).

The level of alcohol consumption that poses a risk during pregnancy remains controversial (NIAAA, 1993; Russell, 1991). FAS has only been reported in infants born to alcoholic mothers, but the variable incidence of FAS among alcoholic women (from 3 to 40 percent) (Abel & Sokol, 1991) suggests that other factors … may influence the expression of FAS (NIAAA, 1993)…. Most studies report an increased incidence of FAE among mothers who consume 14 drinks per week or more (Russell, 1991; Virji, 1991; Forrest, Florey, et al., 1991; Verkerk, Noord-Zaadstra, Florey, et al., 1993), but the effects at lower levels have been inconsistent (Russell, 1991; Jacobson, Jacobson, Sokol, et al., 1993; Streissguth, Barr, & Sampson, 1990). Modest developmental effects have been attributed to light drinking (seven drinks per week) in some studies, but underreporting by heavy drinkers and confounding effects of other important factors (nutrition, environment, etc.) make it difficult to prove or disprove a direct effect of light drinking (NIAAA, 1993; Russell, 1991; Knupfer, 1991). Timing of exposure and pattern of drinking may be important, with greater effects proposed for exposure early in pregnancy and for frequent binge drinking (NIAAA, 1993).

Effectiveness Evidence Base for Intervention

According to the 1996 Second Edition of the U.S. Preventive Services Task Force's *Guide to Clinical Preventive Services* (USPSTF, 1996)—

> There are no definitive controlled trials of treatments for excessive drinking in pregnancy (Schorling, 1993). In several uncontrolled studies, a majority of heavy-drinking pregnant women who received counseling reduced alcohol consumption (Rosett et al., 1983; Larson, 1983; Halmesmaki, 1988) and reductions in drinking were associated with lower rates of FAS (Rosett et al., 1983; Halmesmaki, 1988). Many women spontaneously reduce their drinking while pregnant, however, and women who continue to drink differ in many respects from women who cut down (e.g., heavier drinking, poorer prenatal care, and nutrition). As a result, it is difficult to determine precisely the benefit of screening and counseling during pregnancy. In two trials that

employed a control group, the proportions of women abstaining or reducing consumption were similar in intervention and control groups (Waterson & Murray-Lyon, 1990; Meberg, Halvorsen, Holter, et al., 1986).

The U.S. Surgeon General (Surgeon General, 1981) and the American Academy of Pediatrics (AAP) and American College of Obstetricians and Gynecologists (ACOG) (AAP/ACOG, 1992; American Academy of Pediatrics Committee on Substance Abuse and Committee on Children with Disabilities, 1993) advise counseling all women who are pregnant or planning pregnancy that drinking can be harmful to the fetus and that abstinence is the safest policy. The Canadian Task Force (CTF) recommends that all women be screened for problem drinking and advised to reduce tobacco use during pregnancy (CTF on the Periodic Health Examination, 1994a).

Efficacy and Program Implementation Issues

In the case of alcohol control during pregnancy, the major program implementation issue will relate to the sociodemographic profile of the membership and issues that will need to be addressed relative to cultural sensitivity. The overall community tolerance for alcohol consumption, use, and abuse will be a significant factor.

A major part of the problem is identifying alcohol use in pregnant women, since many will not admit such use. Several studies have demonstrated the value of structured questionnaires as an effective means of ascertaining alcohol use (Chang et al., 1998; Chang, Goetz, Wilkins-Haug, & Berman, 1999; Midanik, Zahnd, & Klein, 1998; Bull, Kvigne, Leonardson, Lacina, & Welty, 1999; Chasnoff, Neuman, Thornton, & Callaghan, 2001).

Another part of the problem is the limited utility of interventions, especially in heavier drinkers and those who do not access early prenatal care. As noted below, results are mixed and not well documented in controlled studies. The better controlled studies did not address the cost-benefit or cost-efficiency of treatment options.

Despite this lack of firm evidence, the hazard posed by alcohol consumption during pregnancy and the apparent ease by which alcohol consumption can be reduced in many pregnant women would seem to indicate that all health care providers should address this issue.

Although they did not provide new findings or evidence, two recent reviews nicely summarized literature more recent than the USPSTF *Guide* (USPSTF, 1996). These are a 1999 review in the *Milbank Quarterly* (Frohna, Lantz, & Pollack, 1999) and a 2000 review from a group at Wayne State University in Detroit (Hankin, McCaul, & Heussner, 2000).

Data Needs Specific to Pregnancy and Alcohol

Collecting the following data would help health plans track the impact of their alcohol- screening intervention. Refer to Appendix D.

- Numbers of cases of FAS and FASD diagnosed in prior year
- Evidence of alcohol-related problems in other members of the managed care plan that might suggest a community-wide alcohol problem
- Medical records data showing use or suspicion of use of alcohol before and during pregnancy

- The number and percentage of these women who quit prior to the first prenatal visit
- Rates of NICU utilization and other hospital services during the first 30 days of life
- Perinatal death rates (infant death rates during the first 30 days of life)
- Comparison of fetal/infant illness, death, and health care utilization through the first 30 days of life, comparing mothers who quit, those who did not, and non-users (as ascertained by interview and documented in the medical record)

Summary of Alcohol Use and Pregnancy

The robust literature indicates that all pregnant women—and those contemplating becoming pregnant—should be screened for the use of alcohol and advised to abstain while pregnant.

Illicit Drugs

Screening pregnant women for use of illicit drugs is classified as "general." This means that strong research supports this for all pregnant women in all managed care and other health care settings. With the exception of withdrawal symptoms at time of delivery, no studies have successfully separated the effects of the illicit drugs on the fetus/infant from the effects of concurrent tobacco and alcohol use and lack of prenatal care. The literature clearly indicates that pregnant women using illicit drugs have poor pregnancy outcomes, but separating the influence of the drug itself from these other risk factors has proven practically impossible (USPSTF, 1996). There are no published studies in which the woman has been given drug treatment without concurrent prenatal care.

The benefits to be pursued are reduction of illicit drug use during pregnancy and elimination of maternal, fetal, and infant complications of such use. At the doctor-patient interface, programming for pregnant women using illicit drugs is probably best delivered in the context of tobacco and alcohol screening and related services for pregnant women. The primary intervention takes place at the first prenatal visit, when a full history is taken and substantial counseling is provided. From the perspective of the health care system, the services are best developed within the context of established services for all life-cycle groups with links to community-based support services.

Intervention

Robust research supports asking every pregnant woman about use of illicit drugs and urging pregnant women to abstain, at least for the duration of the pregnancy, for the benefit of the unborn child. Similarly, the literature provides strong evidence that this message should be reinforced at every outpatient visit for those who historically have used such drugs.

Service-Related Issues Specific to Illicit Drugs and Pregnancy

Information adapted from the recommendation in the 1996 Second Edition of the U.S. Preventive Services Task Force's *Guide to Clinical Preventive Services* (USPSTF, 1996) suggests that—

- Every managed care organization has access to psychiatrists and/or other professional staff who are expert in the diagnosis and management of women who engage in the use of illicit drugs (marijuana, cocaine, heroin, and others) during pregnancy.
- All clinicians in managed care settings

that participate in the provision of prenatal care be trained to recognize signs and symptoms that suggest use of illicit drugs during pregnancy and how best to interview such patients.
- All pregnant women be advised of the potentially adverse effects of drug use on the development of the fetus.
- Routine (blood and urine) screening of pregnant women for illicit drug use is only justified when dealing with populations known to have a high prevalence of use of such drugs (more than 2 percent of pregnant women as ascertained by record review and/or claims data). There is no need for such a screening program in most managed care organizations.
- Organizations dealing with a high prevalence of use of illicit drugs or an otherwise exceptionally high-risk population for such substance abuse are virtually assured of encountering high rates of tobacco use and alcohol abuse. Such organizations can consider their options for screening through modification of one of the alcohol-related screening instruments, and adoption of follow-up of such screenings patterned after their alcohol-control programming.

Review of Literature

Evidence of Need

According to the 1996 Second Edition of the U.S. Preventive Services Task Force's *Guide to Clinical Preventive Services* (USPSTF, 1996)—

> A national probability sample of 2,613 women giving birth in 1992–93 estimated that 5.5 percent used some illicit drug during pregnancy: the most frequently used drugs were marijuana (2.9 percent) and cocaine (1.1 percent) (National Institute on Drug Abuse [NIDA], 1994c). Anonymous urine testing of nearly 30,000 women giving birth in California in 1992 detected illicit drugs in 5.2 percent: marijuana (1.9 percent), opiates (1.5 percent), and cocaine (1.1 percent) were the most frequently detected substances (Vega, Kolodny, Hwang, & Noble, 1993). Prevalence of drug use generally is higher among mothers who smoke or drink, are unmarried, are not working, have public or no insurance, live in urban areas, or receive late or no prenatal care (NIDA, 1994c; Vega et al., 1993; Moser, Jones, & Kuthy, 1993). Anonymous urine testing detected cocaine use in 7–15 percent of pregnant women from high-risk, urban communities (Schulman, Morel, Karmen, et al., 1993) and in 0.2 percent to 1.5 percent of mothers in private clinics and rural areas (Sloan, Gay, & Snyder, 1992; Burke & Roth, 1993).

Drug use during pregnancy has been associated with a variety of adverse outcomes, but problems associated with drug use (e.g., use of alcohol or cigarettes, poverty, poor nutrition, inadequate prenatal care) may be more important than the direct effects of drugs (Mayes, Granger, Borstein, et al., 1992; Robins & Mills, eds., 1993). Regular use of cocaine and opiates is associated with poor weight gain among pregnant women, impaired fetal growth, and increased risk of premature birth; cocaine appears to increase the risk of abruptio placentae (Volpe, 1992). The effects of social use of cocaine in the first trimester are uncertain (Graham, Dimitrakoudis, Pellegrini, et al., 1989; Chasnoff, Griffith, MacGregor, et al., 1989). Cocaine

> has been blamed for some congenital defects (Robins et al., 1993), but the teratogenic potential of cocaine has not been definitively established. Infants exposed to drugs in utero may exhibit withdrawal symptoms due to opiates, or increased tremors, hyperexcitability, and hypertonicity due to cocaine (Robins et al., 1993; Hutchings, 1982). Possible long-term neurologic effects of drug exposure are difficult to separate from the effects of other factors that influence development among vulnerable children (Robins et al., 1993; Frank, Bresnahan, & Zuckerman, 1993; Chasnoff, Griffith, Freier, & Murray, 1992). The effects of marijuana on the fetus remain controversial (Zuckerman, Frank, Hingson, et al., 1989; Day & Richardson, 1991; Bell & Lau, 1995).

Effectiveness: Evidence Base for Intervention

Although the risk of drug use to the mother and fetus is clear, the evidence base for effective interventions during pregnancy is largely limited to observational studies showing a decrease in the risk of low birthweight with increasing numbers of prenatal visits (Chasnoff et al., 1989; Zuckerman et al., 1989).

Two studies published since the 1996 *Guide* reaffirmed that substance abuse in pregnancy continues to be a significant problem (Butz, Lears, O'Neil, & Lukk, 1998; Richardson, Hamel, Goldschmidt, & Day, 1999). Our literature search also identified five clinical trials relating to treatment to secure discontinuation of illicit drug use in pregnancy (Elk, Mangus, Rhoades, Andres, & Grabowski, 1998; Eisen, Keyser-Smith, Dampeer, Sambrano, 2000; Schuler, Nair, Black, & Kettinger, 2000; Jansson et al., 1996; Svikis et al., 1997). All were controlled to some degree, with study populations ranging from 12 (Elk et al., 1998) to 658 (Eisen et al., 2000). Taken together, these studies reaffirm previously established impressions that aggressive provision of basic prenatal care is of substantial value for these women, but supplementary programs for illicit drug use in pregnant women are of only marginal value. In the only one of these studies to address this issue (Eisen, et al., 2000), it was noted that none of the reductions in use of alcohol or illicit drugs was maintained through 6 months postpartum.

Given this circumstance, the recommendation of the American College of Obstetricians and Gynecologists is limited to "a thorough history of substance use and abuse in all obstetric patients, and remain alert to signs of substance use disorder in all women" (USPSTF, 1996; ACOG, 1994).

Efficacy: Program Implementation Issues

According to the 1996 Second Edition of the U.S. Preventive Services Task Force's *Guide to Clinical Preventive Services* (USPSTF, 1996)—

> The diagnostic standard for drug abuse and dependence is the careful diagnostic interview (USPSTF, 1996; APA, 1994). … There are few data to determine whether or not the use of standardized screening questionnaires can increase the detection of potential drug problems among patients. Brief alcohol screening instruments such as the CAGE or MAST [Michigan Alcoholism Screening Test] can be modified to assess the consequences of drug use in a standardized manner (Trachtenberg & Fleming, 1994; Skinner, 1982), but these instruments have not been compared with routine history of clinician assessment. Questionnaires … [that] identify adolescents at increased risk for drug use … have not been

validated in prospective studies (Schwartz & Wirtz, 1990). Other instruments such as the Addiction Severity Index (McLellan, Luborsky, Woody, et al., 1980) are useful for evaluating treatment needs but are too long for screening.

… Drug testing is frequently performed without informed consent in the clinical setting on the grounds that it is a diagnostic test intended to improve the care of the patient. Because of the significance of a positive drug screen for the patient, however, the rights of patients to autonomy and privacy have important implications for screening of asymptomatic persons (Merrick, 1993). If confidentiality is not ensured, test results may affect a patient's employment, insurance coverage, or personal relationships (Rosenstock, 1987). Testing during pregnancy is especially problematic because clinicians may be required by State laws to report evidence of potential harmful drug or alcohol use in pregnant patients.

There is a single recent paper suggesting that primary care clinicians can ask three questions in the context of a prenatal health evaluation to target women for referral to a full clinical assessment for drug and alcohol use (Chasnoff et al., 2001). The three questions are—

1. Have you ever drunk alcohol?
2. How much alcohol did you drink in the month before pregnancy?
3. How many cigarettes did you smoke in the month before pregnancy?

The screen is intended for use by primary practitioners to sort women by risk category.

In at least one high-prevalence population where this issue was addressed in a recent study in Pittsburgh, women commonly denied their use of tobacco, alcohol, and cocaine. Interviews detected only about half of the women whose urine tests were positive for one or more of these substances (Markovic et al., 2000).

There are few controlled trials of interventions for pregnant women who use illicit drugs (USPSTF, 1996). The lack of randomized and controlled studies is not accidental. It is due to the perception by investigators that it would be unethical to deny pregnant women treatment believed to be beneficial (Burkett, Gomez-Martin, Yasin, & Martinez, 1998). As a result, there is a continuing flow of observational studies (Kukko & Halmesmaki, 1999; Newschaffer, Cocroft, Hauck, Fanning, & Turner, 1998; Berkowitz, Brindis, & Peterson, 1998; Clark, Dee, Bale, & Martin, 2001; Corse & Smith, 1998) and one controlled but not randomized study (Burkett et al., 1998) that showed substantial benefit to mother and fetus/infant. These studies suggest, but do not confirm, that detection of substance use disorder in pregnant women should be cost-effective within 12 months of program initiation through reduction in need for NICU services.

The AMA and most other medical organizations endorse urine testing when there is reasonable suspicion of substance use disorder, but none of these groups recommends routine drug screening in the absence of clinical indications (USPSTF, 1996).

Program Implementation Issues: How To Manage the Intervention So That It Succeeds in Securing Desired Benefits

In most health care settings, issues relative to substance use disorders among pregnant members will be limited to assurance that clinicians engaged in prenatal care have the

capacity to recognize such cases and have the capacity to refer such members to appropriate specialists. In those few plans with a prevalence of use of illicit drugs likely to be more than 2 percent of pregnant women, substance use disorder screening and follow-up can be managed in a manner patterned after what should already be well-developed alcohol control programming in those managed care plans.

Data Needs Specific to Illicit Drugs and Pregnancy

The following data should help health plans track and assess the impact of their intervention. Refer to Appendix D.

- Numbers of cases of illicit drug use diagnosed in prior year in pregnant women and newborn infants
- Data from the local criminal justice system that might suggest a community-wide drug problem or specific problems within geographically or demographically defined subpopulations
- Use of NICU services for infants

Summary: Use of Illicit Drugs During Pregnancy

All pregnant women should be asked about their use of illicit drugs and advised to abstain. Those who report using drugs during pregnancy need follow-up, supplementary case management, and counseling to receive optimal medical care.

VI. High-Risk Pregnant Women and Children to Age 5

Preventive services during pregnancy, infancy, and early childhood can reduce the prevalence and severity of future medical, behavioral, and social problems. Risk is highest in low-income and socially disadvantaged family units. The term "high risk" in the literature refers to those low-income, first-time mothers at risk for poverty, welfare dependency, and involvement with the criminal justice system. The term also refers to babies with low birthweight, prematurity, or mental deficits such as retardation. Medicaid and public sector health care systems see large numbers of such families. As poverty is not the only determinant of risk, there are likely to be small numbers of high-risk individuals in every health care system, whether public or private.

Two sets of services are presented. The first is a program of home visitation for family units characterized by social and economic vulnerability. The second is the need for supplemental educational services for the infants and preschool children from these families, plus selective low-birthweight infants; those exposed to substance use disorder during pregnancy; and those born to mothers with mental retardation. Although the provision of the supplemental educational services might not be the role of the health care delivery system, if pediatric staff does not identify the infants in need of service, it is unlikely that the infants will receive the needed services.

Social and Economic Dependency

Family units at highest risk of social and economic dependency are those with one or more of the following risk characteristics: low-income, adolescent pregnant woman or mother, unemployed, fewer than 12 years of education, or membership in a socially vulnerable ethnic, racial, or non-English-speaking group. Individuals with these risk factors tend to depend on Medicaid-oriented managed care plans, public systems of care, or do without routine care altogether. Two sets of services and benefits may be best for these high-risk family units. The first set, focusing on early and comprehensive prenatal care, can reduce prematurity and infant mortality, and by reducing the need for intensive hospital services during the first 30 days of life, reduce health care costs. The second set—addressed here—is primarily nonmedical. This second set, for families that could benefit from these interventions, can yield substantial social, educational,

economic, and behavioral benefits—but is unlikely to generate immediate reductions in health care costs.

Prenatal and infant home visitation to reduce family dependence on welfare is classified as "targeted" in this report. This is an intervention with a strong evidence base, but with social, economic, educational, and other nonmedical goals. The home visit intervention involves nurses visiting homes to deliver education and emotional coaching to low-income, first-time, disadvantaged pregnant women. The intervention consists of prenatal and infancy home visits by nurses every 2 weeks for an average of nine prenatal visits lasting over an hour each. The nurses also screen infants for sensory and developmental problems. There is provision of free transportation to prenatal and well child visits to local clinics, and in some cases, continued home visits for up to 2 years after the birth of the child. While in the home, nurses promote health-related behaviors during pregnancy, appropriate care for infants by parents, and maternal life-course family planning and educational achievement (Olds et al., 1993; 1997).

Home visitation primarily relates to health care organizations that serve socially and economically vulnerable populations. As noted above, however, every health care system is likely to have small numbers of family units that could benefit from such services. Since the benefits are substantial, these services might be implemented by health care systems serving high-risk populations. Other health care systems may choose to be aware of such services and develop the capacity to connect selected families to these outreach and educational programs.

The literature, reviewed below, attests to the benefits of home visitation in the context of a comprehensive program of preventive services in preventing future mother and child illness, handicap, social dependency, and behavioral problems.

Issues and problems addressed include the following:

- Outcomes of pregnancy—low birthweight and infant mortality
- Spacing between pregnancies
- Welfare dependency
- Use of tobacco, alcohol, and illicit drugs
- Nutritional status
- Various measures of child development
- Child abuse
- Criminal behavior
- Infant/child intelligence
- Maternal scholastic achievement

Women who may benefit from the addition of home visitation services—in addition to already comprehensive medical, financial, and social-support services—are women with multiple sociodemographic risk factors such as being an adolescent, being unmarried, having fewer than 12 years of education, and/or being unemployed. The primary benefits relate to welfare dependency. Other benefits included a wide range of health, social, and financial domains. The concept of offsetting savings in other health care costs was not pursued.

These services are not inexpensive. The benefits are unlikely to include substantial short-term reductions in health care costs. This creates a situation where supplemental funding might be pursued to cover the costs of these services. One would expect such funding to be tied to supplemental guidelines and standardized reporting procedures to document the efficacy and efficiency of these services.

Intervention

Possible intervention has two major elements. The first is an institutional infrastructure with a complete array of health and social services, including all needed outpatient and inpatient care modalities, social, financial and psychological support services, health education, and case management. The second element is a highly structured nurse home visitation program for adolescent and/or unmarried and/or otherwise socially or economically vulnerable pregnant women and their infants—to deal with the full array of medical, social, economic, and behavioral issues and problems that reflect the profile of unmet needs of each of the women/infants served.

To be effective and cost-efficient, these services might be best delivered by specially trained staff and in accordance with strictly defined protocols. Training requirements and protocols can be accessed at the Internet site of the National Center for Children Families and Communities (NCCFC) at the University of Colorado Health Sciences Center, www.nccfc.org.

Review of Literature

Olds and Kitzman

A substantial body of literature relating to prenatal and infant home visits for socially and economically vulnerable families has been generated by Drs. Olds and Kitzman. They have explored this intervention in a predominantly White population in semirural Elmira, New York, and in an urban, predominantly African American population in Memphis, Tennessee. They have published long-term follow-up studies to demonstrate continuation of benefit up to 15 years after initial delivery of the service (Eckenrode et al., 2000; Kitzman et al., 2000; Olds et al., 1998; Olds, Henderson, Tatelbaum, & Chamberlin, 1988; Olds, Chamberlin, & Tatelbaum, 1986; Olds, Henderson, Tatelbaum, & Chamberlin, 1986; Kitzman et al., 1997; Olds et al., 1997; Olds, Henderson, Kitzman, & Cole, 1995; Olds, 1994; Olds, Henderson, Phelps, Kitzman, & Hanks, 1993; Olds, 1992). Women in the control groups received free transportation to the clinics and an array of screening and referral services, in addition to routine prenatal and pediatric care. This high level of service to the control population has probably reduced what otherwise might have been even more substantial differences between case and control groups.

Olds and Kitzman published six papers between 1986 and 1994 on their Elmira study, dealing with parental care-giving at 25 to 40 months of age (Olds, 1994); effect of the nurse visitation program on government spending (AFDC, food stamps, Medicaid and Child Protective minus tax revenues from maternal employment (Olds et al., 1993) (AFDC is Aid for Families with Dependent Children, since renamed TANF, Temporary Aid to Needy Families); adverse maternal health behavior, dysfunctional infant care and stressful environmental conditions (Olds, 1992); maternal life course vis-a-vis completion of high school and employment (Olds et al., 1988); prenatal care and outcomes of pregnancy (Olds, et al., 1986); and prevention of child abuse during infancy (Olds et al., 1986). In 1995, Olds et al. (1995) reported interim strongly favorable results relative to child abuse and neglect in Elmira.

In 1997, Kitzman et al. (1997) published the results of their Memphis trial on a number of maternal and infant health measures. Dramatic and highly statistically

significant benefits were shown for pregnancy-induced hypertension, visits and hospitalizations for infant injuries and ingestions, and second pregnancies. There were no program effects on preterm delivery, low birthweight, children's immunization rates, mental development, or behavioral problems or mother's education and employment.

In 1997, Olds et al. (1997) also published a 15-year follow-up on the Elmira study, showing dramatic and highly statistically significant benefits in areas of welfare dependency, child abuse and neglect, arrests, and behavioral impairments related to alcohol and other drugs.

In 1998, Olds et al. (1998) published another 15-year follow-up of the Elmira study. The case families showed substantial clinical benefits and statistically significant differences from the control families in the incidence of running away, arrests, convictions, number of lifetime sex partners, tobacco use, alcohol use, and problems related to alcohol and drugs.

In 2000, Kitzman et al. (2000) published a 3-year follow-up of their trial of home visits to a cohort of 743 mainly African American women in Memphis, Tennessee. These women had no previous live births and at least two of three sociodemographic risk factors (unmarried, fewer than 12 years of education, or unemployed). Modest but strongly statistically significant outcomes were noted, all in favor of the intervention group, for intervals between pregnancies and months of dependence on AFDC and food stamps. This study showed persistence of benefit over the 3-year period with findings consistent with their prior studies of White women in a rural area.

In 2000, the Olds/Kitzman group—this time with Eckenrode as prime author (Eckenrode et al., 2000)—published yet another 15-year follow-up of the Elmira study. The group successfully reached 315 of the 400 families visited during pregnancy and up to 2 years postpartum. The women had been adolescent, unmarried, and/or low-income at the time of initial enrollment. This publication showed a substantial and highly statistically significant reduction in a number of measures of child abuse and neglect, but only among the families that had received postnatal visits, and only among family units with 28 or fewer incidents of domestic violence.

Other Investigators

In 1994, Marcenko and Spence (1994) reported on a home visitation program for women considered to be at risk for out-of-home placement for their newborns. The study included 125 cases and 100 controls, with home visits provided weekly or biweekly from initiation of prenatal care through the first birthday. The authors considered the intervention successful on the basis of greater social support, greater access to services, and less psychological distress among the intervention families, even though more case children were placed out of home than controls.

In 1996, Margolis et al. did a randomized trial involving 93 Medicaid eligible pregnant women in two North Carolina counties to see whether home visitation would do a better job of accessing prenatal care. Results were strongly positive (Margolis et al., 1996).

In 1998, Ramey et al. published the combined results from three trials intended to demonstrate prevention of intellectual disability in low-birthweight and economically vulnerable newborns (Ramey & Ramey, 1998). These early intervention programs were multidisciplinary in that they included early childhood education, family

counseling and home visits, health services, medical services, nursing services, nutrition services, service coordination, special instruction, speech-language services, and transportation. The study relative to the low-birthweight infants (Ramey et al., 1992) is reported in the next section of this report. The Abecedarian and Carolina Approach to Responsive Education (Project CARE) studies were randomized controlled trials of an educational intervention using a 36-month program known as *Partners for Learning*. These two trials showed consistent and substantial improvements in IQ, as measured in cognitive assessments at 6, 12, 18, 24, and 36 months of age.

In 1999, Armstrong et al. published results of a randomized controlled trial of nurse home visits to "vulnerable" families with newborns to see whether they could reduce maternal depression and improve maternal-infant bonding. This study, conducted in Australia with 180 participants and 6 weeks of follow-up measurement, showed strong and highly significant improvement in measures of emotion and maternal-child inter- action.

In 2001, Margolis et al. in North Carolina reported on the results of a validation study expanding this approach to a systematic community-wide intervention involving teams of nursing staff working with both private practitioners and community health centers. Levels of participation by both physician offices and eligible women were very high. Multiple outcome measures very strongly favored the intervention women in this randomized trial (Margolis et al., 2001).

In October of 2003, an independent, nonfederal task force with support from CDC—the task force developing the *Guide to Community Preventive Services*—issued a report recommending early childhood home visitation for the prevention of child abuse and neglect (Task Force on Community Preventive Services, 2003). This was based on a highly structured review of the literature.

Program Implementation Issues: How To Manage the Intervention So That It Succeeds in Securing Desired Benefits

The primary program implementation issue would appear to be the already well-developed system of medical, social, and financial support services, with home visitation added as an extra benefit. The number of home visits is dependent on the judgment of the nurse and study protocols and will vary considerably from family to family. This enables the program to secure maximum benefits without excess expenditures for home care services.

Data Needs Specific to Home Visitation

- As the level of service is fairly intense, it would probably be best to maintain a line listing of cases, with quarterly updates for discussion and presentation quarterly at pediatric quality assurance meetings.
- Program planning, quality assurance, and evaluation should be in accordance with the guidelines available through the National Center for Children, Families and Communities Web site at www.nccfc.org.

Educational Services To Improve the Intelligence of Selective Infants and Preschool Children

The following groups of infants and preschool children are at high risk of subnormal intellectual development—a risk that can be identified by the health care provider, and then addressed through the delivery of specialized educational services:

- Social and economic vulnerability
- Low birthweight
- Exposure to alcohol or illicit drugs during pregnancy
- Offspring of a mentally retarded mother

Research indicates that health care delivery systems should be alerted to the need for supplemental educational services for these infants. Although it may not be incumbent upon the health care system to provide the needed education, these infants are likely to be missed unless detected and brought to the attention of social service agencies by pediatric staff.

The need for supplemental educational services will be most apparent to the pediatric medical and nursing staff if they have been alerted to this problem. Awareness of the problem through in-service education would seem reasonable for all health plans, especially those serving large numbers of at-risk families. Whether or not the needed supplemental educational services are paid for by the health plan or provided by the health care delivery systems will depend on plan-specific scope-of-contract decisions, and plan and health-care-delivery-system definition as to whether such services are considered medical, rather than social or nonmedical (Rosenbaum et al., 2003). If deemed outside the scope-of-contract or nonmedical, research would indicate it is incumbent upon the health care system to refer such cases to appropriate educational and social service programs, and to assist the family in securing the needed service. For these reasons, the provision of the supplemental educational services are classified as "targeted/social and educational" in this report.

These interventions have a moderate evidence base, as reviewed below, and are fully consistent with the larger and more definitive studies presented in the prior section that demonstrate the value of intensified services to economically and socially vulnerable mother/infant dyads. The benefits to be secured from these services are primarily social rather than medical in nature. The literature demonstrating the value of such services for improving infant and child intelligence does not address the possibility that such services might reduce health care costs. As a result, these services are not expected to generate a health care cost-related return on investment.

Intervention

The literature indicates that the services to be provided are educational in nature. They may include infant stimulation, home visitation and special classes in health care, and educational or social service settings. These services can be coordinated with the home visitation and other preventive services provided by the health care delivery system. The health care system case managers can also oversee them.

Such services could be dismissed easily as social and educational in nature and not the concern of health care delivery systems. However, if they are not addressed by pediatric staff, it is unlikely that the families in need of such services will connect with them, regardless of who pays for them.

Provision of such supplemental educational services can be seen as having three distinct stages. The first is detection of the need for such services. The second is delivery of the services. The third is follow-up to determine if the services were provided and whether they were effective in enhancing infant and child intelligence. The decision to pay for or provide the educational service is one to be made by each health care delivery system on

the basis of its scope of coverage and conceptualization of whether such services are medical in nature. However, the research indicates that a good case can be made for all health care systems having the capacity to identify the need for such services and to follow up to help assure that they have been provided effectively.

At the health care system level, the following will be beneficial, based on the literature:

- Periodic educational programming for medical and nursing staff caring for infants and small children as to the conditions suggesting a special need for supplemental educational services, plus how such services are arranged and provided for within or through the health care system
- Policies and procedures by which family units that may have the need for such supplemental educational services are individually assessed to confirm or deny the impression that such services might be needed, and to ascertain the package of services for that family
- Periodic follow-up to include assessment of infant and child intelligence on subsequent "well baby" visits
- Occasional special quality assurance studies to document that infants at risk have been properly identified and that follow-through has been appropriate

Review of Literature

Services to Low-Birthweight Infants To Improve Infant/Child Intelligence

In 1992, Ramey et al. published the results of an eight-site randomized controlled trial of a 3-year intervention consisting of home visitation, parent support groups, and a systematic educational program provided in specialized child development centers. There were 377 intervention families and 608 control families. Both cases and controls received all indicated pediatric care. Both cases and controls showed similar profiles of prematurity.

The results showed statistically significant increases in mean Stanford-Binet IQ scores, comparing cases to controls, and a dose-response relationship within the case population showing increases in IQ with increasing participation in the program, with the low participation group showing a mean IQ about five points higher than controls, and the highest participation group showing a mean IQ almost 15 points higher. Although the factors determining levels of program participation among the cases were not randomly distributed and probably reflected important confounding variables, it seems reasonable to conclude that the three-part intervention did have a significant impact on the child's IQ score at age 36 months (Ramey et al., 1992).

In 1997, McCarton et al. published an 8-year follow-up on a randomized controlled trial of educational services, home-based family support, and pediatric follow-up to low-birthweight infants. The results showed small, but favorable differences, comparing the intervention to control groups, with most of the benefit in the heavier infants (McCarton et al., 1997).

In 1999, Bao et al. published the results of a randomized controlled trial conducted in Beijing, China (Bao, Sun, & Wei, 1999). Enrollees were all low-birthweight infants. The intervention consisted of an educational program that taught mothers techniques of infant stimulation to be used in the home. At the end of the 2-year intervention, the Mental Development Index scores for the intervention infants were approximately 14

points higher than for the low-birthweight controls, and approximately six points higher than the small group of normal birthweight control infants.

Services to Economically and Socially Vulnerable Families To Improve Infant/Child Intelligence

Olds and Kitzman also considered the impact of their home visitation program on infant/child intelligence, but only as one of many outcome parameters being considered. There were no statistically significant treatment effects on infant/child intelligence in either their Elmira (Olds, 1994) or Memphis (Kitzman et al., 1997) studies.

In 1998, Ramey and Ramey published the combined results from three trials intended to demonstrate prevention of intellectual disability in low-birthweight and economically vulnerable newborns (Ramey & Ramey, 1998). The study relative to the low-birthweight infants (Ramey et al., 1992) is reported in the next section of this monograph. The Abecedarian and CARE studies were randomized controlled trials of an educational intervention of a 36-month program known as *Partners for Learning*. These two trials showed consistent and substantial improvements in IQ, as measured in cognitive assessments at 6, 12, 18, 24, and 36 months of age.

Based on this research, it appears that generalized home visitation programs are likely to have a minimal impact on infant/child intelligence, but intensive educational programs can have a significant effect.

Services to Infants Born to Mentally Retarded or Otherwise Challenged Mothers

Two studies published 6 years apart by Ramey and Ramey (Ramey & Ramey, 1992, 1998) provided intensive educational interventions for children of low-IQ mothers to compensate for the mother's inability to provide adequate infant stimulation and education. They reported on two similar randomized trials of infants born to mentally retarded mothers and one trial of low-birthweight infants. The sample sizes in the two studies with mentally retarded mothers were small. The Abecedarian study had 41 cases and 45 controls. The Care study had 24 cases and 15 cases, respectively, in two intervention groups and 23 controls. The impact of the supplemental education was dramatic, in most cases moving the child from an IQ of approximately 90 to an IQ of approximately 110. In addition to education, the interventions also provided medical and nutritional support. The benefits, although substantial, did not appear likely to reduce other health care costs. The studies on this topic did not address the issue of health care cost.

Securing the participation of enough infants of mentally retarded mothers to do reasonably rigorous randomized controlled trials is a difficult task. Given the magnitude of the benefit documented in this study, and the consistency of these results with the results of other studies of intensive support services provided to vulnerable mother/infant dyads, it seems reasonable to accept the results of these studies as strong evidence that intensive educational support services provided as a supplement to reasonably comprehensive medical care can be effective in dramatically improving the intellectual performance of infants born to mentally retarded mothers.

Other

In 1994, Olds published data from the Elmira trial (White, semirural, low-income), which compared intellectual development of infants whose mothers smoke more than 10

cigarettes a day. The study population provided 64 cases and 57 controls. The data showed that the generalized Olds/Kitzman home visitation intervention was effective in preventing intellectual impairment related to smoking in the infants receiving the home visitation intervention (Olds, Henderson, & Tatelbaum, 1994).

In 1994, Black et al. (1994) published results of a small randomized clinical trial, including 31 cases and 29 controls, of home visitation for newborn infants of drug-abusing women. This program of generalized support through biweekly home visits by nurses during the first 18 months of life showed modest improvements in maternal drug-related behavior, improvements in parenting, and improvements in child development. Although this study is weak and far from definitive (it is the only one covering this issue from the perspective of drug-abusing pregnant women), its findings suggest that these women and their infants respond to infant visitation programs offering comprehensive maternal and pediatric care in a manner similar to other vulnerable women and their infants.

Program Implementation Issues: How To Manage the Intervention So That It Succeeds in Securing Desired Benefits

Management of these interventions will probably best be done using collaboration with external agencies than has traditionally been experienced within the managed care community.

Data To Be Gathered

As the level of service is fairly intense, it would probably be best to maintain a line listing of cases, with quarterly updates for discussion and presentation quarterly at pediatric quality assurance meetings.

Summary: High-Risk Women and Children

Targeted interventions, including home visits to at-risk, low-income, pregnant women and developmental/sensory screening of their infants, may yield short-term benefits to the health plan of healthier babies wih fewer problems, and long-term benefits to the mother and child.

VII. Screening Children and Adolescents (5–18 Years)

Screening for child and adolescent behavioral disorders using the Pediatric Symptom Checklist (PSC) is widely used in many medical practices and Medicaid programs. The current literature documents the ability of this brief, one-page instrument to identify children in need of further behavioral evaluation. Unfortunately, there are no randomized, controlled studies that document outcomes on screened individuals or groups, compared with populations not screened. PSC screening is classified "targeted" rather than "general" because the studies needed to provide a firmer evidence base have not been done.

Screening for Evidence of Behavioral Disorder

The PSC is a brief, one-page, 35-question instrument designed for use by parents in the doctor's waiting room. The questionnaire is designed to detect behavioral and psychosocial problems in children from 2 to 16 years of age, and it has been used effectively in persons up to 18 years of age (Bernal et al., 2000). Each of the questions can be answered with a "never," sometimes," or "often," with scores of 0, 1, or 2, respectively, attributed to each answer. Scores of 24, 28, or higher, depending on the age of the child, are considered indicative of a possible behavioral or psychosocial problem and will warrant further exploration by the clinician (Jellinek & Murphy, 1999).

The PSC has been suggested as a tool for universal use with children 2 to 16 years of age to screen for behavioral and psychosocial problems (Jellinek & Murphy, 1988; Walker, LaGrone, & Atkinson, 1989; Murphy, Arnett, Bishop, Jellinek, & Reede, 1992; Jellinek & Murphy, 1999, Gardner, 2002; Jellinek et al., 1999). In use since the 1970s, the PSC has been tested and used in tens of thousands of children; scored well in a test of its usefulness to the Medicaid-sponsored Early and Periodic Screening, Diagnosis, and Treatment (EPSDT) program (Murphy et al., 1996); and is used in several States in the context of their EPSDT programming (Jellinek & Murphy, 1999; Bernal et al., 2000; Gardner, Kelleher, & Pajer, 2002).

The PSC has been found to be acceptable to parents, regardless of socioeconomic status or ethnicity, and to clinicians and clinic office staff (Murphy et al., 1992; Murphy, Reede, Jellinek, & Bishop 1992; Jellinek et al., 1999; Navon, Nelson, Pagano, & Murphy, 2001). It has been validated

against more elaborate classification instruments—the Child Behavior Checklist (CBCL) and the Clinician's Global Assessment Scale (CGAS (Walker et al., 1989; Jellinek & Murphy, 1999). It also routinely generates prevalence rates for pediatric psychosocial and behavioral disorders of approximately 12 percent, which is consistent with other estimates of pediatric behavioral and psychosocial disorders (Jellinek & Murphy, 1999; Jellinek, 1999). The expected increase in psychosocial dysfunction with lower socioeconomic class (Jellinek, Little, Murphy, & Pagano, 1995) and the expected correlation with maternal psychological distress and marital adjustment (Sanger, MacLean, & Van Slyke, 1992) have been clearly documented.

The primary outcome measure noted in the PSC literature has been the percentage of children referred for behavioral or psychosocial evaluation and treatment. This rate of referral has dramatically increased with the introduction of the PSC in every study where this measure has been reported (Navon et al., 2001). In one study, the referral rate increased from 1.5 percent before implementation of the PSC to 12 percent, then dropped back to 2 percent after the PSC screening was discontinued (Murphy et al., 1992). This review found no studies that address the behavioral and psychosocial benefits to the children screened or costs associated with referral of false-positive cases.

One study published in 2000 (Bernal et al., 2000) reported average log costs for health and psychiatric care for all children studied at $393 per year, and costs of those with anxious, depressed symptoms at $805 per year. Chronically ill children showed the highest health care costs, with average log costs of $1,138 per year. Psychosocial dysfunction was associated with higher costs. Unfortunately, this study did not explore whether detection and treatment of the psychosocial dysfunction could lower these costs. With a documented minimum sensitivity (accurately detecting true "positives" or those with the illness) of 80 percent, and a specificity (detecting those without disease) of 68 percent or better (Jellinek et al., 1988; Jellinek & Murphy, 1999), this screening instrument may miss up to 20 percent of children who have serious problems, and refer up to 32 percent of well children to diagnostic interviews that prove negative for any treatable behavioral or psychosocial behavior. Although these efficacy statistics are within acceptable ranges for screening instruments, they do speak to costs of program implementation that need to be considered. Like virtually all other screening programs, little or no benefit will accrue without follow-up treatment for those found to be in need of such treatment. Owing to the research findings, the PSC may be considered a "targeted" service for use in health care delivery settings with providers and health care systems wishing to use it.

The available literature leaves unanswered the possible use of the PSC when the primary care practitioner suspects a significant behavioral problem but does not have enough information to confirm or deny this impression. For such cases, health care systems may wish to make this instrument available to providers for selective use, at their discretion.

The PSC, along with articles describing its proper use on the Pediatric Development and Behavior Web site, is available at www.dbpeds.org/handouts/ (Jellinek & Murphy, 1999) under "screening." It should be used without modification, other than for

translation when working with non-English-speaking families.

The PSC consists of 35 very brief statements to which the parent responds "never," "sometimes," or "often." Presented on a single page with check-off boxes, sample statements include: "Complains of aches/pains; tires easily, little energy; has trouble with a teacher; acts as if driven by a motor … ." The responses are graded on a zero-to-two scale. Depending on age, a score of 24, 28, or greater is considered indicative of significant psychosocial impairment (Jellinek & Murphy, 1999).

Summary: Children and Adolescents 5–18 Years

Screening for potential child and adolescent behavioral disorders using the PSC is widely used in medical practices and Medicaid programs. Because of its low burden (brief), ease of use, wide applicability, and validity, the literature supports its use by health plans with all children in a health care system. In this report, such screening is classified as a "targeted" service rather than "general" because no randomized controlled trials that could document outcomes have been attempted.

VIII. Adolescents (12–18 Years)

There is a substantial body of behavioral literature dealing with adolescents. Most commonly, adolescence is considered to begin within puberty and continue through 18 or 19 years of age. Individual differences in the onset of puberty and full achievement of sexual maturity create a situation in which biological adolescence for some individuals begins as early as 6 years of age and extends into the early 20s. For program planning and evaluation, adolescence can be defined as extending from the 11th or 12th birthday to the 19th birthday. Research supports screening interviews for tobacco, alcohol, and illicit drug use for all adolescents aged 12–18 years, and suggests screening for depression as a "targeted" service.

Adolescence is a period of rapid change and development that offers unique opportunities for interventions that could have substantial impact on future health and quality of life. Addictions and lifelong habits related to tobacco, alcohol, illicit drugs, and high-risk behaviors frequently are formed in adolescence. Most of the literature and most guidelines relating to these issues focus on the adolescent age group and address community, social agency, and educational interventions. Since the vast majority of adolescents use relatively little medical care, screening of adolescents in health care settings has not been a cornerstone of most adolescent-related preventive behavioral programming. Almost all preventive behavioral programming is conducted in school and community settings, and occasionally in correctional settings (Schinke et al., 2002).

Depression and suicide are major concerns in adolescence. Unfortunately, the adult screening tests for depression are not as specific or sensitive for adolescents. This means that there will be more false-positives and more false-negatives. Furthermore, no studies have examined treatment outcomes for children or adolescents identified by primary care clinicians through screening (USPSTF, 2003). This lack of adolescent-specific, primary-care–specific research makes it difficult to suggest screening of all adolescents for depression as a "general" service. Preventive behavioral services to adolescent pregnant women are the same for adolescents and adults.

According to the 1996 Second Edition of the U.S. Preventive Services Task Force's *Guide to Clinical Preventive Services* (USPSTF, 1996), the following is suggested for male adolescents and nonpregnant female adolescents:

> Organizations developing clinical recommendations recommend universal (interview) screening of adolescents for tobacco, alcohol, and illicit drug use—with follow-up on

positive findings to confirm the impression from screening and provide needed counseling and other services. These include the American College of Physicians (American College of Physicians Health and Public Policy Committee, 1986), the American Academy of Family Practice, the American Academy of Family Physicians (1994), the American Academy of Pediatrics (AAP, 1994), the American College of Obstetrics and Gynecology (ACOG, 1993), the American Medical Association (AMA , 1994), and others (ADA, 1992; CTF on the Periodic Health Examination, 1994b; NIH, 1989, 1994); American Academy of Otolaryngology—Head and Neck Surgery, 1992; Green, ed., 1994; USPSTF, 1996). Although available interventions are limited in efficacy, these services appear to be of enough value to the adolescents reachable by these means to be recommended as universal services for all adolescents being seen in all health care systems (USPSTF, 1996).

With the exception of adolescents who are pregnant or suffering from a major chronic disease, it is unlikely that health care systems can anticipate a significant immediate reduction in other health care costs that result from providing behavioral screening and follow-up services. The universality of these guidelines for health care systems is based on the perception that attitudes and habits developed during adolescence will have a lifetime impact on health risk profiles and quality of life.

Tobacco

Tobacco screening and follow-up for adolescents is classified as "general" because of the addictive nature of tobacco products and because of the severe harm tobacco products cause. This classification also takes into account the lack of substantial evidence to show the value of clinician interventions in either preventing tobacco use or in getting adolescents to quit. These recommendations are not limited to cigarettes and cigars because a substantial number of teens use snuff or chewing tobacco (DHHS, 1994).

There are two major reasons to address tobacco control in adolescents. The first and most significant reason is to prevent future illness and death. Most smokers start during adolescence, and if someone does not begin to smoke until after the age of 21, it is very unlikely that smoking will become a lifelong addiction (DHHS, 1988; Henningfield, Cohen, & Pickworth, 1994). The second and less important reason relates to immediate prevention of physical deterioration and illness.

Tobacco-related interventions have proven effective enough in practice to be universally implemented. This is backed up by the fact that all major health care organizations and authorities recommend routine clinician counseling of adults, pregnant women, parents, and adolescents to avoid or discontinue smoking and use of smokeless tobacco (USPSTF, 1996; American College of Physicians Health and Public Policy Committee, 1986; American Academy of Family Physicians, 1994; AAP, 1994, 1988; ACOG, 1993; Manley et al., 1991; AMA, 1993; American Dental Association [ADA], 1992; CTF on the Periodic Health Examination, 1994b; NIH, 1989, 1994; AMA, 1994a; American Academy of Otolaryngology—Head and Neck Surgery, 1992; Green, ed., 1994).

Intervention

The primary care physician or nurse may inquire about the use of tobacco products at every visit, counsel not to initiate tobacco use, and reinforce this message at every visit.

A primary focus of adolescent tobacco-related programming (as opposed to pregnant women and adults) is the initiation of tobacco use.

Review of Literature

A more substantial review of the tobacco and health literature is presented in the discussion of tobacco in the Adults (19 Years and Older) section of this report.

Evidence Base for Intervention

According to the 1996 Second Edition of the U.S. Preventive Services Task Force's *Guide to Clinical Preventive Services* (USPSTF, 1996)—

> The scope of this report does not permit an examination of each study of the health effects of smoking or the nature of the risk relationship (e.g., relative risk, dose-response relationship) between smoking and each disease. Detailed reviews of this extensive literature have been published elsewhere (CDC, 1990, 1993a; DHHS, 1986, 1989; U.S. Environmental Protection Agency [EPA], 1992; National Cancer Institute [NCI], 1993). A number of consistent findings from this body of evidence are well established. First, tobacco is one of the most potent of human carcinogens, causing an estimated 148,000 deaths among smokers annually due to smoking-related cancers (CDC, 1993a). The majority of all cancers of the lung, trachea, bronchus, larynx, pharynx, oral cavity, and esophagus are attributable to the use of smoked or smokeless tobacco (DHHS, 1986, 1989). Smoking also accounts for a significant, but smaller proportion of cancers of the pancreas (CDC, 1990; Howe, Jain, Burch et al., 1991; Bueno de Mesquita, Miasonneuve, Moerman, et al., 1991), kidney (DHHS, 1989), bladder (CDC, 1990; Hartge, Silverman, Schairer et al., 1993), and cervix (CDC, 1990; Coker, Rosenberg, McCann, et al., 1992; Sood, 1991; Gram, Austin, & Stalsberg, 1992); … 100,000 deaths from coronary heart disease … [and] 85,000 deaths from pulmonary diseases … . Children and adolescents who are active smokers have an increased prevalence and severity of respiratory symptoms and illnesses, decreased physical fitness, and potential retardation of lung growth (DHHS, 1994)… the nicotine in tobacco is an addictive drug … initiation of tobacco use at an early age is associated with more severe addiction as an adult.

There is a large body of evidence from prospective cohort and case-controlled studies showing that many of these health risks can be reduced by smoking cessation (CDC, 1990).

There have been no published trials that have adequately evaluated interventions by clinicians in preventing tobacco use initiation. Since the mid-1970s, however, more than 90 controlled trials of school-based tobacco use prevention interventions have been published (DHHS, 1994). School-based programs reduce the incidence (Hansen, Johnson, Flay, et al. 1988; Abernathy & Bertrand, 1992) and prevalence (Elder, Wildey, de Moor, et al., 1993; Botvin, Dusenbury, Tortu, et al., 1990) of tobacco use in adolescents at 2 to 4 years follow-up. However, longer follow-up has shown little long-term benefit … suggesting that program effects need to be reinforced (Flay, Koepke, Thomson, et al., 1989; Murray, Pirie, Luepker, et al., 1989). All major health care organizations and authorities recommend routine

clinician counseling of adults, pregnant women, parents, and adolescents to avoid or discontinue smoking and use of smokeless tobacco (USPSTF, 1996; American College of Physicians Health and Public Policy Committee, 1986; AAFP, 1994; AAP, 1994, 1988; ACOG, 1993; Manley, et al., 1991; AMA, 1993; ADA, 1992; CTF on the Periodic Health Examination, 1994b; NIH, 1989, 1994; AMA, 1994a; American Academy of Otolaryngology—Head and Neck Surgery, 1992; Green, ed., 1994).

This literature search failed to yield significant new literature on the topics noted above since publication of the *Guide*. The problem is not negative literature, but an absence of literature on clinician interventions for adolescents.

For adolescents other than pregnant women, the evidence base for the recommended interventions (clinician counseling to prevent tobacco use or to encourage cessation of tobacco) is weak, but the health-status cost of becoming addicted to tobacco products or continuing an established addiction is so extreme, that programming of even minimal effectiveness is considered standard practice.

Program Implementation Issues

According to the 1996 Second Edition of the U.S. Preventive Services Task Force's *Guide to Clinical Preventive Services* (USPSTF, 1996), certain strategies can increase the effectiveness of counseling to end tobacco use (NIH, 1986, 1989, 1994; AMA, 1994a; AAFP, 1987; Kenford, Fiore, Jorenby, 1994):

- Direct, face-to-face advice and suggestions
- Reinforcement
- Office reminders to the physician
- Self-help materials
- Community programs for additional help in quitting
- Drug therapy (nicotine patch or gum and related products)

Data To Be Tracked For Surveillance, Member Selection, Feasibility Assessment, and Program Evaluation

Data To Be Gathered

Refer to Appendix D, Procedures for Implementation and Evaluation of Preventive Services, and the sections on tobacco use in pregnant women and adults.

Alcohol

Alcohol screening and follow-up for adolescents are classified as "general" because of the severe immediate harm caused by alcohol use by adolescents, including auto accidents and problems in school. This classification was established in the face of no substantial evidence base from randomized controlled trials to show the value of clinician interventions in either preventing alcohol use or getting adolescents to quit.

Intervention

The primary care physician or nurse may choose to inquire as to use of alcohol at every visit, counsel abstention or moderation, and reinforce this message at every visit.

Service-Related Issues Specific to Alcohol and Adolescents

- As with tobacco and illicit drugs, practitioners seeing adolescents may choose to address the topic of alcohol, urge abstinence or no more than very

moderate use, and explore whether there is a problem in need of additional discussion.

- High-quality, validated screening questionnaires that are brief enough to be practical in primary care settings are available for screening adolescents and adults for problem drinking. Adults may be periodically screened for problem drinking or alcohol dependence. In most primary care settings, the two-question, two-item conjoint screen (TICS) or four-question CAGE (Chan, 1994) or CUGE (Cut down/Under the influence driving/Guilty/Eye opener) (Aertgeerts et al., 2000) screening instruments may be most useful. In emergency room and psychiatric inpatient settings, the CAGE (four yes/no questions), Audit (10 multiple-choice questions), or Michigan Alcoholism Screening Test (MAST) (Selzer, 1971) (25 questions) may be considered. These are all described below. In community health centers and facility-based primary care outpatient settings with provision for nurses or social workers to conduct initial patient settings, use of the 10-question Adult Use Disorders Identification Test (AUDIT) instrument may be very helpful.
- Special studies may be needed to identify whether the health care system has a high enough incidence of car crashes, injuries, homicides, or suicides within any segment of its adolescent population to warrant partnering with appropriate community agencies to address possibly severe alcohol-related problems.

Review of Literature

A more substantial review of the alcohol and health literature can be found in the section on Adults (19 Years and Older) in this report. The adult alcohol discussion includes the most important alcohol screening questionnaires. Literature specific to use of alcohol during pregnancy is presented in the section called Pregnant Women.

Evidence Base for Intervention

According to the 1996 Second Edition of the U.S. Preventive Services Task Force's *Guide to Clinical Preventive Services* (USPSTF, 1996)—

> … Use of alcohol by adolescents and young adults has declined over the past decade but remains a serious problem (NIDA, 1993). Among 12–17 year-olds surveyed in 1993, 18 percent had used alcohol in the last month, and 35 percent in the last year (SAMHSA, 1994). In a separate 1993 survey, 45 percent and 33 percent, respectively, of male and female 12th graders reported binge drinking (five or more drinks on one occasion) within the previous month (CDC, 1995b). The leading causes of death in adolescents and young adults—motor vehicle and other unintentional injuries, homicides, and suicides—are each associated with alcohol or other drug intoxication in approximately half of the cases. Driving under the influence of alcohol is more than twice as common in adolescents than in adults (CDC, 1987). Binge drinking is especially prevalent among college students: half of all men and roughly one third of all women report heavy drinking within the previous 2 weeks (NIDA, 1993; Wechsler, Davenport, Dowdall, et al., 1994). Most binge drinkers report numerous alcohol-related problems, including problems with school work, unplanned or unsafe sex, and trouble with police (Wechsler et al., 1994).

The American Academy of Pediatrics

(AAP), AMA Guidelines for Adolescent Preventive Services (GAPS), the Bright Futures Guidelines, and the American Academy of Family Physicians (AAFP) all recommend careful discussion with all adolescents regarding alcohol use and regular advice to abstain from alcohol (American Academy of Pediatrics Committee on Adolescence, 1995; AMA, 1994b; Green, ed., 1994; AAFP, 1994).

Program Implementation Issues From the Published Literature

In a 2002 review of alcohol-problem related screening questionnaires (NIAAA, 2002), the National Institute on Alcohol Abuse and Alcoholism (NIAAA) stated: "The Alcohol Use Disorders Identification Test (AUDIT) is relatively free of gender and cultural bias (Cherpitel, 1999; Reinert & Allen, 2002; Volk, Steinbauer, Cantor, & Holtzer, 1997). In addition, it shows promise for screening adolescents and older people—populations in which standard screening instruments produce inconsistent results (Steinbauer, Canton, Holzer, & Volk, 1998; Reinert & Allen, 2002; Clay, 1997; Chung, Colby, Barnett, et al., 2000; Chung, Colby, Barnett, & Monti, 2002). The major disadvantage of AUDIT is its length (10 questions) and relative complexity (multiple choice); clinicians require training to score and interpret the test results (Allen & Columbus, 1995)."

According to the 1996 Second Edition of the U.S. Preventive Services Task Force's *Guide to Clinical Preventive Services* (USPSTF, 1996)—

> Laboratory tests generally are insensitive and nonspecific for problem drinking in both adolescents and adults.

Numerous studies demonstrate that clinicians frequently are unaware of problem drinking by their patients (USPSTF, 1996; NIAAA, 1993). Early detection and intervention may alleviate ongoing medical and social problems due to drinking and reduce future risks from alcohol abuse.

A 1990 Institute of Medicine (IOM) report concluded that specific recommendations for the treatment of alcohol problems in young persons were impossible, due to disagreement over what constitutes a drinking problem in adolescents, the wide variety of interventions employed, and the absence of any rigorous evaluation of different treatments (IOM, 1990). Recent reviews of school-based programs found that most effects were inconsistent, small, and short-lived; programs that sought to develop social skills to resist drug use seem to be more effective than programs that emphasize factual knowledge (Ennett, Tobler, Ringwalt, et al., 1994; Hansen, 1992).

All the data available regarding the efficacy of clinical interventions at the time of the 1996 report are from studies in adults, not adolescents. The studies needed to document the efficacy of such interventions in adolescents simply have not been done, leaving us with a situation where we either ignore alcohol problems in adolescents or extrapolate the results from adults to adolescents until such time as the needed studies can be conducted, peer-reviewed, and published. As noted above, AMA, AAP, and AAFP all have opted to recommend intervention in adolescents despite the lack of adolescent-specific studies.

According to the 1996 Second Edition of the U.S. Preventive Services Task Force's *Guide to Clinical Preventive Services* (USPSTF, 1996)—

> Typical of the results for nondependent drinkers, a meta-analysis of six brief intervention trials (5–15 minutes of clinical counseling) showed an average reduction in alcohol consumption of 24 percent, comparing cases to controls. Although self-reported consumption may be subject to bias, reported changes in drinking correlated with measures of GTT [glucose tolerance test] and blood pressure in most studies (Babor & Grant, eds., 1992). It is important to note that this and most other such studies suffered from important methodological limitations.
>
> For adults with alcohol-dependence, completing either inpatient treatment or 12 weeks of outpatient treatment, some studies have shown approximately 60 percent long-term abstinence rates. These data are difficult to interpret, however, because of inadequate control groups, insufficient or selective follow-up, and selection bias due to the characteristics of patients who successfully complete voluntary treatment programs (IOM, 1989; Thurstin, Alfano, & Sherer, 1986; Emrick, 1987). Since spontaneous remission occurs in as many as 30 percent of alcoholics (Smart, 1975/76; Saunders & Kershaw, 1979), reduced consumption may be inappropriately attributed to treatment. Successful treatment is likely to represent a complex interaction of patient motivation, treatment characteristics, and the post-treatment environment (family support, stress, etc.) (IOM, 1990; NIAAA, 1993). The IOM review concluded that treatment of other life problems (e.g., with antidepressant medication, family or marital therapy, stress management) and [counsel with] empathetic therapists were [factors] likely to improve treatment outcomes (IOM, 1989).

Data To Be Gathered

Refer to Appendix D. There are no specific supplemental data needs relative to alcohol and adolescents.

Illicit Drugs

Programming to control use of illicit drugs by adolescents is classified as "general" because of the severe immediate harm caused by drug use by adolescents—including auto accidents and problems in school. A number of studies demonstrate the efficacy of clinical interventions in reducing or eliminating drug use among symptomatic adolescents. Although community interventions have demonstrated value in preventing adolescent drug use, there is no substantial evidence that stand-alone clinical interventions can prevent drug experimentation and use. There is no substantial evidence base to show the value of clinician interventions in getting asymptomatic adolescent drug users to quit. In each instance, the needed adolescent-specific studies have not been done. Given these circumstances, the severe harm caused by drugs in adolescents, and the difficulty in ascertaining which adolescents are using illicit drugs (because many parents do not know and many adolescents are unlikely to be forthright on this issue with adult authority figures), the most prudent course appears to be brief universal screening of adolescents for drug use (by interview at each primary care visit), with follow-up as appropriate.

Intervention

The primary care physician or nurse may wish to inquire as to the use of illicit drugs at every visit, counsel abstention, and reinforce this message at every visit.

Service-related issues specific to illicit drugs and adolescents are as follows:

- To approach discussion of use of illicit drugs in a nonjudgmental manner, clinicians should consider establishing a trusting relationship with patients and properly respect their concerns about the confidentiality of disclosed information. This would mean that physicians and other clinicians would need to spend much more time with their adolescent patients so they can get to know each other and begin to establish the trusting relationships needed. Although common sense suggests these steps to be taken to enhance the ability of health care delivery systems to deal with alcohol and related issues in adolescent populations, we know of no randomized controlled trials that demonstrate their efficacy. Here, again, the needed studies have not been done.
- Clinician inquiry as to use of illicit drugs at every visit with clinician counseling at every visit not to initiate use of illicit drugs.
- Health care systems may wish to consider the need to develop and maintain special training programming to educate and assist clinicians in establishing relationships with adolescents and in communicating with them about illicit drugs and related topics.
- Health care systems may wish to consider the need for reimbursement and payment systems that will enable clinicians to spend the time required to establish and maintain the desired trusting relationships with adolescents. Such reimbursement mechanisms would eliminate current financial disincentives to longer clinic visits.

Review of Literature

Evidence Base for Intervention

According to the 1996 Second Edition of the U.S. Preventive Services Task Force's *Guide to Clinical Preventive Services* (USPSTF, 1996)—

> In a national household survey in 1993, 14 percent of adults ages 18–25 years and 3 percent of those over 35 reported using illicit drugs within the last month (SAMHSA, 1994).
>
> Among high school seniors in 1994, 22 percent reported using an illicit drug in the past month: marijuana (19 percent), stimulants (4 percent), inhalants (3 percent), and hallucinogens (3 percent) were more common than cocaine (1.5 percent) or heroin (0.3 percent) (NIDA, 1994b). Abuse of inhalants is a leading drug problem in younger adolescents (NIDA, 1994b) and can cause asphyxiation or neurologic damage with chronic abuse (Sharp, 1992). Abuse of anabolic steroids in adolescent boys and young men can cause psychiatric symptoms and has been associated with hepatitis, endocrine, and cardiovascular problems.
>
> Drug use is more common among men, unemployed adults who have not completed high school, and urban residents. The overall prevalence of drug use does not differ greatly among White, African American, and Hispanic/Latino populations, but patterns of drug use may differ (NIDA, 1994a). Adverse effects of drug use are

greatest in heavy users and those dependent on drugs, but some can occur from even occasional drug use. Cocaine can produce acute cardiovascular complications (e.g., arrhythmias, myocardial infarction, cerebral hemorrhage, and seizures), nasal and sinus disease, and respiratory problems (when smoked) (Perper & Van Thiel, 1992; Warner, 1993). Dependence on cocaine produces diminished motivation, psychomotor retardation, irregular sleep patterns, and other symptoms of depression (Gold, Washton, & Dackis, 1985). "Crack," a popular and cheaper smokeable form of cocaine, is also highly addictive. Mortality among injection drug users (IDUs) is high from overdose, suicide, violence, and medical complications from injecting contaminated materials (e.g., human immunodeficiency virus [HIV]) infection, hepatitis, bacterial endocarditis, chronic glomerulonephritis, and pulmonary emboli); in some cities, up to 40 percent of IDUs are infected with HIV (National Center for Infectious Diseases, 1993). Although the extent of adverse effects of marijuana use is controversial, chronic use may be associated with respiratory complications or amotivational syndrome (Schwartz, 1987; Jones, 1984). In a 1991 survey, 8 percent of cocaine users and 21 percent of marijuana users reported daily use for 2 weeks or more (Keer, Colliver, & Kopstein, 1994).

The indirect medical and social consequences of drug use are equally important: criminal activities related to illicit drugs take a tremendous toll in many communities. Use of injection drugs and crack are major factors in the spread of HIV infection (CDC, 1994; Edlin, Irwin, Faruque, et al., 1994)… . Drugs play a role in many homicides, suicides, and motor vehicle injuries… . Nearly half of all users of cocaine or marijuana reported having driven a car shortly after using drugs (Schwartz, 1987; Keer et al., 1994).

Early intervention has the potential to avert some of the serious consequences of drug abuse, including injuries, legal problems, and medical complications. Although various treatments have been proven effective in persons with drug dependence, they have largely been studies in patients who have already developed medical, social, or legal problems due to their drug use. There is much less evidence that systematic screening and earlier intervention is effective in improving clinical outcomes among asymptomatic persons, who may be less motivated to undergo treatment than more severely impaired drug users. Here, again, the needed studies have not been done.

Treatment of adolescent substance use disorders has been recently reviewed for nearly 1,500 primary middle-class adolescents aged 12–19 years who entered inpatient or residential treatment programs (Bergmann, Smith, & Hoffman, 1995). Compared to use before treatment, there was a significant reduction in regular drug use (weekly or more) 1 year after treatment (85 percent versus 29 percent), and 50 percent of teens had been abstinent for 6 months. Increasing parental participation in treatment was associated with greater levels of abstinence.

High school primary prevention programs that emphasize "life skills" have reduced tobacco or alcohol use

over the short term (1 year) (Botvin & Botvin, 1992), but long-term effects on illicit drug use have not been well studied. In a 6-year randomized trial among 3,597 high school students, a prevention curriculum delivered in grades 7–9 significantly reduced smoking and alcohol use, but not marijuana use, in high school seniors; a subgroup of students who received a more complete intervention were less likely to use marijuana regularly (5 percent versus 9 percent) (Botvin, Baker, Dusenbury, et al., 1995).

The American Medical Association (AMA, 1988) and the American Academy of Family Physicians (AAFP, 1994) advise physicians to include an in-depth history of substance use disorder as part of a complete health examination for all patients. The … AAFP (1994), AMA Guidelines for Adolescent Preventive Services (GAPS) (AMA, 1994b), Bright Futures recommendations (Green, ed., 1994), and American Academy of Pediatrics (AAP, 1989; AAP Committee on Substance Abuse, 1993) suggest that clinicians discuss the dangers of drug use with all children and adolescents and include questions about substance use disorder as part of routine adolescent visits.

The AMA and most other medical organizations endorse urine testing (for drugs) when there is reasonable suspicion of substance use disorder, but none of these groups recommends routine drug screening in the absence of clinical indications.

Program Implementation Issues From the Literature

According to the 1996 Second Edition of the U.S. Preventive Services Task Force's *Guide to Clinical Preventive Services* (USPSTF, 1996)—

The diagnostic standard for drug abuse and dependence is the careful diagnostic interview (APA, 1994)… .

There are few data to determine whether the use of standardized screening questionnaires can increase the detection of potential drug problems among patients. Brief alcohol screening instruments such as the CAGE or MAST can be modified to assess the consequences of drug use in a standardized manner (Trachtenberg & Fleming, 1994; Skinner, 1982), but these instruments have not been compared with routine history of clinician assessment. Questionnaires to identify adolescents at increased risk for drug use have not been validated in prospective studies (Schwartz & Wirtz, 1990). Other instruments, such as the Addiction Severity Index (McLellan et al., 1980), are useful for evaluating treatment needs but are too long for screening.

Toxicological tests can provide objective evidence of drug use… . Sensitivity of these tests generally is above 99 percent compared with reference standards (Armbruster, Schwartzoff, Hubster, et al., 1993); sensitivity for detecting drug use in individuals, however, depends directly on timing of drug use and the urinary excretion of drug metabolites. Marijuana may be detected for up to 14 days after repeated use, but evidence of cocaine, opiates, amphetamines, and barbiturates is present for only 2 to 4 days after use. Various techniques may be employed by drug users who wish to avoid detection that further reduces the sensitivity of urine testing: water loading, diuretic use, ingestion of interfering substances, or adulterating urine samples. Most importantly, toxicologic tests do not distinguish

between occasional users and individuals who are dependent on or otherwise impaired by drug use.

False-positive results from urine drug screening are possible due to cross-reaction with other medications or naturally occurring compounds in foods (ElSohly & ElSohly, 1990). To prevent falsely implicating persons as users of illicit drugs, screen-positive samples are usually confirmed with more specific (and expensive) techniques, such as gas chromatography-mass spectroscopy (GC-MS). These procedures reduce, but do not eliminate, the possibility of false-positive results due to cross-reactions, contamination, or mislabeled specimens. Proficiency testing of nearly 1,500 urine specimens sent to 31 U.S. laboratories produced no false-positive results and three percent false-negative results (Frings, Bataglia, & White, 1989). A similar study of 120 clinical laboratories in the U.K. demonstrated higher error rates (4 percent false-positive, 8 percent false-negative), largely due to laboratories that did not use confirmatory tests (Burnett, Lader, & Richens, 1990).

Drug testing is frequently performed without informed consent in the clinical setting on the grounds that it is a diagnostic test intended to improve the care of the patient. Because of the significance of a positive drug screen for the patient, however, the rights of patients to autonomy and privacy have important implications for screening of asymptomatic persons (Merrick, 1993). If confidentiality is not ensured, test results may affect a patient's employment, insurance coverage, or personal relationships (Rosenstock, 1987). Testing during pregnancy is especially problematic, because State law may require physicians to report evidence of potential harmful drug or alcohol use in pregnant patients.

Data To Be Gathered

See Appendix D. Because optimal two-way communication with adolescents, especially regarding use of illicit drugs, requires longer clinic visits, health care systems may wish to establish some means by which they can track time spent by primary care staff and time spent by those specializing in adolescent health in clinic visits.

Depression

Depression in adolescents presents risk of suicide, risks relative to substance use disorder, inhibition of development of scholastic and emotional skills, and for those with a chronic illness (such as asthma, diabetes, or even severe obesity), risk of non-adherence to prescribed regimens of care.

The incidence of documented suicides by adolescents and young adults has dramatically increased in recent decades, with 5,000 youths committing suicide each year and perhaps as many as 500,000–1,000,000 making an attempt (Greydanus, 1986; USPSTF, 1996).

In 2002, the U.S. Preventive Services Task Force issued the recommendation that all adults should be screened for depression in health care settings, but concluded that evidence was insufficient to extend this recommendation to children and adolescents because of the limited number and quality of available studies specific to children and adolescents (USPSTF, 2002b, 2003; Pignone et al., 2002). The problem here is that few adolescent-specific studies have been done, and none has been done in primary care

settings (USPSTF, 2003). The studies that have been done in other settings suggest that available screening procedures are less reliable in adolescents than adults, but that treatment is comparable in efficacy.

A discussion of the adult literature and screening procedures that may be considered are both presented in the discussion about depression in the section of this report called Adults (19 Years and Older).

The available literature on depression in adolescents clearly shows an increase in risk and severity of depression among children and adolescents with a depressed parent, as well as adolescents who have economic, social, and educational vulnerabilities. As a matter of practicality, it will probably be easier for primary care practitioners to directly screen the adolescent for depression with a brief screening instrument than it would be to explore whether or not one or both parents might be depressed and explore possible sociodemographic risk factors. Preventive interventions aimed at such children, when they are showing "subsyndromal" depressive symptoms can be very effective in preventing future episodes of major depression (Clarke et al., 2001).

Depression and suicide are major concerns in adolescence. Unfortunately, the adult screening tests for depression, although fairly good, are not as specific or sensitive for adolescents. This means that there will be more false-positives and more false-negatives. Furthermore, no studies have examined treatment outcomes for children or adolescents identified by primary care clinicians through screening (USPSTF, 2003). This lack of adolescent-specific, primary-care–specific research creates a situation where screening of all adolescents for depression cannot be suggested as a "general" service. It may be advisable to screen adolescents for depression as a "targeted" service. The case for screening of preadolescent children is much less clear; it may be advisable to alert clinicians to signs and symptoms of depression in such children rather than having them apply universal screening.

Intervention

Primary care practitioners can use their clinical judgment in deciding which adolescents to screen for depression, and the screening procedures that should be used. The health care delivery system should assure that practitioners seeing large numbers of adolescents are familiar with the research on this topic. All such practitioners should be alert to signs and symptoms of depression in both children and adolescents.

Review of Literature

A more substantial review of the literature on depression appears in the section of this report called Adults (19 Years and Older).

Evidence Base for Intervention

Depression is common among adolescents, with a point prevalence estimated at 3–8 percent (Clarke et al., 2001; Birmaher et al., 1996). By 18 years of age, as many as 25 percent of adolescents have had at least one depressive episode (Lewinsohn, Hops, Roberts, Seeley, & Andrews, 1993). Children and adolescents with a depressed parent are up to six times more likely to develop depression than other children (Downey & Coyne, 1990; Beardslee, Versage, & Gladstone, 1998).

Evidence now exists that psychosocial interventions may prevent depression (Beardslee et al., 1993; Clarke et al., 1995; Jaycox, Reivich, Gillham, & Seligman, 1994). A frequently studied group consists of

individuals who do not meet full DSM–IV criteria for an affective episode, but who report significant "subsyndromal" depressive symptoms. Full-blown depression is more likely to develop in these individuals (Roberts, 1987; Horwath, Johnson, Klerman, & Weissman, 1992; Weissman, Fendrich, Warner, & Wickramaratne, 1992). Such individuals have been the subject of several targeted prevention interventions (Clarke et al., 1995; Jaycox et al., 1994).

Clarke et al. (2001) published such a study in a managed care population in Oregon. The Clarke team enrolled 45 cases and 49 controls, including adolescent children showing "subsyndromal" depressive symptoms who had at least one depressed parent. Those offspring who met the diagnostic criteria for full-blown depression were treated and studied separately. Those with no depressive symptoms were not subsequently followed up. Those offspring with subdiagnostic levels of depressive symptoms insufficient for a diagnosis were invited to receive the experimental intervention, and adolescents who chose to participate were randomly assigned to the experimental intervention versus the usual-care group. In this small but well-designed randomized controlled trial, the intervention was a 15-session group cognitive therapy prevention program. In the year after intake, cases experienced 11 days of depression, compared with 44 days for controls. Over a mean follow-up period of 15 months, 9.3 percent of the cases experienced one or more depressive episodes, compared with 28.8 percent of the controls. Much but not all of this preventive benefit persisted through the 24-month follow-up, suggesting a durable but fading level of protection.

A parallel study by the Clarke team, of children and adolescents who were already experiencing major depression at time of intake showed no net benefit from the cognitive therapy intervention (Clarke et al., 2002).

In an earlier study (Clarke et al., 1995), the Clarke team tested 1,625 high school students with the CES-D (depression questionnaire) and then conducted a randomized controlled trial of 150 students with "subsyndromal" depressive symptoms who agreed to participate in the study. After randomizing them and providing the same 15-session cognitive therapy intervention, cases showed a 14.5 percent rate of depressive episodes over the next 12 months, compared with 25.7 percent of the controls—a level of risk and benefit similar to the children of depressed parents noted above. This high school study did not explore parental mental health conditions or other potential risk factors.

In a thought-provoking ecological study published in 2001, Podorefsky et al. (Podorefsky, McDonald-Dowdell, & Beardslee, 2001) interviewed low-income families with parental depression and explored alliance-building as an intervention to reduce both parental and child depression. Sixteen families participated in the study. Without exception, mothers described depression as a reaction to traumatic or chronic stressful conditions. The research team felt that at least some of these families were living under conditions of overwhelming adversity. The intervention involved alliance-building at the community level, as well as with caregivers and family. It focused on family resilience and immediate daily concerns—with promising preliminary results. This study suggests, but does not prove, that for at least some families with depression under certain circumstances, assistance with dealing with environmental

causes of the depression might be of value—and might be within reach of agency social work staff and community partners.

The literature on the prevalence of depression in adults and the efficacy of screening and follow-up procedures is reviewed in the section of this report on adult depression and will not be duplicated here.

Summary: Adolescents 12–18 Years

Research supports screening interviews for tobacco, alcohol, and illicit drug use for all adolescents aged 12–18 and suggests screening adolescents for depression as a "targeted" service. The literature supporting screening adolescents for depression is less robust than its counterpart in adults because the randomized, adolescent-specific studies have not been done.

IX. Adults (19 Years and Older)

Screening and follow-up for tobacco and alcohol use disorders and for depression/anxiety are the primary topics here that are addressed for adults. Each topic is associated with a few brief questions, followed by various low-cost interventions.

In persons without major medical or behavioral comorbidities, the medical benefits of screening and follow-up are substantial but are spread out over too many years to generate immediate health care cost savings. The literature shows tobacco and alcohol quit rates in the range of 5–30 percent (comparing cases to controls) and frequent relapse, but even with these relatively modest quit rates, the benefits are substantial enough to suggest universal implementation. Adult guidelines differ from the adolescent and pregnancy guidelines in that preventing use of illicit drugs is not as urgent an issue.

With depression and anxiety, the short-term benefit of cost savings depends on the presence or absence of other medical and behavioral comorbidities. In persons without such comorbidities, the benefits are substantial but primarily related to quality of life and workplace productivity. In persons with such comorbidities, reductions in health care costs can be substantial and immediate.

Detailed guidelines and literature reviews are presented for tobacco, alcohol, depression, and anxiety. These guidelines include the specific screening questions to be used, and guidelines for follow-up. A brief discussion is provided relative to substance abuse in adults. Depression-related disorders are presented in detail, with a separate discussion of depression screening, follow-up, and cost-effectiveness related to heavy users of health care services and those with major chronic diseases.

Separate analyses were done for adults older and younger than 65 years of age. Problems related to use and misuse of multiple prescription drugs in persons over 65 years of age were considered to be outside the scope of this report. Otherwise, preventive guidelines and projected benefits for tobacco, alcohol, and depression screening were so similar for adults older and younger than 65 years of age that the guidelines for all adults are presented in a single section of this monograph for adults 19 years of age and older.

Tobacco

After reaching 21 years of age, initiation of tobacco use is rarely a problem. For those who already smoke, the issue to be addressed is prevention of future tobacco-related medical illness through reduction or elimination of current tobacco use. In randomized trials, inexpensive clinical interventions for cessation of tobacco use have shown increases in abstinence rates in

the range of 3–25 percent at one year, compared with controls (Wilson, Taylor, Gilbert, et al., 1988; Okene, Kristeller, Goldberg, et al., 1991; Bronson, Flynn, Solomon, et al., 1989; Hollis, Lichtenstein, Vogt, Stevens, & Biglan, 1993; Cohen, Stookey, Katz, et al., 1989; Curry, Marlatt, Gordon, et al., 1988; Stevens & Hollis, 1989). The key to success is consistent reinforcement by clinicians.

Tobacco-related disease is prevalent enough and serious enough that even with limited efficacy of clinical interventions, such interventions have been deemed worthy of universal implementation. In fact, all major health organizations that have addressed this topic have supported this recommendation. As a result of these findings, tobacco cessation programming for adults and seniors is classified as "general."

This literature search uncovered no literature dealing directly with the issue of cost-effectiveness for tobacco control programming for adults and seniors. The problem here is two-fold. First, the benefits for adults and seniors without major chronic diseases are too far in the future, and their health care service utilization is too small for smoking cessation to substantially reduce other health care costs within 12 months. Second, for those with major chronic diseases, the major impact is likely to be a reduction in short-term mortality. This reduction in mortality is a substantial patient benefit, but it may increase health care costs by keeping these sick patients alive longer, thereby nullifying the savings from marginal reductions in health care use by these same persons with chronic diseases.

This literature review found no direct evidence that tobacco use influenced a patient's ability and willingness to follow prescribed regimens of care. The near-term reductions in health care costs attributable to addressing alcohol use, use of illicit substances, and depression do not appear to be a benefit of tobacco cessation programming. As a result, from a health-care–cost perspective, smoking cessation will have little or no immediate impact on aggregate health care costs.

As tobacco use becomes less and less socially acceptable, fewer people will smoke, and those who do smoke will smoke less. One suggested way to pursue this objective, on a societal basis, is to have every adult and senior asked about tobacco use at every primary care visit, and to have every tobacco user briefly counseled to quit. Although this approach is not amenable to randomized controlled trials, it seems reasonable to presume that action along this line could play a significant role in reducing adult and senior tobacco use.

Interventions

The literature suggests that the topic of tobacco use should be brought up at every outpatient visit. Those who smoke or otherwise use tobacco products may be counseled to cease such use. If immediate cessation seems out of reach, smokers may be counseled to reduce the amount of tobacco they use and to consider enrollment in tobacco cessation programming.

If not already accomplished, steps can be taken to assure that all health and medical facilities are totally smoke-free. This is important for a number of reasons, the most important of which may be communicating to staff and patients that smoking is simply not acceptable because of its extreme hazard to the health of both smokers and persons exposed to secondhand tobacco smoke.

Review of Literature

Evidence Base for Intervention

According to the 1996 Second Edition of the U.S. Preventive Services Task Force's *Guide to Clinical Preventive Services* (USPSTF, 1996)—

> … Detailed reviews of the extensive literature on the health effects of smoking, dose-response relationships, and nicotine addiction have been published elsewhere (CDC, 1993a; DHHS, 1986, 1989, 1990b; EPA, 1992; NCI, 1993). A number of consistent findings from this body of evidence are well established. First, tobacco is one of the most potent of human carcinogens, causing an estimated 148,000 deaths among smokers annually due to smoking-related cancers (CDC, 1993a). The majority of all cancers of the lung, trachea, bronchus, larynx, pharynx, oral cavity, and esophagus are attributable to the use of smoked or smokeless tobacco (DHHS, 1986, 1989). Smoking also accounts for a significant but smaller proportion of cancers of the pancreas (CDC, 1990; Ghadirian, Simard, & Baillargeon, 1991; Howe et al., 1991; Bueno de Mesquita et al., 1991), kidney (DHHS, 1989), bladder (CDC, 1990; Hartge et al., 1993), and cervix (CDC, 1990; Coker et al., 1992; Sood, 1991; Gram et al., 1992)… . 100,000 deaths from coronary heart disease … [and] 85,000 deaths from pulmonary diseases … .
>
> There is a large body of evidence from prospective cohort and case-controlled studies showing that many of these health risks can be reduced by smoking cessation (CDC, 1990). A number of clinical trials have demonstrated the effectiveness of certain forms of clinician counseling (Wilson et al., 1988; Okene et al., 1991; Bronson et al., 1989; Hollis et al., 1993; Kottke, Battista, DeFriese, et al., 1988; Cohen et al., 1989) and group (Kottke et al., 1988; Curry et al., 1988; Stevens & Hollis, 1989) in changing the smoking behavior of patients… . A meta-analysis of 39 clinical trials in nonpregnant adults examined different types of clinical smoking cessation techniques involving various combinations of counseling, distribution of literature, and nicotine replacement therapy. It found higher cessation rates in the intervention group compared with the control groups, with differences averaging 6 percent after 1 year (Kottke et al., 1988). Subsequent published trials have demonstrated increases in abstinence rates of 3–7 percent in patients receiving clinician counseling (Wilson et al., 1988; Okene et al., 1991; Bronson et al., 1989; Hollis et al., 1993; Cohen et al., 1989) and 8–25 percent with group counseling, compared with controls (Curry et al., 1988; Stevens & Hollis, 1989). The key elements of effective counseling seem to be providing reinforcement through consistent and repeated advice from a team of providers to stop smoking, setting a specific "quit date," and scheduling follow-up contacts or visits. Using additional modalities, such as self-help materials, referral to group counseling, advice from more than one clinician, or chart reminders identifying patients who smoke, seems to further enhance effectiveness (Kottke et al., 1988; Cohen et al., 1989; Russell, Wilson, Taylor, et al., 1979; Janz, Becker, Kirscht, et al., 1987; Sanders, Fowler, Mant, et al., 1989).
>
> As adjuncts to counseling, the prescription of nicotine products can facilitate smoking cessation (Lam,

Sze, Sacks, et al., 1987; Jarvis, Raw, Russell, et al., 1982; Jackson, Stapleton, Russell, et al., 1986; Tonnesen, Fryd, Hansen, et al., 1988; Hughes, Gust, Kennan, et al., 1989; Tonnesen, Norregaard, Simonsen, et al., 1991; Stapleton, Russell, Feyerabend, et al., 1995; Transdermal Nicotine Study Group, 1991; Daughton, Heatly, Prendergast, et al., 1991; Muller, Abelin, Ehrsam, et al., 1990; Sachs, Sawe, & Leischow, 1993; Fiore, Kenford, Jorenby, et al., 1994; Hurt, Dale, Fredrickson, et al., 1994; Fiore, Smith, Jorenby, et al., 1994). Randomized controlled trials have found that 12-month cessation rates after brief clinician counseling and multiple follow-up visits double from 4 percent to 9 percent with placebo to 9 percent to 25 percent with the nicotine patch (Tonnesen et al., 1991; Stapleton et al., 1995; Sachs et al., 1993; Hurt et al., 1994). When used correctly and in combination with clinician advice to stop smoking, nicotine gum increases long-term smoking cessation rates by approximately one third (Oster, Huse, Delea, & Colditz, 1986; Tang, Law, & Wald, 1994)… . Two meta-analyses of controlled trials of nicotine replacement therapies found a significant benefit for all modalities with no modality being significantly better than another (Tang et al., 1994; Silagy, Mant, Fowler, et al., 1994)… . The evidence suggests that nicotine products are most effective as adjuncts to ongoing smoking cessation counseling (Silagy et al., 1994; Fiore, Jorenby, Baker, et al., 1992). Furthermore, patients need proper instruction on how to use the nicotine replacement therapies. Patients have been reported to use nicotine patches and gum without discontinuing smoking, thus increasing the risk of nicotine toxicity (Johnson, Steven, Hollis, et al., 1992; Orleans, Resch, Noll, et al., 1994).

All major health care organizations and authorities recommend routine clinician counseling of adults, pregnant women, parents, and adolescents to avoid or discontinue smoking and use of smokeless tobacco (USPSTF, 1996; American College of Physicians Health and Public Policy Committee, 1986; AAFP, 1994; AAP, 1988, 1994; ACOG, 1993; Manley et al., 1991; AMA, 1993, 1994a; ADA, 1992; CTF on the Periodic Health Examination, 1994b; NIH, 1989, 1994; American Academy of Otolaryngology—Head and Neck Surgery, 1992; Green, ed., 1994).

The effects on patients with coronary heart disease quitting smoking was reviewed by Critchley and Capewell (Critchley & Capewell, 2003). In this 2003 literature review, they concluded that "quitting smoking is associated with a substantial reduction in risk of all-cause mortality among patients with coronary heart disease. This risk reduction appears to be consistent regardless of age, sex, index cardiac event, country, and year of study commencement." Thus there is a strong evidence base for a modest reduction in tobacco use through clinician counseling to encourage cessation. The evidence suggests that the health risks of continuing an established tobacco addiction are so extreme, however, that programming of even minimal effectiveness would reap considerable benefits when offered as routine clinical practice.

Nurse-assisted counseling for smokers may be considered by health care systems that provide primary care services in large clinic settings. In 1993, Kaiser Permanente

(Portland, Oregon) published a randomized controlled trial (Hollis et al., 1993) showing 86 percent physician participation in delivering brief advice, and quit rates of approximately 7 percent in nurse-counseled patients, compared with approximately 3.9 percent for physician advice alone at one year. Prior to the study, physicians participated in a 1-hour training session to encourage them to use their own words to deliver a basic message lasting no more than 30 seconds:

> *The best thing you can do for your health is to stop smoking, and I want to advise you to stop as soon as possible. I know it can be very hard; many people try several times before they finally make it. You may or may not want to stop now, but I want you to talk briefly with our health counselor, who has some tips to make stopping easier when you decide the time is right.*

The nurse counseling session included a 10-minute video and an assortment of aids and stop-smoking literature. There were three different study interventions—individual, group, and combination—all with similar quit rates (Hollis et al., 1993). The study was limited, given that only about half of the participating cases and controls provided saliva samples for the follow-up testing. Those results were still highly statistically significant, but with results 30–50 percent lower than noted above, if all those who did not submit saliva samples were counted as continuing smokers.

Program Implementation Issues

According to the 1996 Second Edition of the U.S. Preventive Services Task Force's *Guide to Clinical Preventive Services* (USPSTF, 1996)—

> Although the significant health hazard of tobacco use and the benefits of cessation are well established, studies suggest that many clinicians fail to counsel patients who smoke to stop tobacco use (CDC, 1993c; Anda, Remington, Sienko, et al., 1987; Frankowski & Secker-Walker, 1989; USPSTF, 1996). This reluctance to intervene may be the result of a number of variables, including lack of confidence in the ability to provide adequate counseling, lack of patient interest, lack of financial reimbursement or personal reward, insufficient time, and inadequate staff support (Kottke, Willms, Solberg, et al., 1994). As described above, however, a number of studies have shown that clinician counseling can change behavior, even when the intervention is relatively brief. Nearly 50 percent of all living individuals who have ever smoked have stopped (CDC, 1994a), and 30 percent of quitters report being urged to quit by a physician (Fiore, Novotny, Peirce, et al., 1990). Approximately 90 percent of successful quitters have quit without intensive counseling but by stopping abruptly or with the help of quitting manuals (Fiore et al., 1990). A cost-effectiveness study supports the clinical value of offering smoking cessation counseling during the routine office visit of patients who smoke (Cummings, Rubin, & Oster, 1989).

Certain strategies can increase the effectiveness of counseling against tobacco use (NIH, 1986, 1989, 1994; AMA, 1994a; AAFP, 1987; Kenford et al., 1994):

- Direct, face-to-face advice and suggestions
- Reinforcement
- Office reminders to the physician

- Self-help materials
- Community programs for additional help in quitting
- Drug therapy (nicotine patch or gum and related products)

One recent study (McAfee, Grossman, Dacey, & McClure, 2002) suggested that in a managed care setting (Group Health Cooperative, Tukwila, Washington), a quality improvement initiative using an automated billing system with performance feedback and senior-level incentives could dramatically increase tobacco-related counseling and frequency of intervention, as well as secure the data through the billing system.

Data To Be Gathered

Refer to the section in this monograph called Procedures for Implemention and Evaluation of Preventive Services. Special data issues relative to tobacco and adults are limited to special attention to tobacco use in patients with major chronic diseases. Although not caused by tobacco use, diabetes carries a much higher rate of major complications in smokers.

Alcohol

Alcohol screening for all adults, including college students, is classified as "general" because of the severity of both immediate and long-term harms caused by alcohol use by adults. Since both acute use and immediate problems are most severe among college students and other college-age young adults, special attention is directed to this age group (18–29 years of age). The efficacy of clinical interventions to reduce harmful alcohol use is modest, but the severity of the harm—both short-term and long-term—mandates that health care providers and health care delivery systems do what they can to reduce such harmful use. With tobacco and illicit drugs, any use is harmful. With alcohol, however, moderate use can have a favorable effect on all-cause death rates, and on death rates from coronary heart disease (Bradley, Donovan, & Larson, 1993; Stampfer, Rimm, & Walsh, 1993; Maclure, 1993; Klatsky, Armstrong, & Friedman, 1990; Stampfer, Golditz, Willett, et al., 1988; Gaziano, Buring, Breslow, et al., 1993).

There is relatively little clinicians can do to prevent initial excessive use of alcohol, but available, reasonably inexpensive interventions can significantly reduce future excessive use and the behavioral, social, and injury-related complications of such use. In persons with one or more chronic diseases, reducing excessive alcohol use may be of value in improving patient adherence to prescribed regimens of care and avoiding medical complications of excessive alcohol use.

From a primary care perspective, alcohol-related problems can be divided into two major categories: alcohol dependence/addiction and nondependent problem drinking. The research suggests that those with addiction/dependence should be referred for specialized care. The primary care physician, however, often can successfully manage the nondependent problem drinkers. Separate sections of this report address use of alcohol by pregnant women and by adolescents.

Suggested Interventions

As with tobacco use, the topic of alcohol use may be brought up at every outpatient visit, with follow-up counseling as needed. Unlike tobacco, there appears to be no harm, and some benefit, from one or two drinks per day. This benefit, however, is not substantial enough to recommend that nondrinkers begin to consume alcohol. Practitioners may

be careful not to communicate the benefits of moderate use as an excuse for more substantial consumption of alcohol.

Special Service-Related Issues Specific to Adults and Alcohol

- High-quality, validated screening questionnaires that are brief enough to be practical in primary care settings are available for screening adolescents and adults for problem drinking. Adults should be periodically screened for problem drinking or alcohol dependence. In most primary care settings, the two-question/two-item conjoint screen (TICS) or four-question CAGE or CUGE screening instruments may be most useful. In emergency room and psychiatric inpatient settings, the CAGE (four yes/no questions), Audit (10 multiple-choice questions), or Michigan Alcoholism Screening Test (MAST) (Selzer, 1971) (25 questions) may be considered. These are all described below. In community health centers and facility-based primary care outpatient settings that allow nurses or social workers to conduct initial patient settings, use of the 10-question Adult Use Disorders Identification Test (AUDIT) instrument may be considered seriously.
- Clinicians must be able to differentiate problem drinking from alcohol dependence. Problem drinking usually can be successfully managed by the primary care practitioner. Alcohol dependence requires much more intensive intervention, and either specialized programming or specialized health care staff.
- For nondependent problem drinkers, research suggests that the most effective and most well-documented primary care intervention is the Trial for Early Alcohol Treatment (TrEAT) protocol. This involves a defined set of materials and two physician-patient sessions of 10 to 20 minutes apiece. The evidence for this protocol and against single-visit and shorter protocols is described below.
- Unlike tobacco and illicit drugs, modest use of alcohol can have health benefits, such as reducing the risk of heart disease.

Review of Literature

Additional alcohol-and-health literature is presented in the sections of this report addressing the needs of pregnant women and adolescents.

Evidence Base for Intervention

Burden of Suffering

According to the 2003 National Institute on Alcohol Abuse and Alcoholism (NIAAA) health practitioner's guide to helping patients with alcohol problems (NIAAA, 2003)—

> Alcohol problems are common: 14 million American adults suffer from alcohol abuse or alcoholism (Grant, Harford, Dawson, et al., 1994), and more than 100,000 people die from alcohol-related diseases and injuries each year (Stinson, Nephew, Dufour, & Grant, 1996). About a third of all adults engage in some kind of risky drinking behavior, ranging from occasional to daily heavy drinking (NIAAA, 2002). Over the past few generations, patterns of alcohol consumption have changed notably: people start drinking at increasingly earlier ages, the likelihood of dependence has risen in drinkers, and women's drinking patterns and rates of dependence have become increasingly similar to men's (Grant, 1997).

According to the 1996 Second Edition of the U.S. Preventive Services Task Force's *Guide to Clinical Preventive Services* (USPSTF, 1996)—

> Over half a million Americans are under treatment for alcoholism, but there is growing recognition that alcoholism (i.e., alcohol dependence) represents only one end of the spectrum of "problem drinking" (IOM, 1990). Many problem drinkers have medical or social problems attributable to alcohol (i.e., alcohol abuse or "harmful drinking") without typical signs of dependence (APA, 1994; WHO, 1992), and other asymptomatic drinkers are at risk for future problems due to chronic heavy alcohol consumption or frequent binges (i.e., "hazardous drinking"). Heavy drinking (more than five drinks per day, five times per week) is reported by 10 percent of adult men and 2 percent of women (SAMHSA, 1994). In large community surveys using detailed interviews (Helzer & McEvoy, 1991; Grant et al., 1994; Kessler et al., 1994), the prevalence of alcohol abuse and dependence in the previous year among men was 17–24 percent among 18–29 year-olds, 11–14 percent among 30–44 year-olds, 6–8 percent among 45–64 year-olds, and 1–3 percent for men over 65; among women in the corresponding age groups, prevalence of abuse or dependence was 4–10 percent, 2–4 percent, 1–2 percent, and less than 1 percent, respectively. Problem drinking is even more common among patients seen in the primary care setting (8–20 percent) (Bradley, 1994).
>
> Medical problems due to alcohol dependence include alcohol withdrawal syndrome, psychosis, hepatitis, cirrhosis, pancreatitis, thiamine deficiency, neuropathy, dementia, and cardiomyopathy (NIAAA, 1993). Nondependent heavy drinkers, however, account for the majority of alcohol-related morbidity and mortality in the general population (IOM, 1990). There is a dose-response relationship between daily alcohol consumption and elevations in blood pressure and risk of cirrhosis, hemorrhagic stroke, and cancers of the oropharynx, larynx, esophagus, and liver (Klatsky, Armstrong, & Friedman, 1992; Boffetta & Garfinkel, 1990; Anderson, Cremona, Paton, et al., 1993). A number of studies have reported a modest increase in breast cancer among women drinking two drinks per day or more, but a causal connection has not yet been proven (Rosenberg, Metzger, & Palmer, 1993). Three large cohort studies, involving more than 500,000 men and women, observed increasing all-cause mortality beginning at four drinks per day in men (Klatsky et al., 1992; Boffetta & Garfinkel, 1990) and above two drinks per day in women (Fuchs, Stampfer, Colditz, et al., 1995). Women achieve higher blood alcohol levels than do men, due to their smaller size and slower metabolism (Klatsky et al., 1992; Fuchs et al., 1995). Compared to nondrinkers and light drinkers, overall mortality was 30 percent to 38 percent higher among men, and more than doubled among women who drank six or more drinks per day (Klatsky, et al., 1992; Boffetta & Garfinkel, 1990). Of the more than 100,000 deaths attributed to alcohol annually, nearly half are due to unintentional and intentional injuries (CDC, 1990), including 44 percent of all traffic fatalities in 1993 (National Highway Traffic Safety

Administration, 1994) and a substantial proportion of deaths from fires, drownings, homicides, and suicides …

The social consequences of problem drinking are often as damaging as the direct medical consequences. Nearly 20 percent of drinkers report problems with friends, family, work, or police due to drinking (NIAAA, 1993). Persons who abuse alcohol have a higher risk of divorce, depression, suicide, domestic violence, unemployment, and poverty (NIAAA, 1993). Intoxication may lead to unsafe sexual behavior that increases the risk of sexually transmitted diseases, including human immunodeficiency virus (HIV). Finally, an estimated 27 million American children are at risk for abnormal psychosocial development due to the abuse of alcohol by their parents (Sher, ed., 1991).

Moderate alcohol consumption has favorable effects on the risk of coronary heart disease (CHD) (Bradley et al., 1993; Stampfer et al., 1988, 1993; Maclure, 1993; Klatsky et al., 1990; Gaziano et al., 1993). CHD incidence and mortality rates are 20 percent to 40 percent lower in men and women who drink one to two drinks/day than in nondrinkers (Fuchs et al., 1995; Klatsky et al., 1990; Stampfer et al., 1988). A meta-analysis of epidemiologic studies suggests little additional benefit of drinking more than 0.5 drinks per day (Maclure, 1993). The exact mechanism for the protective effect of alcohol is not known but may involve increases in high-density lipoprotein (Gaziano et al., 1993) and/or fibrinolytic mediators (Ridker, Vaughan, Stampfer, et al., 1994).

In an update published in 2002, Naimi et al. (2002) noted that nationwide, binge drinking increased from 1993 to 2001. Binge drinking episodes among U.S. adults increased from 1.2 billion to 1.5 billion (25 percent increase), while binge-drinking episodes per person increased by 17 percent, from 6.3 percent to 7.4 percent. Men accounted for 81 percent of binge drinking episodes. Rates of binge drinking episodes were highest among those aged 18–25 years. Binge drinkers were 14 times more likely to drive while impaired by alcohol compared with nonbinge drinkers. There were substantial State and regional differences in per capita binge drinking.

Brief Summary of Available Alcohol Screening Tests for Use in Primary Care Settings

There are a number of screening tests available, ranging from 1 to 25 questions in length, and with substantial variation in sensitivity, specificity, and staff training required for optimal use. None is perfect, but all are better than no screening at all. All of these questionnaire instruments are for screening, not diagnosis. Positive responses appear best when followed up with more extensive interview to confirm or deny the presence of an alcohol-related problem and to differentiate between alcoholism and nondependent problem drinking. These are all described in greater detail in the following section, with sample questions provided.

Single Question: "*On any single occasion during the past 3 months, have you had more than five drinks containing alcohol?*"

Two-Question: "*In the last year, have you ever drank or used drugs more than you meant to?*" and "*Have you felt you wanted*

or needed to cut down on your drinking or drug use in the last year?"

Four-Question: "CAGE"

C: *"Have your ever felt you ought to* ***C****ut down on drinking?"*

A: *"Have people* ***A****nnoyed you by criticizing your drinking?"*

G: *"Have you ever felt bad or* ***G****uilty about your drinking?"*

E: *"Have you ever had a drink first thing in the morning to steady your nerves or get rid of a hangover (****E****ye opener)?"*

Four-Question: "CUGE" The CUGE questionnaire replaces the "*annoyed you by criticizing your drinking" question with "Have you often driven under the influence?*"

Ten-Question: "AUDIT" (Alcohol Use Disorders Identification Test)

1. *How often do you have a drink containing alcohol?*
2. *How many drinks containing alcohol do you have on a typical day when you are drinking?*
3. *How often do you have six or more drinks on one occasion?* (Interviewers are then instructed to skip to questions 9 and 10 if the answer to question 2 is fewer than three drinks, and if the answer to question 3 is "never.")
4. *How often during the last year have you found that you were not able to stop drinking once you had started?*
5. *How often during the last year have you failed to do what was normally expected from you because of drinking?*
6. *How often during the last year have you needed a first drink in the morning to get yourself going after a heavy drinking session?*
7. *How often during the last year have you had a feeling of guilt or remorse after drinking?*
8. *How often during the last year have you been unable to remember what happened the night before because you had been drinking?*
9. *Have you or someone else been injured as a result of your drinking?*
10. *Has a relative, or friend, or doctor, or another health worker been concerned about your drinking, or suggested you cut down?*

25-Question: "MAST" The 25-question Michigan Alcoholism Screening Test (MAST) is relatively sensitive and specific, but it generally is considered too lengthy for routine screening in primary care settings. It is commonly used in psychiatric outpatient and inpatient settings.

Most studies seem to recommend the four-question CAGE and CUGE questionnaires for primary care settings, with a minimum of paraprofessional support and use of the 10-question AUDIT questionnaire where non-physician staff are available to administer and score the questionnaire. The CAGE and CUGE questionnaires require only yes/no answers and are easily memorized by primary care practitioners. The 10-question AUDIT questionnaire has multiple choice questions and a formalized scoring procedure.

More Detailed Discussion of the Accuracy and Utility of Alcohol Screening Tests

According to the 1996 Second Edition of the U.S. Preventive Services Task Force's *Guide to Clinical Preventive Services* (USPSTF, 1996)—

Laboratory tests generally are insensitive and nonspecific for problem drinking in both adolescents and adults.

Accurately assessing patients for drinking problems during the routine clinical encounter is difficult. The diagnostic standard for alcohol dependence or abuse (Diagnostic and Statistical Manual of Mental Disorders [DSM] IV) (APA, 1994) requires a detailed interview and is not feasible for routine screening. Physical findings … are only late manifestations of prolonged, heavy alcohol abuse (Glaze & Coggan, 1987). Asking the patient about the quantity and frequency of alcohol use is an essential component of assessing drinking problems, but it is not sufficiently sensitive or specific by itself for screening. In one study, drinking 12 or more drinks a week was specific (92 percent) but insensitive (50 percent) for patients meeting DSM criteria for an active drinking disorder (Buchsbaum, Welsh, Buchanan, et al., 1995). The reliability of patient report is highly variable and dependent on the patient, the clinician, and individual circumstances. Heavy drinkers may underestimate the amount they drink because of denial, forgetfulness, or fear of the consequences of being diagnosed with a drinking problem.

A variety of screening questionnaires have been developed which focus on consequences of drinking and perceptions of drinking behavior. The 25-question Michigan Alcoholism Screening Test (MAST) (Selzer, 1971) is relatively sensitive and specific for DSM-diagnosed alcohol abuse or dependence (84 percent to 100 percent and 87 percent to 95 percent, respectively) (Selzer, 1971; Pokorny, Miller, & Kaplan, 1972), but it is too lengthy for routine screening. . . . The four-question CAGE instrument is the most popular screening test for use in primary care (Ewing, 1984), and has good sensitivity and specificity for alcohol abuse or dependence (74 percent to 89 percent and 79 percent to 95 percent, respectively) in both inpatients (Bernadt, Mumford, Taylor, et al., 1982; Bush, Shaw, Cleary, et al., 1987) and outpatients (King, 1986; Buchsbaum, Buchanan, Centor, et al., 1991; Chan, Pristach, & Welte, 1994).

The CAGE is less sensitive for early problem drinking or heavy drinking (Chan et al., 1994; Hays & Spickard, 1987). Both the CAGE and MAST questionnaires share important limitations as screening instruments in the primary care setting: an emphasis on symptoms of dependence rather than early drinking problems, lack of information on level and pattern of alcohol use, and failure to distinguish current from lifetime problems (Chan, Pristach, Welte, et al., 1993).

Some of these weaknesses are addressed by . . . AUDIT, a 10-item screening instrument developed by the World Health Organization (WHO) in conjunction with an international intervention trial. The AUDIT incorporates questions about drinking quantity, frequency, and binge behavior along with questions about consequences of drinking (Saunders, Aasland, Babor, et al., 1993). . . . AUDIT had high sensitivity and specificity for "harmful and hazardous drinking" (92 percent and 94 percent, respectively) as assessed by more extensive interview (Saunders et al., 1993). . . . Because it focuses on

drinking in the previous year, however, AUDIT is less sensitive for past drinking problems (Schmidt, Barry, & Fleming, 1995).

The World Health Organization (WHO) recommends use of the AUDIT questionnaire in all primary care settings. A guidelines document for use with AUDIT is available free of charge from WHO (Babor TF, Higgins-Biddle, & Monterio, 2001). The questionnaire consists of 10 questions dealing with consumption of alcohol, symptoms of dependence, and social and behavioral evidence of harm. Each of the questions is scored on a scale of 0–4, with scores of 16–19 warranting supplemental counseling and continued monitoring. Scores in the range of 20–40 suggest referral to a specialist for diagnostic evaluation and treatment.

The AUDIT and MAST questionnaires require written forms and formal scoring procedures, which in turn require more staff training. These are not problems with the shorter and simpler TICS, CAGE, and CUGE, which are short enough to be easily memorized by the primary care physicians and nurses and elicit yes/no answers.

Use of Screening Tests for Alcohol Problems

Numerous studies demonstrate that clinicians frequently are unaware of problem drinking by their patients (USPSTF, 1996; NIAAA, 1993; Weisner & Matzger, 2003). Early detection and intervention may alleviate ongoing medical and social problems resulting from drinking and reduce future risks from alcohol abuse (USPSTF, 1996).

In 1998, the Substance Abuse Task Force of the Society for Academic Emergency Medicine issued a statement urging emergency room physicians to use screening questionnaires to improve their detection of alcohol-related problems in the emergency department setting. The Task Force asserted that early detection of alcohol problems would provide an opportunity for early intervention, which in turn might reduce subsequent morbidity and mortality (D'Ononfrio et al., 1998).

In a review of the quality of health care provided to adults in the United States, published in the *New England Journal of Medicine* in 2003, McGlynn et al. reported that, of all quality measures explored, adherence to quality measures for alcohol dependence was documented in only 10.5 percent of records reviewed. This compares with approximately 40 percent to 78 percent for most other quality measures in this study (McGlynn et al., 2003). This study gathered data from adult surveys and medical record reviews in 12 metropolitan areas of the United States for the most recent 2-year period.

Several recent papers urged screening of patients with depression (Abraham & Fava, 1999), schizophrenia (Agelink, Ullrich, Lemmer, Dirkes-Kersting, & Zeit T, 1999) and/or mood, anxiety, and substance use disorder (DeGraff, Bijl, Smit, Vollenbergh, & Spijker, 2002) for alcohol-related problems, given the high prevalence of comorbid alcohol problems in these patients as well as self-medication with alcohol.

A brief overview of screening tests for alcohol problems can be found on the Web site of the National Institute on Alcohol Abuse and Alcoholism (NIAAA) at www.niaaa.nih.gov/publications/aa56.htm. This April 2002 review (NIAAA, 2002) makes the following major points:

- Both questionnaires and blood tests are available. The blood tests (GGT [Gamma-glutamyl transferase]; CDT

[Carbohydrate Deficient Transferrin]; MCV [Mean Corpuscular Volume]; and possibly FAEEs [Fatty Acid Ethel Ethers]) probably are of little value in screening for chronic alcohol problems, but may be of significant value in tracking the progress of alcoholics and problem drinkers under care.

- The screening tests are not diagnostic. They identify individuals who may be interviewed more carefully to confirm or deny the impression of an alcohol-related problem, before establishing the need for further investigation, treatment, or referral.
- Use of screening tests is very effective both in identifying individuals with alcohol-related problems, and getting them the appropriate therapy (Fiellin, Reid, & O'Connor, 2000).
- The CAGE questionnaire (Ewing, 1984) has been verified extensively, with sensitivities for detecting alcohol abuse and alcoholism (Fiellin et al., 2000) ranging from 43 to 94 percent. It is well suited to primary care practice because it poses four straightforward yes/no questions that the clinician can easily remember, and it requires less than a minute to complete. This test, however, may fail to detect low but risky levels of drinking (Fiellin et al., 2000), and often performs less well among women and socially vulnerable populations (Cherpitel, 1999; Steinbauer et al., 1998).
- The performance of CAGE can be improved by incorporating questions about the quantity and frequency of drinking, as recommended by NIAAA in The Physicians Guide to Helping Patients With Alcohol Problems (NIAAA, 1995). This approach worked well in a general population sample (Dawson, 2000) and did better than CAGE alone among African Americans in an urban emergency room (Friedman, Saitz, Gogineni, Zhang, & Stein, 2001).
- The Alcohol Use Disorders Identification Test (AUDIT) (Saunders et al., 1993) also incorporates questions about quantity and frequency of alcohol use. In contrast to CAGE, AUDIT compares favorably with other instruments in detecting risky drinking but is less effective in identifying alcohol use and alcoholism (Fiellin et al., 2000; Reinert & Allen, 2002). AUDIT has proven useful among medical and psychiatric inpatients, in emergency rooms (Reinert & Allen, 2002), and in the workplace (Reinert & Allen, 2002; Hermansson, Helander, Huss, Brandt, & Ronnberg, 2000; Hermansson, Helander, Brandt, Huss, & Ronnberg, 2002). AUDIT is relatively free of gender and cultural bias (Cherpitel, 1999; Reinert & Allen, 2002; Volk et al., 1997). In addition, it shows promise for screening adolescents and older people, populations in which standard screening instruments produce inconsistent results (Steinbauer et al., 1998; Reinert & Allen, 2002; Clay, 1997; Chung et al., 2000; 2002). The major disadvantages of AUDIT are its length (10 questions) and relative complexity (multiple choice); clinicians require training to score and interpret the test results (Allen & Columbus, 1995).
- Alcohol consumption puts people at greater risk of injury. It plays a role in a large percentage of trauma incidents, including motor vehicle crashes. RAPS4 is a four-item questionnaire derived in part from TWEAK and AUDIT. In both

primary care and emergency room settings, RAPS4 showed consistently high sensitivity for detecting alcoholism across gender and ethnic subgroups, although its utility for screening for risky drinking or alcohol abuse has yet to be proven (Cherpitel, 2000; Borges & Cherpitel, 2001).

More information on these and other alcohol-related screening tests also can be found on the NIAAA Web site at www.niaaa.nih.gov.

In a study published in 2000, Aertgeerts (Aertgeerts et al., 2000), working from Catholic University in Belgium, compared several screening questionnaires in a population of 3,564 consecutive college freshman and concluded that a modified CAGE questionnaire, which is called "CUGE," may improve screening in college students. The CUGE questionnaire replaces the "annoyed you by criticizing your drinking" question with "often driving under the influence."

A series of four recent papers (Williams & Vinson, 2001; Taj, Devera-Sales, & Vinson, 1998; Aertgeerts, Buntinx, Ansoms, & Fevery, 2001; Seppa, Lepisto, & Sillanaukee, 1998) reported that variants on the theme of a single "five-shot" question generated results comparable to CAGE and AUDIT in adult male and female patients. The basic question was: "On any single occasion during the past 3 months, have you had more than five drinks containing alcohol?" Perhaps the most reasonable interpretation is that of Taj et al. (1998): "A single question about alcohol can detect at-risk drinking and current alcohol-use disorders with clinically useful positive and negative predictive values."

Another recent study (Brown, Leonard, Saunders, & Papasouliotis, 2001) presented promising, but as yet unverified results for a two-question questionnaire—the two-item conjoint screen (TICS) for alcohol and other drug abuse that can be incorporated easily into routine clinical practice. The two questions are: "In the last year, have you ever drunk or used drugs more than you meant to?" and "Have you felt you wanted or needed to cut down on your drinking or drug abuse in the last year?"

Of all studies considered, the four-item CAGE and CUGE questionnaires are probably the most appropriate for most primary care settings. They are detailed earlier in this chapter.

Alcohol Abuse Diagnostic Criteria

The following criteria have been adapted from the Diagnostic and Statistical Manual of Mental Disorders, Fourth Edition (DSM–IV), published by the American Psychiatric Association. This is as published in the NIAAA Health Practitioner's Guide (NIAAA, 2003). The criteria are as follows, with one or more of these situations occurring at any time in the past 12 months:

- Failure to fulfill major role obligations at work, school, or home because of recurrent drinking
- Recurrent drinking in hazardous situations
- Recurrent legal problems related to alcohol
- Continued use despite recurrent interpersonal or social problems

Alcohol Dependence Diagnostic Criteria

The following criteria have been adapted from the Diagnostic and Statistical Manual of Mental Disorders, Fourth Edition (DSM–IV), published by the American Psychiatric Association. This is as published

in the NIAA Health Practitioner's Guide (NIAAA, 2003). The criteria are follows, with three or more of these situations occurring at any time in the past 12 months:

- Tolerance (need to drink more to get the same effect)
- Withdrawal syndrome or drinking to relieve withdrawal
- Impaired control (unable to stop drinking)
- Drank more or longer than intended
- Neglect of activities
- Time spent related to drinking or recovering
- Continued use despite recurrent psychological or physical problems

Effectiveness of "Brief Interventions" for Nondependent Problem Drinkers

Typical of the results for nondependent drinkers, a meta-analysis of six brief intervention trials (5–15 minutes of clinical counseling) showed an average reduction in alcohol consumption of 24 percent, comparing cases to controls. Although self-reported consumption may be subject to bias, reported changes in drinking correlated with measures of GTT and blood pressure in most studies (USPSTF, 1996; Babor et al., 1992). It is important to note, however, that this and most other such studies suffered from important methodological limitations (USPSTF, 1996). Since publication of the 1996 Guide (as quoted above), there have been several publications, which among them appear to bring this issue into clearer focus for nondependent problem drinkers.

In mid-1996, WHO published the results of a randomized, controlled trial of two brief interventions in 1,260 men and 299 women in study centers scattered across 10 countries, including the United States (WHO Brief Intervention Study Group, 1996). The subjects were selected to be nondependent, heavy drinkers. The two interventions tested were a single, 5-minute "simple advice" session and a 20-minute "brief counseling" session, both supported with various written educational materials. Each intervention was delivered in a single session, with patients followed up 9 months later. On interview 9 months later, men reported 17 percent lower average daily alcohol consumption, and women reported a 10 percent decrease. There was no difference between those getting the 5-minute "simple advice" and those receiving the more intensive 20-minute "brief counseling" session. Although promising, weaknesses in the study design raise questions about the firmness of the findings. This WHO study frequently is referenced in newspapers and other nonresearch publications as proof that even the briefest of interventions are of value; however, this conclusion has not been borne out in other studies.

In 1999, Poikolainen published a meta-analysis of brief interventions in problem drinkers comparing single-session "brief interventions" with multi-session "extended brief interventions" (Poikolainen, 1999). His review of the literature did not include the WHO study referenced above because it apparently did not meet his criteria for inclusion in the review on methodological grounds. His review of multiple other publications, including 14 separate datasets, concluded that the single-session brief interventions were of little or no value, and that the multiple-session interventions were clearly beneficial in women, and sometimes but not always beneficial in men.

The best documented and methodologically strongest recent trial is the Project TrEAT (Trial for Early Alcohol

Treatment) published by Fleming et al. in a series of papers from 1997 to 2000 (Fleming, Mundt, French, Manwell, Stauffacher, & Barry, 2000; Fleming, Manwell, Barry, Adams, & Stauffacher, 1999; Fleming, Barry, Manwell, Johnson, & London, 1997). This series of papers looked at nondependent problem drinkers in 17 primary care and managed care sites in Wisconsin. There were 382 controls and 392 intervention patients. The intervention consisted of two 10–15 minute counseling sessions by the primary care physician, with written support materials. Patients were followed up at 6 months and 12 months. Depending on the measure, differences in alcohol consumption between cases and controls were in the range of 20–50 percent at 12 months. This difference was significant enough to reduce emergency room and hospital bed use within the first 12 months to more than cover the $205 estimated average per-case cost of the intervention. Considering only health care costs, the benefit-cost ratio was about 2.5:1. If avoided costs of crime and motor vehicle accidents are included, the benefit-cost ratio increases to 5.6:1.

Yet another controlled clinical trial demonstrating the lack of efficacy of single-session counseling sessions was published in 2000 (Freeborn, Polin, Hollis, & Senft, 2000). This trial, with 514 participants in a managed care setting (Kaiser Permanente, Portland, Oregon) showed a nonsignificant reduction in alcohol consumption at 6 months, but no reduction in health care utilization when comparing cases with controls.

Effectiveness of "Brief Interventions" for Dependent/Addicted Drinkers

For adults with alcohol-dependency completing either inpatient treatment or 12 weeks of outpatient treatment, some studies have shown long-term abstinence rates of approximately 60 percent. These data are difficult to interpret, however, because of inadequate control groups, insufficient or selective follow-up, and selection bias due to the characteristics of patients who successfully complete voluntary treatment programs (USPSTF, 1996; IOM, 1989; Thurstin et al., 1986; Emrick, 1987). Since spontaneous remission occurs in as many as 30 percent of alcoholics (USPSTF, 1996; Smart, 1975/1976; Saunders & Kershaw, 1979), reduced consumption may be inappropriately attributed to treatment. Successful treatment is likely to represent a complex interaction of patient motivation, treatment characteristics, and the posttreatment environment (family support, stress, etc.) (USPSTF, 1996; IOM, 1990; NIAAA, 1993). The IOM review concluded that treatment of other life problems (e.g., with antidepressant medication, family or marital therapy, or stress management) and counseling with empathetic therapists were likely to improve treatment outcomes (USPSTF, 1996; IOM, 1989).

Program Implementation Issues: How To Manage the Intervention So That It Succeeds in Securing Desired Benefits

- Based on the research, the primary program implementation issue relative to alcohol-related screening and intervention appears to be strict adherence to the details of screening and intervention protocols, especially if the TrEAT protocol is to be used. Given the nature of the protocol, it is all too easy to defer the counseling sessions from the primary care physicians to other staff, or to reduce the content length of the sessions. The literature shows, however,

that doing so may substantially reduce, if not eliminate, the benefit to be secured from the intervention.

- The second program implementation issue relative to alcohol-related screening has to do with the structure and staffing of the primary care setting. In settings without adequate nursing and/or health education support staff, the research indicates that it may be better to proceed with one of the simpler one to four question screening instruments than to attempt to use the 10-question AUDIT instrument on a selective or inconsistent basis.
- Finally, special attention can be paid to policies and procedures and staff and physician education to ensure adequate screening and follow-up, and to enable the staff to better differentiate between alcohol dependence/addiction and nondependent problem drinking.

Data To Be Gathered

Refer to Appendix D. Supplemental data needs relative to alcohol and adults include the following:

- Prevalence of alcoholism, cirrhosis, and other specific alcohol-related disorders
- Incidence of alcohol-related injury, suicide, and homicide within the enrolled population
- Alcohol-related utilization of outpatient, inpatient, and emergency services
- Separate tracking of services to address problem drinking and alcohol dependence, with follow-up to prevent and address relapse, and to document the success (or lack thereof) of the programming

Adult Use/Abuse of Illicit Drugs

There is remarkably little in the way of published, peer-reviewed literature dealing with the issue of prevention of adult use of illicit drugs. The conventional wisdom appears to be that initiation of illicit drug use is relatively uncommon beyond young adulthood unless such use is self-medication for stress, depression, or another behavioral disorder. There seems to be no need for health care systems to initiate specific programming to prevent initiation of illicit drug use by adults.

Treating adults, especially younger adults, for use of illicit substances is an important therapeutic issue and generally is handled in the emergency room and by mental health professionals, rather than by primary care practitioners. Preventive issues generally are limited to those noted in the following review of pertinent literature.

A related topic is misuse and abuse of prescription medications among adults, especially older adults who have minor depression and/or who use multiple medications to control multiple chronic diseases. This is a serious problem, but because it is more therapeutic than preventive, it is considered beyond the scope of this current literature review.

Intervention

Although clinical management of adult use of illicit drugs is appropriate, no screening or other preventive services are suggested for adults concerning illicit drugs. A partial exception may be the need to counsel older adults about possible abuse of prescription medication. Further discussion of this topic is beyond the scope of this report.

Review of Pertinent Literature

Although none of the studies noted below is a randomized clinical trial, the studies do provide background information on the issue of adult use/abuse of illicit drugs for health

care policymakers who wish to further explore this issue.

In a 1998 literature review, Drake et al. (Drake, Mercer-McFadden, Mueser, McHugo, & Bond, 1998) noted that patients with severe mental disorders, such as schizophrenia and co-occurring substance use disorders, frequently receive treatment for their disorders from multiple clinicians in parallel treatment systems. Their review provides promising evidence that integrating the treatment of these patients through a single set of clinicians can yield promising results in terms of remission of the underlying mental disorder, reduction in substance use disorder, and use of health care resources.

Frankin and Hendrix, in an uncontrolled study published in 2001 (Franken & Hendriks, 2001), noted that screening persons with substance use disorder for underlying anxiety and mood disorders using the SCL-90 (Symptom Checklist 90) questionnaire (Franken & Hendricks, 2001) could be of significant value in controlling both disorders and reducing the need for more extensive psychiatric diagnostic evaluation.

Schermer and Wisner, in a record review of patients suffering from major trauma, published in 1999 (Schermer & Wisner, 1999), urged screening of patients suffering from major trauma for methamphetamines and cocaine. This California study noted a doubling of methamphetamine rates from 7.4 percent to 13.4 percent in patients suffering from major trauma from 1989 to 1994; minimal increases in cocaine positivity, from 5.8 percent to 6.2 percent; and a decrease in alcohol positivity, from 43 percent to 35 percent.

In a record review published in 2001, Chitwood et al. (Chitwood, Sanchez, Comerford, & McCoy, 2001), noted that injection drug users, other sustained drug users, and "heavy" alcohol users were less likely to avail themselves of preventive services than other patients being seen in their Miami, Florida, center.

Bennet and Beaudin, in an opinion piece published in 2000 (Bennett & Beaudin, 2000), provided a guide to facilitate collaboration between employers and managed care plans to address substance use disorder in the workplace.

Data To Be Gathered

Since there are no suggested screening or other preventive services, there are no data needs specific to preventive services, illicit drugs, and adults.

Depression and Anxiety

Depression-related disorders (generalized anxiety disorder, minor depression, major depression, and bipolar disorder) are common, serious, readily treatable, and more often than not either missed or ignored in primary care settings. Effective and cost-efficient screening procedures are readily available, but they should be used with caution because of the importance of differentiating between the depression-related disorders noted above.

From a preventive perspective, it is important to differentiate major depression from the other listed disorders, and to consider separately the consequences of depression in otherwise healthy adults as compared with adults who have major medical and/or psychiatric comorbidities. In both populations, depression dramatically increases the risk of suicide, dramatically reduces the quality of life, and unfavorably affects workplace productivity. Among those with major chronic diseases, however,

depression dramatically reduces the ability and willingness of the patient to adhere to prescribed regimens of care. In this chronic disease group, detection and skilled management of the depression has been shown in research to be cost-effective in terms of other health care costs.

Routine screening for depression among all adult outpatients was given a universal rating by the U.S. Preventive Services Task Force in 2002 (USPSTF, 2002b, 2003). There are no medical means to prevent depression (Munoz, 1993). There are, however, effective means to screen and then manage the depression in a cost-efficient way to improve the quality of life of the patient, reduce other health care costs, and substantially reduce the risk of suicide.

Intervention

Rigorous research demonstrates that all adults should be screened for depression at every outpatient visit. A simple two-question screen is likely to be as effective as longer screening instruments. The two questions are: "Over the past 2 weeks, have you felt down, depressed, or hopeless?" and "Over the past 2 weeks, have you felt little interest or pleasure in doing things?" (USPSTF, 2002b, 2003). These questions are not diagnostic, but they do serve as a starting point for further exploration of depressive symptoms to determine the need for referral to mental health specialists and/or prescription of antidepressant medications.

The literature supports every health care delivery system developing and maintaining the capacity to follow up with more definitive diagnostic interviews and appropriate patient management. Although much of this can be managed with supplemental training of primary care practitioners, it is important to have access to mental health professionals for the more difficult cases, and to properly differentiate anxiety disorders and minor depression from major depression, as well as unipolar depression from bipolar (manic-depressive) disorder.

Summary of 2002 U.S. Preventive Services Task Force Recommendations: Depression

In April 2002, the U.S. Preventive Services Task Force (USPSTF) issued an updated report on depression (Pignone et al., 2002; USPSTF, 2003). The USPSTF is an independent panel of experts in primary care and prevention that systematically reviews the evidence of effectiveness and develops recommendations for clinical preventive services (USPSTF, 2003). These new recommendations have been incorporated into the newly developing *Guide to Clinical Preventive Services*, 3rd Edition, 2000–2003. This update guide is not yet available in book form, but it is readily accessible on the Internet site of the Agency for Healthcare Quality Research (AHRQ) at www.ahrq.gov.

The best way to access the depression recommendation and evidence base is to: 1) go to the Web site; 2) click on "Clinical Information: Preventive Services," 3) click on "U.S. Preventive Services Task Force (USPSTF)," 4) click on "Mental Disorders and Substance Abuse," and 5) click on "Depression: Screening." This will lead to the summary and full text of the April 2002 literature review. The site and all its reports are available to the public, free of charge, with no requirement for a password or any form of registration.

The following provides a series of quotations from the summary and the literature review, which have been selected to meet the needs of health care system administrators, benefit managers, and fiscal

officers. Those desiring more detailed information are urged to access the full recommendations and full literature review on the AHRQ Web site.

Summary of Recommendations

The U.S. Preventive Services Task Force (USPSTF) recommends screening adults for depression in clinical practices that have systems in place to assure accurate diagnosis, effective treatment, and follow-up. [The USPSTF] gave a "B" recommendation [which means] clinicians should routinely provide the service to eligible patients; [there is] at least fair evidence that the service improves important health outcomes and [USPSTF] concludes that benefits outweigh harms.

. . . Trials that have directly evaluated the effect of screening on clinical outcomes have shown mixed results. Small benefits have been observed in studies that simply feed back screening results to clinicians. Larger benefits have been observed in studies in which the communication of screening results is coordinated with effective follow-up and treatment.

The USPSTF concludes that the amount and rigor of research to date are insufficient to recommend for or against routine screening of children or adolescents for depression.

Epidemiology and Clinical Consequences

… In primary care settings, the point prevalence of major depression ranges from 5 to 9 percent among adults, and up to 50 percent of depressed patients are not recognized. Other disabling depressive illnesses (that also are amenable to treatment) include dysthymia (a chronic low-grade depression) and minor depression (an episodic, less severe illness). These two illnesses are as common as major depression in primary care settings.

Diagnosis of Major Depression

The prevailing standard of the American Psychiatric Association for the diagnosis of depression is the opinion of an examining clinician that a patient's symptoms meet the criteria described in the fourth edition of the Diagnostic and Statistical Manual of Mental Disorders (DSM–IV) (APA, 1994). This creates a situation in which, following the initial screening, there must be further questioning by the primary care practitioner to confirm or deny the impression of possible depression, and differentiate minor from major depression.

The diagnosis of major depression is based upon the daily presence of four or more of the following symptoms, along with sadness or apathy, for at least 2 weeks (Dornbrand, Hoole, & Pickard, 1992):

1. Decreased or increased appetite, weight change
2. Insomnia or increased sleeping
3. Observable change in psychomotor activity, either agitation or retardation
4. Persistent inability to enjoy usually pleasurable activities, including sex
5. Fatigue
6. Feelings of worthlessness or guilt
7. Slowed thinking or decreased concentration
8. Recurrent thoughts of death or suicide

Accuracy and Reliability of Screening Tests

… Assuming optimal test performance and a prevalence of major depression of 5–10 percent in

primary care settings, approximately 24–40 percent of patients who screen positive will have major depression. Some patients with "false-positive" results on screening may have dysthymia or subsyndromal depressive disorders (depressed, but not depressed enough to meet diagnostic criteria for major depression) that might benefit from treatment or closer monitoring; others may have comorbid disorders such as anxiety disorder, substance abuse, panic disorder, posttraumatic stress disorder, or grief reactions; still others may have no disorder at all. The finding of a positive screen therefore requires further diagnostic questioning by the clinician to establish an appropriate diagnosis and initiate a plan for treatment and follow-up.

Effectiveness of Early Treatment

Effective treatments are available for patients with depressive illness detected in primary care settings. Antidepressant medications for major depression are clearly more effective than placebo. Newer agents (medications) perform similarly to older agents.

Psychosocial and psychotherapeutic interventions are probably as effective as antidepressant medications for major depression, but they are clearly more time-intensive. Few studies have examined the effect of combining medications and psychotherapy.

Effectiveness of Screening

Trials that examined the effect of feedback of screening results on the proportion of depressed patients who received treatment showed mixed results: in four fair-to-good quality trials that used feedback alone, there was no significant effect on treatment rates, but four of the five trials that combined feedback with treatment advice or other systems support reported increased treatment rates in the intervention group.

All three trials that compared the effects of integrated recognition and management programs with usual care in community primary care practices showed significantly improved patient outcomes. Integrated programs included feedback, provider and/or patient education, access to case management and/or behavioral care, telephone follow-up, and institutional commitment to quality improvement.

Potential Harms of Screening and Treatment

The potential harms of screening include false-positive screening results, the inconvenience of further diagnostic workup, the adverse effects and costs of treatment for patients who are incorrectly identified as being depressed, and potential adverse effects of labeling. None of the research reviewed provided useful empirical data regarding these potential adverse effects.

Recent History and Recent USPSTF Recommendation

Much of the expanded interest in depression is due to the advent of better-tolerated antidepressant medications (Olfson et al., 2002) and the cost-effectiveness of screening for depression and managing depression in patients with major medical and psychiatric comorbidities. These factors converged to increase the percentage of adult outpatients treated for depression from 0.73 per 100 in 1987 to 2.23 in 1997. During this same period, the proportion of individuals treated with antidepressant medications increased

from 37.3 percent to 74.5 percent. Use of psychotherapy also decreased in these patients from 71.1 percent to 60.2 percent, and the locus of much of this care moved from psychiatrists to primary care practitioners (Olfson et al., 2002).

In presenting their recommendations, the USPSTF suggested the use of a simple two-question screen as likely to be as effective as longer screening instruments. The two questions are: "Over the past 2 weeks, have you felt down, depressed, or hopeless?" and "Over the past 2 weeks, have you felt little interest or pleasure in doing things?" (USPSTF, 2002b, 2003). These questions are not diagnostic, but they do serve as a starting point for further exploration of depressive symptoms to determine the need for referral to mental health specialists and/or for prescription of antidepressant medications.

In making these recommendations, the Task Force was careful to specify that such screening should only be done on a routine basis in health care delivery systems with the capacity to follow up with more definitive diagnostic interviews and appropriate patient management. This last caveat was apparently inserted to refer to education of primary care practitioners and access to mental health professionals to properly differentiate anxiety disorders and minor depression from major depression, and unipolar depression from bipolar (manic-depressive) disorder.

The USPSTF recommendation relative to screening for depression is based on case-series studies showing the ability to detect depression using a variety of screening procedures, as well as the efficacy of treating the cases detected using the screening procedure—with the efficacy of such treatment well documented in randomized controlled trials.

A major practical issue at the interface of the primary care physician and patient is the differentiation of anxiety disorders and minor transient depression from major recurrent depression. Although all these disorders can benefit from counseling, guidance, and antidepressant medication and all affect workplace productivity, major depression is the one with the most substantial impact on health care costs and the highest risk of suicide. Differentiating anxiety disorders and minor depression from major depression also is important because once diagnosed, medication for major depression should be maintained for at least 6 months to prevent current and future relapses. For patients with uncomplicated general anxiety or minor depression, reassurance, counseling, relaxation therapy, and stress management techniques often are effective without medication (Margolis & Swartz, 2002). Major depression generally requires more aggressive treatment.

Differential Diagnosis (From a Management/Policy Perspective)

Generalized Anxiety Disorder

Patients with a problem of "nerves" account for approximately 10–30 percent of encounters in general medical practice. They may complain of being "shaky," "tense," "irritable," or "uptight," or the diagnosis may be made in the course of evaluating a somatic complaint (Dornbrand et al., 1992). Initial manifestations most commonly present between 20 and 35 years of age, with a slight preponderance in women (Tierney, McPhee, & Papadakis, 2003). Generalized anxiety disorder that presents for the first time after the age of 40 should probably be considered evidence of depression until proven otherwise (Dornbrand et al., 1992).

Anxiety disorders appear to be

underrecognized and untreated even though treatment interventions have been shown to be effective and cost-efficient (Rice & Miller, 1998). Unfortunately, there are no verified questionnaire instruments short enough for routine use in primary care settings, as with alcohol use disorders and depression.

Depression

According to the 2002 Systematic Evidence Review, which serves as the basis for the USPSTF depression guideline (Pignone et al., 2002; USPSTF, 2003)—

Burden of Suffering

Depressive disorders are common, chronic, and costly. Lifetime prevalence rates from community-based surveys range from 4.9 percent to 17.1 percent (Kessler et al., 1994; Robins & Regier, 1991; Depression Guideline Panel, 1993). In primary care settings, the prevalence of major depression is 6–8 percent (Katon, 1987). Longitudinal studies suggest that approximately 80 percent of individuals experiencing a major depressive episode will have at least one more episode during their lifetime, with the rate of recurrence even higher if minor or subthreshold episodes are included (Judd, 1997). Approx-imately 12 percent of patients who experience depression will have a chronic, unremitting course (Judd, 1997). The substantial public health and economic significance of the chronic illness is reflected by the considerable utilization of health care visits and tremendous monetary costs: $43 billion (1990 dollars) annually, with $17 billion of that resulting from lost work days (Greenberg, Stiglin, Finkelstein, & Berndt, 1993).

The burden of suffering from depression is substantial. Suicide, the most severe of depressive sequelae, has a rate of approximately 3.5 percent among all cases with major depression, a risk that increases to approximately 15 percent in people who have required psychiatric hospitalization (Blair-West & Eyeson-Annan, 1997). The specific risk for suicide associated with depressive disorders is elevated 12- to 20-fold compared with the general population (Harris & Barraclough, 1997). The World Health Organization (WHO) identified major depression as the fourth leading cause of worldwide disease burden in 1990, causing more disability than either ischemic heart disease or cerebrovascular disease. Its associated morbidity is expected to increase; unipolar depressive illness is projected to be the second leading cause of disability worldwide in 2020. Furthermore, depression appears to contribute to increased morbidity and mortality from other medical disorders, such as cardiovascular disease (Musselman, Evans, & Nemeroff, 1998).

Both the chronicity and recurrence of depressive illness play a large role in depression's heavy disease burden. The more severe a depression becomes and the longer it lasts, the greater the likelihood that the depression will become chronic (Consensus Development Panel, 1985). Consequently, early effective identification and management of depressive illness will not only decrease the substantial morbidity associated with the current episode but may also decrease the likelihood that the illness will become chronic, with its additional associated morbidity (Pennix et al., 1998).

According to the 1996 Second Edition of

the U.S. Preventive Services Task Force's *Guide to Clinical Preventive Services* (USPSTF, 1996)—

> Depression is more common in persons who are young, female, single, divorced, separated, seriously ill, or who have a prior history or family history of depression (Weissman, 1987).
>
> Major depressive disorder can result in serious sequelae. The suicide rate in depressed persons is at least eight times higher than that of the general population (Monk, 1987). In 1993, 31,230 suicide deaths were reported, although the actual number is probably much higher (National Center for Health Statistics, 1994). Most persons who commit suicide have a mental disorder, with depression associated with approximately half of suicides (Greenberg et al., 1993; Weissman, 1987). The incidence of documented suicides by adolescents and young adults has dramatically increased in recent decades, with 5,000 youths committing suicide each year and perhaps as many as 500,000–1,000,000 making an attempt (Greydanus, 1986).
>
> On a population basis, the most important effect of major depression may be on quality of life and productivity rather than suicide. This effect is widespread and has been shown to be comparable to that associated with major chronic medical conditions such as diabetes, hypertension, or coronary heart disease (Wells, Stewart, Hayes, et al., 1989; Broadhead, Blazer, George, & Tse, 1990). Also, depressed persons frequently present with a variety of physical symptoms—three times the number of somatic symptoms of controls in one study (Waxman, McCreary, Weinrit, & Carner, 1985). If their depression is not recognized, these patients may be subjected to the risks and costs of unnecessary diagnostic testing and treatment (Katon & Russo, 1989; Katon, Berg, Robins, & Risse, 1986).

The main task of evaluation in primary care settings is to identify the 5–13 percent of patients with the specific psychobiologic disorder—major depression—that will require 6 months of medication and long-term follow-up (Dornbrand et al., 1992).

Greenberg et al. estimated the total cost of depression to American society to be approximately $43.7 billion in 1990 (Greenberg et al., 1993). Given the frequent co-occurrence of anxiety and depressive disorders (in which the anxiety would be considered a symptom of the depression), this estimate is reasonably consistent with the estimates provided by DuPont, Rice, and Miller (DuPont et al., 1996; Rice & Miller, 1998) in the preceding discussion of generalized anxiety disorder.

The economic cost of anxiety disorders in the United States is highlighted in two papers by DuPont, Rice, and Miller, one each published in 1996 and 1998 (DuPont et al., 1996; Rice & Miller, 1998). Considering all costs to American society, both medical and nonmedical, they estimated that the total cost of all mental illnesses to American society was $148.8 billion in 1990. Anxiety disorders were estimated to affect more than 10 percent of the U.S. population at some point in their lives, with a total cost of $46.6 billion in 1990. Of this, approximately three quarters were due to lost productivity. This demonstrates that the major economic impact is in the workplace, not in health care costs. Affective disorders, with much of

the cost related to depression, cost American society another $30.4 billion in 1990. Given that anxiety can present as a symptom of depression, this group of disorders (anxiety and depression combined) account for more than half of the total cost of mental disorders in the United States.

In 2003, Stewart et al. (Stewart, Ricci, Chee, Hahn, & Morganstein, 2003) published data from a survey of employed individuals who participated in the American Productivity Audit, conducted August 1, 2001, through July 31, 2002. This study was based on 692 persons who responded affirmatively to two depression screening questions, and a stratified random sample of 435 persons who responded in the negative. All of these individuals were then recruited for and completed a supplemental interview.

Extrapolating from this sample, workers with depression lost 5.6 hours per week of health-related productive time, compared with 1.5 hours per week for those without depression. Eighty-one percent of the time lost was due to reduced performance while at work. Major depression accounted for 48 percent of the lost productive time among those with depression and a majority of the time lost as reduced performance while at work. Stewart et al. estimated that employees with depression cost employers $44 billion annually because of health-related lost productive time, $31 billion in excess of those without depression. These costs do not include labor costs associated with short- and long-term disability.

Service-Related Issues Specific to Depression and Adults

Rigorous research suggests the following at the level of the health care delivery system:

- Policies, procedures, and physician and staff education to promote the screening, differentiation of anxiety disorders, and minor depression from major depression, as well as to promote optimal use of depression-related medications and mental health staff resources
- Tracking of members being treated for major depression (per HEDIS guidelines) to promote treatment of adequate duration (6 months) and consistency
- Separate tracking of patterns of health care utilization of members with both a depressive disorder and a major medical or behavioral comorbidity
- Resources within every health care delivery system to assure that all adults with likely depressive disorders can be appropriately diagnosed and treated
- Direct outreach by telephone to patients with depression can be of significant value in assuring adherence to prescribed regimens of care and in identifying additional issues to be addressed by medical and ancillary staff.
- Since behavioral disorders—with anxiety and depression most prominent among them—have a major impact on worker productivity, managed care plans marketing their services to employers may wish to consider offering an expanded package of screening and treatment services to reduce worker absenteeism and otherwise improve employee productivity.

Rigorous research suggests the following at the clinic visit:

- Routine screening of all adults for depressive disorders, using two simple questions ("*Over the past 2 weeks, have you felt down, depressed, or hopeless?*" and "*Over the past 2 weeks, have you felt little interest or pleasure in doing*

things?") (USPSTF, 2002b, 2003) should be done at most, if not all outpatient visits, with follow-up as appropriate relative to psychotherapy and medication. This screening may be conducted at every primary care visit for otherwise well adults and at every primary care and specialist visit for members with excessive ambulatory care utilization and/or major medical or psychiatric comorbidity.

- Patients selected to receive antidepressant medication for major depression would then be followed for a full 6 months to ensure adherence to prescribed regimens of care and success in addressing depressive symptoms and the complications of depression (per HEDIS guidelines). Whether such patients are managed entirely by the primary care physician or by a mental health professional would depend on the training and comfort level of the primary care physician and the availability of specialized mental health staff and other resources available within the managed care plan or health care delivery system.
- Primary care practitioners may be made aware of the frequency that they are likely to encounter generalized anxiety disorder and depressive disorders in their practice and be made aware of the treatment options within their respective health care delivery systems. This in turn will require the managed care plan or other health care delivery system to develop policies and procedures as well as education and outreach to primary care practitioners and their staff to ensure that the guidelines are understood and effectively implemented. This probably is best done through the use of facilitators reaching out to primary care offices and clinics in the context of quality improvement programming, as described elsewhere in this report.

Evidence for Clinical Benefit: All Adults

According to the 1996 Second Edition of the U.S. Preventive Services Task Force's *Guide to Clinical Preventive Services* (USPSTF, 1996)—

> It has been repeatedly documented that primary care providers do not recognize major depression in approximately half of their adult patients with this disorder (Schulberg et al., 1985; Borus, Howes, Devins, Rosenberg, & Livingston, 1988; Wells et al., 1989; Coyne, Schwenk, & Smolinski, 1991; Attkisson & Zich, 1990). Because the majority of persons with depression are seen by nonpsychiatrist physicians (Regier et al., 1993), and because effective treatments—drugs, psychotherapy, or a combination of the two—are available for the treatment of depression (Elkin, Shea, Watkings, et al., 1989), it has been proposed that routine depression screening could result in improved recognition and earlier treatment of depression with improved patient outcome (USPSTF, 1996). Clinical trials have shown that use of depression screening tests in primary care settings can increase clinician detection of depression (Attkisson & Zich, 1990; Moore, Lilmperi & Bobula, 1978; Linn & Yager, 1980; Zung, Magill, Moore, & George, 1983; US-PSTF, 1996). Separate research has found that treatment of persons with depression leads to improved outcome (Elkin et al., 1989; USPSTF, 1996).

In a study published in 2001, Schriger et al. (Schriger, Gibbons, Langone, Lee, & Altshuler, 2001) demonstrated a limitation of screening for behavioral disorders. A

randomized controlled trial was done in an emergency room setting in which the cases and controls were screened with a 7-minute questionnaire known as PRIME-MD to detect undiagnosed psychiatric illness. In the case group, the physicians were given the report of the screening. In the control group, this information was not provided to the physician. In this study with 92 cases and 98 controls, 42 percent of the patients received a psychiatric diagnosis from the PRIME-MD questionnaire. Only 5 percent of these patients were diagnosed by the physician. Either way, very few of these patients received either additional diagnostic evaluation or treatment for their behavioral disorder—whether diagnosed by the questionnaire or the physician. This study graphically illustrates the need to have policies, procedures, and a system in place if screening for behavioral disorders is to have a favorable impact on behavioral outcomes. Schriger's conclusion was basically the same as that reached by Schade et al. in a 1998 literature review (Schade, Jones, & Wittlin, 1998) where they found that screening did not necessarily lead to increased medical management of depression.

Tutty et al., in a study of telephone counseling as an adjunct to antidepressant treatment in the primary care system (Tutty, Simon, & Ludman, 2000), documented that a relatively inexpensive telephone outreach system to patients significantly improved depression-related outcomes without affecting the number of visits for treatment of depression. This controlled but nonrandomized study was quickly followed by three more studies which were well-done randomized controlled studies leading to the same conclusion—that enhanced management of depression in primary care settings can significantly improve patient outcomes in a cost-efficient manner.

In a study published in 2001, Katon et al. (2001) used three telephone visits and two visits with a depression specialist. In another randomized trial of telephone support, Hunkeler et al., working in a managed care setting (Hunkeler et al., 2000), demonstrated substantial improvements in depression-related symptoms with an intensive nurse telehealth intervention. The intervention consisted of 12–14, 10-minute phone calls from the nurse to the patient over a 16-week period with benefits continuing the duration of the 6-month follow-up period. In a multicenter randomized controlled trial involving 181 primary care practitioners in 46 clinics in six managed care plans, Wells, Schoenbaum, et al., (Wells et al., 2000; Schoenbaum et al., 2001) demonstrated that a quality improvement initiative aimed at improving the quality of the physician and nurse care for depression in these clinics could effectively yield substantial improvements in medication compliance and patient outcomes.

Program Implementation Issues: Managing Depression Screening and Follow-Up

The prevalence and impact of depression have been demonstrated clearly in both primary care and specialty settings, and the benefits of psychotherapy, cognitive therapy, and pharmacological management likewise have been amply demonstrated in well-done studies. A limited number of well-done studies demonstrate a dramatic cost-effectiveness for detection and management of depression in selected patients with one or more major chronic diseases (Vickery et al., 1983; Olfson et al., 1999; Koproski, Pretto, & Poretsky, 1997). Unfortunately, the broader literature is not consistent in findings or quality of study, and many

common clinical situations are not addressed. There also are cautionary notes to be considered when addressing depression in patients who have selected chronic diseases, relative to interactions with other drugs being prescribed, and direct adverse effects of selected antidepressive medications on the underlying chronic illness (Wamboldt, Yancey, & Roesler, 1997; Greenberg, Scharf, & Green, 1993; Storch, 1996; Gill & Hatcher, 2000; Goodnick, 2001).

Yet another factor is that some patients with one or more major chronic diseases will not be willing to accept either psychotherapy or medication to address their depression (Yohannes, Connolly, & Baldwin, 2001). Fortunately, the available literature suggests that all or almost all patients of all ages and conditions are willing to accept psychoeducational counseling or group sessions to improve their coping skills, stress management, and other behavioral capabilities (Thomas & Weiss, 2000; Spiegel, 1995; Arean, Alvidrez, Barrera, Robinson, & Hicks, 2002). Furthermore, the limited literature in this arena also suggests that group psychoeducational sessions generally are as effective as one-on-one sessions, where group sessions are feasible. The limited benefits available from the psychoeducational interventions may be enough to meet the needs of many of the patients suffering from anxiety disorders and minor depression and may be of limited value to some with major depression or bipolar disorder. For the rest, however, more definitive management of the depression, probably including pharmacotherapy, will be required if optimal outcomes and reduction of other health care costs are to be secured.

In 1997, Lustman et al. (Lustman, Griffith, Freedland, & Clouse, 1997) reported on 5-year follow-up of 25 persons with diabetes who had participated in an 8-week trial of depression treatment. In this follow-up, response to antidepressant therapy was rapid and dramatic, but depression frequently recurred, with 23 (92 percent) of the patients experiencing an average of 4.8 depression episodes over the 5-year period. Presence and severity of depression at follow-up correlated with worse glycemic control and neuropathy. Research supports the approach of frequently rescreening patients who have been treated for depression to detect possible relapse.

In a series of randomized controlled trials of antidepressant treatment of persons with diabetes, published from 1995 to 2000, Lustman et al. demonstrated improvement in both depressive symptoms and glycemic control with nortriptyline (Lustman et al., 1997), fluoxetine (Lustman, Freedland, Griffith, & Clouse, 2000), alprazolam (Lustman et al., 1995), and cognitive behavioral therapy (Lustman, Freedland, Griffith, & Clouse, 1998; Lustman, Griffith, Freedland, Kissel, & Clouse, 1998).

When comanaging depression and a major chronic disease in a given patient, one can expect improvement in both disorders, but in most cases, clinical outcomes are not as favorable for either condition than when dealing with a depressed patient without a chronic disease, or a chronic disease patient without depression. This appears to be because of the interaction of the two sets of disorders and in some cases, interactions between the drugs used to manage the two disorders.

The research suggests optimal management of depression, from both preventive and therapeutic perspectives, in patients of all ages, with and without medical comorbidities, involves a multistep process, as follows:

- Detection of symptoms suggestive of

depression

- Confirmation of diagnosis and determination as to whether the patient has minor depression, major depression, depression related to bipolar (manic/depressive) disorder, other mental illness, or a purely situational reaction without mental illness. Treatments differ substantially, depending on diagnosis. The possibility exists that treatment of depression related to bipolar disorder as if it were unipolar depression could make things worse. The USPSTF, in its 2002 recommendation for universal screening of adults, makes the following point: "Clinical practices that screen for depression should have systems in place to ensure that positive screening results are followed by accurate diagnosis, effective treatment, and careful follow-up. Benefits from such screening are unlikely to be realized unless such systems are functioning well." (USPSTF, 2003)
- Decision as to course of treatment (drugs, cognitive behavioral therapy and/or psychotherapy), duration of treatment, and whether or not a psychiatrist or other mental health professional will be involved
- Follow-up to assure 6 months of drug treatment for major depression
- Specialists dealing with specific chronic diseases may be encouraged and enabled to include psychoeducational elements in the education they provide patients for self-management of their chronic disease. These elements may include general coping skills and management of stress, anxiety, and depression.
- These same specialists, according to the literature, also should become expert in the interactions between the various antidepressant medications, the chronic disease they specialize in, and the medications used to manage that chronic disease.
- These educational interventions with psychoeducational components could be made readily available to family practitioners managing such patients without specialist referral.
- Consultation relative to appropriate selection of antidepressant medication also could be made readily available to family practitioners in their management of patients with medical comorbidities.
- Both health care system policy development and extensive physician and nurse education are in order relative to depression for the following reasons:
  - The high prevalence of depression in primary care populations, with an even higher prevalence among patients with major illnesses
  - The wide range of therapeutic options
  - The need for a full 6 months of pharmacotherapy for major depression
  - The reluctance of many patients to be referred to psychiatrists or other behavioral health specialists
  - The relative shortage of psychiatrists and other behavioral health specialists in most health care systems
  - The potential harm of managing a bipolar depressive patient as if he or she were a unipolar depressive patient
  - The 2002 recommendation by the U.S. Preventive Services Task Force that all adult primary care patients be screened for depression, but only if the health care system has the capacity to confirm the diagnosis and follow up as appropriate (USPSTF, 2003; Pignone et al., 2002)
- The need for both primary care and specialist physicians to be familiar with

the diagnosis and management of depression in their patients with major chronic diseases
- A continuing high volume of new research and new policy recommendations relating to diagnosis and management of depression
- Circumstances currently surrounding the diagnosis and management of depression are such that annual review of the policies and annual reeducation of the medical staff may be in order, at least over the next few years.

Data To Be Gathered

Refer to Appendix D. Data needs specific to adults and depression are as follows:

- HEDIS parameters relative to outpatient visits and duration of pharmacotherapy relative to outpatient visits and duration of pharmacotherapy for patients diagnosed with major depression
- Incidence and prevalence of major depression and other depressive disorders as determined by claims data, pharmacy data, and/or record review
- Separate tracking of these data for patients with diabetes, asthma, and other major chronic diseases
- Separate tracking should be considered to identify (from claims data) members who appear to be exceptionally high users of outpatient and/or inpatient services for the purpose of flagging members who might benefit from supplemental psychoeducation and/or behavioral health consultation.

Depression in Patients With a Major Chronic Medical or Psychiatric Illness

According to a review of the literature on depression and chronic illness by Katon in 1998 (Katon, 1998)—

Depression can impact chronic medical illness in a number of ways, all of which can unfavorably impact health care costs. In an elderly cohort of 1,711 ambulatory internal medicine patients with a mean of four chronic medical diagnoses, Calahan et al. (Callahan, Hui, Nienafer, et al., 1994) found that patients with depression had mean total outpatient charges of $1,210 over a 9-month period compared with $752 in nondepressed controls. Unutzer et al. (Unutzer, Patrick, Simon, et al., 1997) in an elderly cohort of 2,558 patients from an HMO with a mean of 1.25 chronic medical conditions found that patients with depression had total medical costs over a 1-year period of $1,510, compared with $1,129 in nondepressed controls after adjustment for chronic medical illness. Simon et al. (Simon, Von Korff, & Barlow, 1995), in a similar study, showed health care costs of $4,246 for depressed patients versus $2,880 for nondepressed patients after adjustment for chronic medical illness. These differences were seen at every level of increasing medical comorbidity (Callahan et al., 1994; Unutzer et al., 1997; Simon et al., 1995).

The first of the major ways that depression can affect major chronic illness is through amplification of symptoms. This means that patients with depression can have more symptoms, more severe symptoms, and more functional impairment from those symptoms than nondepressed controls with similar severity of chronic illness. This has been demonstrated by Walker et al. (Walker, Gelfand, Gelfand, et al., 1996) in patients with inflammatory bowel disease, by Fann et al. (Fann, Katon, Uomoto, et al., 1995) in patients with head injury; by Dwight et al. (Dwight, Ciechanowski, Katon, et al., 1997)

in patients with Hepatitis C; and by Lustman et al. (Lustman, Clouse, & Carney, 1988) in persons with diabetes. Unfortunately, both primary care physicians and medical specialists can easily confuse worsening of symptoms due to worsening of depression with worsening of the underlying medical condition, leading to unneeded medical testing and unneeded increases in medication dosages (Katon, 1998; Bridges & Goldberg, 1985). Two randomized double-blind studies have shown that effective treatment of major depression is associated with a significant decrease in physical symptoms of chronic medical illness. Sullivan et al. demonstrated this in patients with chronic tinnitus (Sullivan, Katon, Russo, et al., 1993). Borson et al. demonstrated this for patients with chronic obstructive pulmonary disease (Borson, McDonald, Gayle, et al., 1992).

The second major way that depression can affect patients with major chronic illness is by reducing their social and vocational functionality. In these cases, severity of underlying illness and severity of depression seemed to have additive impact on both perceived severity of symptoms and functional disability (Wells et al., 1989). Three papers have shown that severity of functional disability varies over time with severity of depression (Bruce & Hoff, 1994; Bruce, Seeman, Merrill, et al., 1994; Lebowitz, Pearson, Schneider, et al., 1997). Sullivan et al. (Sullivan, LaCroix, Grothasu, et al., 1997) reported that functional impairment in patients with coronary artery occlusion of 70 percent or more at baseline was more highly correlated with symptoms of depression and anxiety than with the number of coronary arteries occluded over a 1-year period. Rovner et al. (Rovner, Zisselman, & Shmuely, 1996) had similar findings in elderly patients with visual impairment. Depression has also been shown to reduce the effectiveness of rehabilitation in older patients with stroke, Parkinson's disease, heart disease, fractures, and pulmonary disease (Katz, 1996).

Finally, depression can adversely affect a patient's ability and willingness to adhere to prescribed regimens of care. In a case series exploring this issue, Lin et al. (Lin et al., 2000) noted that 32–42 percent of patients with depression did not refill their initial antidepressant prescriptions—and that this rate was basically the same among those with and without resolution of depression-related symptoms. This finding is similar to that found in the control groups of studies demonstrating the value of supplemental interventions to improve compliance with prescribed regimens of care for depression (Tutty et al., 2000; Katon et al., 2001; Schoenbaum et al., 2001). This has also been demonstrated for management of diabetes (Glasgow, 1991); coronary artery disease (Carney, Freedland, Eisen, et al., 1995); participation in rehabilitation following myocardial infarction (Blumenthal, Williams, Wallace, et al., 1982); and persons urged to quit smoking (Anda, Williamson, Escobedo, et al., 1990).

Stated in other terms, diagnosis and appropriate management of depression in a chronic disease patient can reduce health care costs and provide the following patient benefits (Lustman, Clouse, & Freedland, 1998):

- Relief of depression and anxiety
- Restoration of normal sleep and eating habits
- Improved social, occupational, and physical functionality
- Improved pain tolerance
- Improved coping with symptoms of illness

- Decreased preoccupation with symptoms of illness
- Enhanced sexual functioning
- Improved adherence with prescribed regimens of care

Since depression can severely adversely affect the ability of a chronic disease patient to adequately self-manage his or her diabetes, asthma, or other illness, screening for depression and management of depression is of special importance to this group of comorbid patients. There is a substantial body of literature documenting the efficacy of effective management of depression in patients with major chronic diseases in improving health-related outcomes for the patient, while substantially reducing medical complications and use of emergency room visits and hospitalization. An entire section of this literature review is devoted to management of these comorbid patients. Although the same is probably true for a wide range of other behavioral disorders, the evidence base of well-designed randomized controlled trials is strongest for management of major depression.

When only health care costs are considered, screening and enhanced management of depression in primary care patients without major medical or behavioral comorbidities is highly efficacious and cost-efficient in terms of the dollar cost of the health benefits secured for the patients (Katon et al., 2001; Wells et al., 2000; Schoenbaum et al., 2001; Tutty et al., 2000). These services are cost-efficient, but do not result in reductions in use of emergency room and inpatient services sufficient to generate a return on investment related to reductions in other health care costs within 12 months of program initiation. By contrast, screening and enhanced management of depression in patients with major medical and behavioral comorbidities generates substantial returns on investment in terms of reductions in other health care costs (Katon, 1998; Callahan et al., 1994; Unutzer et al., 1997; Simon et al., 1995).

Intervention

Research indicates that the most appropriate depression-related intervention for adults with major chronic diseases is the same as that for all adults—screening with two questions at every outpatient visit, with follow-up as appropriate. This separate section for adults with major chronic diseases is presented because of the potential for such screening to result in improved management of the chronic disease along with concomitant reduction in health care costs.

Evidence for Clinical Benefit and Impact on Health Care Cost: Adults With Major Chronic Illness

Egede et al., in a record-review study published in 2002 (Egede, Zheng, & Simpson, 2002), compared 825 adults with diabetes to 20,688 adults without diabetes using the 1996 Medical Expenditure Panel Study. He found that individuals with diabetes were 2.5 times as likely to suffer depression as individuals without diabetes, and that health care costs per diabetic were approximately double for those with depression, compared with those without depression. These general findings held even after adjustment for age, sex, race/ethnicity, marital status, poverty, and comorbidity. Findings were similar in a study by Jiang et al. published in 2001 (Jiang et al., 2001), after reviewing records of patients with congestive heart failure in a single medical center. Jiang et al. found readmission and mortality rates at both 3 months and 1 year

to be approximately double for patients with depression, after adjusting for major clinical risk factors. Very similar findings relative to the impact of depression on a major chronic disease were published by Abramson et al. in 2001 (Abramson, Berger, Krumholz, & Vaccarino, 2001) when doing a record review of the risk of heart failure among older persons with isolated systolic hypertension.

In a case report associated with a literature review, Zeigelstein (2001) noted a very high prevalence of depression in patients following myocardial infarction and observed that depression was associated with noncompliance with physician recommendations and increased mortality. His paper did not explore whether management of the depression could have improved patient outcomes.

Asthma and chronic obstructive pulmonary disease are common lung disorders for which tricyclic antidepressants are problematic because of their effect on pulmonary and cardiovascular function (Wamboldt et al., 1997; Greenberg et al., 1993). A number of randomized and nonrandomized clinical trials of short courses of cognitive behavioral therapy (one to 10 visits) have shown significant benefit for symptoms of depression and anxiety and self-management, but not lung function (Perez, Feldman, & Caballero, 1999; Ringsberg, Lepp, & Finnstrom, 2002); for lung function, but not symptoms of depression and anxiety (Kunik et al., 2001; Eiser, West, Evans, Jeffers, & Quirk, 1997); or both (Grover, Kumaraiah, Prasadrao, & D'souza, 2002; Colland, 1993).

Depression in High-Cost Patients Without a Major Chronic Disease

In 1998, Panzarino (1998) explored the direct and indirect costs of nontreatment of depression. In this paper, he noted that depression is underdiagnosed in primary care, and that up to 50 percent or more of patients presenting in primary care settings have no diagnosable medical illnesses. The most common symptoms that could not be traced to a known organic cause were back pain, dyspnea, insomnia, abdominal pain, and numbness (Kroenke & Mangelsdorff, 1989). In addition, studies of overutilizers of medical care by Katon et al. (1990, 1992) and Simon (Simon, GE, 1992) showed a high prevalence of psychiatric illness and 68 percent with a past or current history of depression. These data invite consideration of the possibility that screening for and effective treatment of depression might reduce these physical complaints and visits. Katzelnick et al. published a randomized clinical trial of depression management for high users of ambulatory services (Katzelnick et al., 2000). This paper showed dramatic improvements in both behavioral and physical health domains. A follow-up paper a year later (Simon et al., 2001) confirmed the improvements in health indices and an increase in health care costs. A similar follow-up study by Katon et al. (1992) showed similar results—but in this study, the control patients also showed substantial reductions in health care utilization, suggesting the possibility that contamination of the controls with the case intervention may have masked a possible benefit. High users of ambulatory services also are addressed in a separate section of this report dealing with somatization and hypochondriasis.

In 1995, Simon et al. published another paper on health care costs associated with depressive and anxiety disorders in primary care (Simon, Ormel, Von Korff, & Barlow, 1995). In this case series, the authors noted

that patients with anxiety or depressive disorders had baseline costs approximately double those with subthreshold disorders or no anxiety or depression, with these differences reflecting differences in medical (as opposed to psychiatric) costs. He also noted that improvement in depression over 1 year of follow-up did not reduce health care costs. In 1997, Simon and Katzelnick (1997) reviewed the older literature on the relationship between depression and health care costs. In this review, they noted the same general conclusions—that depression is associated with substantially higher health care costs, and that the limited available data from studies with substantial methodological limitations did not demonstrate a reduction in health care costs from diagnosis and management of the depression.

Intervention

The literature indicates that the depression-related intervention that may be most effective for high-cost patients without a major chronic disease is the same as that for all adults—screening with two questions at every outpatient visit, with follow-up as appropriate. This separate section for high-cost patients without a major chronic disease is presented because of the potential for such screening to result in improved patient outcomes with concomitant reduction in health care costs.

Summary: Adults Aged 19 and Over

For adults aged 19 and over, the literature suggests some screening and follow-up services are more well-researched than others. The recent USPSTF universal recommendation to screen all adults for depression is the most well-documented. Good evidence exists that brief screening is effective (using either the four-item CAGE or CUGE instruments or the 10-item AUDIT) for detecting misuse of alcohol. The studies on screening and preventive interventions for illicit drug use by adults reveal that drug use initiation is primarily in adolescence; hence, in adults the goal is discontinuance of use. On the topic of tobacco use, the literature indicates screening for tobacco use at every adult outpatient visit. The results are substantial, although they are not immediate, except for patients with major medical comorbities. (Immediate benefits to the health plan of tobacco screening are most substantial in smoking cessation by pregnant women.)

X. Psychoeducation for Three Categories of Patients

Psychoeducation, as explained earlier, is health education combined with behavioral counseling. The counseling component of psychoeducation deals with emotions, perceptions, coping, relaxation, and self-care. Psychoeducation is of value for three categories of patients: (1) Those with major chronic diseases; (2) persons scheduled to undergo surgical procedures; and (3) high users of health care services. Psychoeducation can help—

- Improve coping with pain, distress, and other unpleasant symptoms
- Improve adherence to recommended regimens of care

Why Psychoeducation?

Patients, even with the best of intentions, rarely follow prescribed regimens of care perfectly—and often disregard them completely. For many aches, pains, and other distressing symptoms, medical science often offers either imperfect relief or therapy more distressing than the initial symptoms. Psychoeducation is an effective way to help close some of these gaps between the theoretical ideal and the reality each of us must live with on a daily basis. For some, it offers innovative ways to control pain and other distressing symptoms, and by doing so, speeds recovery and improves the quality of their lives. For others, it helps reduce the psychological and psychosocial barriers that inhibit effective adherence to prescribed regimens of care.

A definition of psychoeducation on a Web site devoted to patients with psychiatric disorders and their families reads as follows:

> Psychoeducation is the education of a person in subject areas that serve the goals of treatment and rehabilitation. Psychoeducation involves teaching people about their problem, how to treat it, and how to recognize signs of relapse so that they can get necessary treatment before their difficulty worsens or occurs again. Family psychoeducation includes teaching coping strategies and problem-solving skills to families, friends, and/or caregivers to help them deal more effectively with the individual (PsychoEducation, 2003).

Part of the problem is undiagnosed and untreated psychiatric disorders. Fulop et al. (Fulop, Strain, Fahs, Schmeidler, & Snyder, 1998) in a 1998 study explored the impact of psychiatric comorbidity on length of hospital stays of elderly medical-surgical inpatients. Of the 467 admissions included

in the study, 208 (44 percent) met the standards for one or more DMS-III-R psychiatric diagnoses. Fifty-one (10.9 percent) had an anxiety disorder, 88 (18.8 percent) had a depressive disorder, and 126 (27 percent) had a cognitive impairment. Although no difference in length of stay was noted for those with and without anxiety or depression, those with cognitive impairments had significantly longer lengths of stay (14.6 versus 10.6 days). Part of the solution is mobilizing the resiliency and inner strength of human beings—and helping them more effectively help themselves to deal with painful and difficult circumstances.

The literature demonstrating the need for and effectiveness of psychoeducation in patients with chronic disease, those scheduled for surgery, and those with a somatization disorder is reviewed briefly in each of the following sections of this report.

Intervention

Research indicates that it would be useful for primary care practitioners and those who provide health education and counseling to patients and their families to be trained in psychoeducational counseling and learn enough about cognitive behavioral therapy and the more common psychiatric comorbidities to recognize when specific patients should be referred to mental health professionals for more intensive counseling and care. Psychoeducation can be provided by these primary care practitioners, health educators, and surgical staff, with support and guidance from a designated mental health professional.

The health care delivery system may wish to consider the following:

- Designate a lead mental health professional to oversee psychoeducation and somatization-related programming.
- Educate primary care and specialty staff as to somatization and psychoeducation at least once every 2 years. Clinicians may be reminded that the presence of substance use disorders, schizophrenia, and other behavioral health disorders does not rule out the possibility of concurrent depression and anxiety, and that worsening of the depression and anxiety may masquerade as worsening of other physical or behavioral health disorders.
- The designated mental health professional may work closely with the clinical and health education staff to incorporate psychoeducational components into the health education and disease management protocols.
- It may be beneficial to periodically review the efficacy of the health education programming by record review, and by small informal surveys or focus group-like discussions with groups of patients and groups of clinical staff.
- In health care delivery systems where behavioral health services are carved out or otherwise separated from the main stream of medical care, steps may be taken to facilitate appropriate comanagement of behavioral and medical disorders in patients with such comorbidities (Olfson et al., 1999).

Psychoeducation for Patients With Chronic Disease

In 1989, Spiegel et al. (1989) reported the results of what he called "psychosocial treatment" in a randomized controlled trial involving 86 patients with metastatic breast cancer. The cases and controls were similar in severity of illness and treatment modalities. The intervention consisted of 90-

minute group meetings with a psychiatrist on a weekly basis for a year, with professional and group member support between the meetings. Mean survival time for the cases was 36.6 months postrandomization, compared with 18.9 months for the controls—a highly statistically significant difference—attributed by the authors to better patient and family coping skills, more effective relationships with the oncology staff, social support, and more effective control of anxiety, depression, and pain.

In 1995, Devine and Reifschneider (1995) reported on a meta-analysis of 102 studies to determine the effects of psychoeducation on care of adults with hypertension. They concluded that substantial and statistically significant beneficial effects on blood pressure were due primarily to improved compliance with medication and improved compliance with health care appointments.

In 1998, Roter et al. (1998) reported on a meta-analysis of 153 studies to assess the effectiveness of interventions to improve patient compliance. They concluded that the most substantial benefits were for chronic disease patients, including those with diabetes, hypertension, cancer, and mental health problems. Comprehensive interventions combining cognitive, behavioral, and affective components were more effective than single-focus interventions.

In 1998, Clarkin et al. (Clarkin, Carpenter, Hull, Wilner, & Glick, 1998) reported the results of a randomized controlled trial of a psychoeducational intervention for married patients with bipolar disorder and their spouses. The intervention resulted in improved functioning and improved medication compliance but did not affect the symptom levels beyond that to be expected from the medication compliance. Similarly favorable results were reported by Miklowitz et al. (2000) in a randomized trial of family-focused psychoeducation for bipolar disorder.

In 1999, Dusseldorp et al. (1999) reported on a meta-analysis of 37 studies of the effects of psychoeducational (health education and stress management) programs for coronary heart disease patients. The results suggested that these programs yielded a 34 percent reduction in cardiac mortality, a 29 percent reduction in recurrence of myocardial infarction, and statistically significant positive effects on blood pressure, cholesterol, body weight, smoking behavior, physical exercise, and eating habits. The pattern of results by study suggested that the mortality and recurrent infarction end points were primarily related to the more proximal improvements in risk profiles.

In 1999, Robinson et al. (Robinson, Faris, & Scott, 1999) reported on the results of a randomized controlled trial of a group psychoeducational intervention to improve compliance with prescribed regimens of vaginal dilatation for women undergoing radiotherapy for gynecological carcinoma. Such dilatation is required to maintain vaginal health and good sexual functioning, but compliance generally is low. The intervention was highly effective, especially in younger women in increasing vaginal dilatation and reducing fears about sex after cancer. The authors concluded that such women are unlikely to follow the recommendation to dilate unless given assistance in overcoming their fears and taught behavioral skills.

In 2001, Lorig at al. demonstrated that a single, low-cost psychoeducational program can be used across a number of different chronic diseases, including heart disease, lung disease, stroke, or arthritis (Lorig, et al., 2001).

In 2002, Mishel et al. (2002) reported on a randomized trial of a nurse-delivered psychoeducational intervention by telephone for 134 White men and 105 African-American men who had undergone surgery or radiation treatment for localized prostate carcinoma. They were enrolled either immediately after surgery or in the first 3 weeks of radiation therapy. The two interventions both consisted of weekly phone calls for 8 weeks. The intervention groups reported significantly better control of incontinence by 4 months postbaseline, fewer treatment side effects, and better sexual functioning. Levels of improvement were similar in the two racial groups.

In each of the studies noted above, the psychoeducational intervention group was compared with a "usual care" group who received usual physician counseling, presumably with little or no psychoeducational content. The conclusions that can be drawn from the literature reviewed to date are limited by the lack of specific psychoeducational protocols and the presence of many studies of health education interventions where the studies do not include adequate description of the interventions to determine the presence or types of psychoeducational content.

Although additional research should be done to proposed specific educational protocols by patient type and disease, the currently available literature clearly indicates that the efficacy of patient educational programming for chronic disease patients can be enhanced substantially by the inclusion of psychoeducational content. This enhancement of educational content should be seen as a desirable addition to the screening of all such patients for depression and mental health assessment of those with other evidence of behavioral disorders.

Psychoeducation for Patients Scheduled for Surgical Procedures

A number of studies have been published demonstrating the value of psychoeducational interventions for patients scheduled to undergo surgery. These studies, the oldest of which date back to 1964 (Egbert et al., 1964), present a very strong case for investment in specially trained staff to educate patients as to the nature of the surgical procedure, what they may anticipate in terms of pain and discomfort following the surgery, and techniques they can use to reduce pain, speed recovery, and reduce their postsurgical in-hospital convalescence. These same staff also can flag patients who might benefit from more definitive psychiatric consultation and intervention prior to the surgical procedure to further improve postsurgical recovery.

In a 1964 study, Egbert et al. (1964) randomized 97 patients scheduled to undergo elective intra-abdominal surgery. The intervention consisted of expanded presurgical education by the anesthetist, including what to expect postsurgery, how best to relax, how to take deep breaths, and how to move to remain comfortable postoperatively. This simple intervention reduced the need for postoperative narcotic medication by half and reduced the average hospital stay by almost 3 days.

In 1982, Mumford et al. (1982) published a meta-analysis of 34 controlled studies of surgical and heart attack patients and demonstrated an average 2-day reduction in what otherwise would have been a 10-day hospital stay for these patients. Although the protocols varied, most or all included general patient education coping techniques and interventions to address fear, pain, and psychological distress. In a similar meta-analysis published in 1983, which covered

49 studies, both controlled and uncontrolled, Devine and Cook (1983) showed very similar results.

In 1988, Devine et al. (1988) conducted a controlled, but not randomized study of a nurse-based psychoeducational intervention in a post-DRG (diagnostic related group) managed-care-type setting in two rural hospitals owned by the same corporation. The primary intervention in the study hospital was a 3-hour, two-stage workshop for staff nurses to enhance their ability to provide educational and psychosocial support to patients undergoing abdominal and prostate surgery. This study showed that even in a managed care environment, supplemental psychoeducational services can cut the use of sedatives, antiemetics, and hypnotics by half, and shave another half-day off the hospital stay.

In 1995, Jay et al. (1995) reported a clinical trial of cognitive behavioral therapy (CBT) versus general anesthesia for 18 patients with pediatric cancer (ages 3–12 years) undergoing bone marrow aspirations. The CBT children exhibited more behavioral distress for the first minute on the treatment table, but according to the parents, showed significantly better behavioral adjustment 24 hours following the procedure than the children who had been anesthetized.

Psychoeducation for Patients With Somatization

Somatization is a term used to describe true physical symptoms and true physical illness that are psychogenic in nature. The term "mind/body connection" is used to denote the role of the human mind in creating, exaggerating, minimizing, or totally eliminating symptoms and perceptions of pain in patients with and without diagnosable organic illness. By some criteria, 20–84 percent of patients in general medical settings have been estimated to show somatic complaints for which no organic cause can be found (Smith et al., 1995; Kellner et al., 1985; Kellner, 1965; Mayou, 1976, 1978).

The preventive issue with somatization and mind/body connection relates to reduction in health care costs through effective management of these disorders. Somatization is common in primary care, and it is generally accepted that there is a connection between the mind and the body and that many diseases are caused by the mind-body connection. The problem, from the perspective of this report, is that few high-quality studies demonstrating the efficacy of clinical interventions to address these disorders are available. This section is included in this report to alert health care managers to somatization and mind/body connection so they may consider possible education and intervention, and so that they may remain alert to further developments in these rapidly evolving fields.

When somatization is fully developed, the proper diagnostic term is "somatization disorder" or "Birquet's Syndrome" or "hysteria." The full-blown syndrome is characterized by multiple physical complaints referable to several organ systems. Anxiety, panic disorder, and depression often are present. Polysurgery often is part of the history, and preoccupation with medical and surgical therapy becomes a lifestyle that excludes most other activities (Tierney et al., 2003). Although the full-blown syndrome is relatively uncommon, somatoform behavior that does not meet the full diagnostic criteria for somatization disorder is quite common, and quite costly in utilization of health care services. Recent reviews have estimated the prevalence of somatoform disorders in the

range of 10–15 percent of primary care patients (Kroenke et al., 1998; Kirmayer & Robbins, 1991; Spitzer et al., 1994; Kellner et al., 1985) and have documented the impact of these disorders on both quality of life and health care utilization (Kroenke et al., 1998; Katon et al., 1991; Smith et al., 1986, 1995; Swartz et al., 1991; Kroenke et al., 1997; Escobar et al., 1989; Deighton, Nicol, 1985; Hiller et al., 1995).

Effective management of these patients requires recognition of this possibility by the primary care practitioner and great sensitivity in approaching this issue to avoid suggesting that the patient is either "crazy" or faking the illness. Although management of full-blown somatization disorder tends to be frustrating for both patient and physician, there is at least one recent randomized study (Smith et al., 1995) and a recent review by the Lewin Group (Fifer et al., 2003) suggesting that recognition and intervention in patients with somatizing behavior not meeting the diagnostic criteria of full-blown somatization disorder may be of value in improving the patient's quality of life and in reducing health care costs by reducing health care use.

Although there are several studies suggesting that screening for somatization, followed by diagnosis and management of psychiatric illness and psychoeducational interventions are of value (Smith et al., 1995; Fifer et al., 2003), specification of exact screening and follow-up procedures are insufficient to suggest implementation of psychoeducational services for somatization as a "general" clinical preventive service.

Summary of Psychoeducation

Psychoeducation has been shown to improve health outcomes and reduce short-term health care costs for patients with major chronic diseases and for patients scheduled for surgical procedures. The literature has demonstrated the service's ability to shorten the length of inpatient stay, to reduce pain, and to increase adherence to a regimen of care. Psychoeducation may also be of value for selected high-cost patients whose illnesses may be psychosomatic in origin.

XI. Conclusions

This report summarizes the literature on preventive behavioral services to be delivered by health care systems to improve both medical and mental health outcomes. Some of the interventions covered in this report demonstrate potential to reduce health care expenditures within 12 months of program initiation, thus providing a "return on investment" in terms of short-term health care costs. Because of the enormity of the literature, not all potential behavioral preventive services that might be considered for implementation in health care settings have been covered. This report updates a previous SAMHSA literature revew on this topic published in 2000 (Dorfman, 2000).

This updated analysis of the literature suggests the following clinical preventive behavioral services as worthy of consideration for implementation in all health care settings:

- Universal screening of pregnant women for use of tobacco, alcohol, and illicit drugs
- Home visitation for selected pregnant women, and some children up to age 5
- Supplemental educational services for vulnerable infants from disadvantaged families
- Screening children and adolescents for behavioral disorders
- Screening adolescents for tobacco, alcohol, use of illicit drugs, depression, and anxiety
- Screening adults for use of tobacco, excessive use of alcohol, depression, and anxiety
- Psychoeducation for persons scheduled for major surgical procedures, persons with major chronic diseases, and selected other heavy users of health care services

Of these, the following have the potential to reduce overall health care costs within 12 months of initiation of new or expanded preventive services:

- Screening pregnant women for use of tobacco, alcohol, and illicit drugs
- Screening for depression in persons with major chronic medical disease
- Psychoeducation for persons scheduled for major surgical procedures, persons with major chronic diseases, and selected other heavy users of health care services

For many of these clinical preventive behavioral services, the effect size in randomized controlled trials is in the range of 5–30 percent. Therefore, the preventive interventions can be expected to reduce the burden of behavioral illnesses and substance use disorders, but not totally prevent them.

Some of the reduction in burden will be the result of eliminating the problem entirely for some patients—usually those with mild or moderate risk of illness or substance use. The preventive services may also reduce the severity of illness in those more severely affected. Even with such seemingly modest effect sizes, the adverse consequences of the underlying disorders are such that the preventive services can be expected to pay for themselves in reduced health care costs and improved clinical and/or social outcomes.

Because of these seemingly modest effect sizes, health care systems are urged to track risk factors, process indicators, outcomes, and costs to document the efficacy and cost-efficiency of each of the suggested preventive interventions. These data will also be of value in securing the support of health care managers and fiscal officers for these preventive services. This monograph includes suggestions and guidelines for tracking these measures in a practical and cost-efficient manner.

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XIII. Appendix A: Literature Search Methods and Results

This Appendix supplements the information presented in the Methods section of this monograph. Details of the advanced searches conducted and their results, key words or search terms and methods used, and notes on selected search findings are presented here. In addition to the PubMed literature review for publications from 1964 through 2002, selected additional references were included in this report, as published between July 20, 2002, and October 27, 2003.

Keywords for Searches in PubMed for 1998–2002

The primary database used was PubMed. The following advanced searches were conducted:

1. Preventive health services OR preventive medicine OR preventive psychiatry OR primary prevention AND mental disorders NOT specific topics listed in items 2–9 below
2. Mass screening and mental disorders NOT in topics 3–9 below
3. Health education OR health promotion OR patient education AND mental disorders NOT topics 2, or 4–9
4. Home care services or home nursing AND mental disorders
5. Self-care and mental disorders (Note: there was no way to separately search on health risk appraisal in PubMed.)
6. Prenatal care OR perinatal care AND mental disorders
7. Disease management AND managed care AND mental disorders
8. Case management AND mental disorders
9. Psychoeducational (any reference where this term was used in title, abstract, or text; there is no MeSH term on this topic)

The literature search initially focused on the identification of pertinent and well-conducted randomized controlled trials (RCTs). This was done to conduct the initial evaluation of interventions that deserve consideration for widespread implementation by health care systems. The search included the RCTs, literature reviews, and meta-analyses integrating data from multiple trials. Once this search was accomplished, additional literature on the selected topics was explored.

Table 5: Searches From 1964 To 2002 to Collect "Negative Studies" and More Recent Studies, Relative to the Interventions Recommended in the SAMHSA 2000 Report

These searches were conducted using an alternative PubMed search technique; that is,

Table 3: Tabular Summary of Initial PubMed Search for 1998–2002

	Topic	Initial Download	Selected to Pull Abstracts	Abstracts Pulled	Total RCTs*	Pertinent RCTs[1]
1	Preventive Health Services[2]	258	41	10	0	0
2	Mass Screening[3]	1,041	132	77	3	0
3	Health Education[4]	240	37	10	1	1
4	Home Care Services	314	36	20	5	3
5	Self-Care	426	105	17	6	5
6	Prenatal/Perinatal Care	139	56	26	4	4
7	Disease Management	482	99	68	15	14
8	Case Management	373	154	59	22	2
9	Psychoeducational	163	80	54	20	20
	TOTALS	3,436	740	341	76	49

1. RCT = Randomized Controlled Trial
2. Excluding topics 2–9
3. Excluding topics 3–9
4. Excluding topic 2, and topics 4–9; limited to MeSH terms rather than all fields

Note: Since the search terms used for this initial search captured all the studies included relative to the six SAMHSA 2000 monograph topics, the numbers of abstracts and RCTs presented in this table, and the table immediately following, reflect only those not included in the SAMHSA 2000 search.

Table 4: Notes on Randomized Controlled Trials in Advanced Searches

	Topic	Randomized Controlled Trials Rejected as Not Pertinent	Randomized Controlled Trials Considered Pertinent[1]
1	Preventive Health Services[2]	(No RCTs)	The lack of RCTs appeared to be an artifact of the literature search procedure.
2	Mass Screening[3]	Two were misclassified— they were not RCTs. The third was too poorly conducted to be of practical value (Schriger et al., 2001)	(None) It is important to note that the USPSTF guidelines on screening for depression are based on non-RCT studies of the screening procedures plus RCT studies of the efficacy of treatment of depression in persons detected by the screening procedures.
3	Health Education[4]	(None rejected)	Perry et al., 1999 (Perry, Tarrier, Morriss, McCarthy, & Limb, 1999)—successful RCT on educational program for patients with bipolar disease to reduce the frequency of manic relapse
4	Home Care Services	Two were purely therapeutic, with no preventive content	Two studies—Armstrong, Fraser, Dadds, & Morris, 1999, and Lagerberg, 2000—were preventive interventions to families with children considered at high risk because of social deprivation or "environmental factors." Both showed positive results. Largerberg was a literature review. The third study—Gitlin, Corcoran, Winter, Boyce, & Hauck, 2001—was outreach to caregivers of patients with dementia, also showing positive results.
5	Self-Care	One study (Pouwer & Snoek, 2001) dealt with diabetes, depression, and gender and appeared to be severely flawed	Three were meta-analyses or literature reviews—one each dealing with "adult problem behaviors," dementia, and depression. The two RCTs addressed "chronically mentally ill outpatients" and anxiety attacks. All five are considered worthy of a closer look. The one on dementia is included to see if the intervention is for the patient or the caregiver.

1. RCT = Randomized Controlled Trial
2. Excluding topics 2–9
3. Excluding topics 3–9
4. Excluding topic 2, and topics 4–9; limited to MeSH terms rather than all fields

(table continues...)

Table 4 (continued): Notes on Randomized Controlled Trials in Advanced Searches

6	Prenatal/Perinatal Care	(None Rejected)	Two RCTs dealt with depression, and one each with alcohol and drugs.
7	Disease Management	(None Rejected)	Nine of the 15 dealt with the cost-effectiveness of various approaches to treatment of depression. While therapeutic instead of preventive, these relate to the guideline to screen for depression. Of the other six, three dealt with alcohol, and one each with tobacco and depression.
8	Case Management	20 of the 22 were purely therapeutic, with no preventive components	Of the two pertinent studies, one (Azrin & Teichner, 1998) was an instructional program to improve medication compliance for "chronically mentally ill" outpatients and the other (Buckwalter et al., 1999) dealt with a nursing intervention to decrease depression in caregivers of persons with dementia.
9	Psychoeducational	(None Rejected)	Most of the 20 studies in this group are therapeutic and lessen the progression of an illness or improve self-efficacy by the patient. Three have been pulled as "anchor" studies: - Misri et al., 2000 (Misri, Kostaras, Fox, & Kostaras, 2000) deals with partner support in the treatment of postpartum depression. - Von Korff et al., 1998 is a study of the treatment of depression - Ostwald et al., 1999 (Ostwald, Hepburn, Caron, Burns, & Mantell, 1999) is an intervention for caregivers of patients with dementia

1. RCT = Randomized Controlled Trial
2. Excluding topics 2–9
3. Excluding topics 3–9
4. Excluding topic 2, and topics 4–9; limited to MeSH terms rather than all fields

Table 5: Searches From 1964 To 2002 To Collect Negative Studies

	Topic	Papers Utilized as basis for Searches	Total References	Controlled Trials and Meta-Analyses	Comment
D1	Prenatal and Perinatal Home Visits	Olds	141	25	67 unduplicated abstracts (duplicates eliminated in Ramey and Field counts)
		Ramey	107	17	
		Field	115	25	
D2	Tobacco Cessation	Marks	118	26	
D3	Short-Term MH Therapy	This category was deleted as a discrete category from this 2004 update, with the various interventions distributed to other categories not represented in the 2000 report.			
D4	HRA/Self-Care/Self Help	Kemper	251	54	102 unduplicated abstracts. The Vickery 48 exclude papers listed in Kemper search. One study by S. Moore (1980) showed no significant effects.
		Vickery	109	48	
D5	Presurgical Education	Devine	107	4	The Mumford 12 exclude papers listed in Devine Search.
		Mumford	109	12	
D6	Brief Education and Counseling To Reduce Alcohol Use	Fleming	172	Estimated–120	This is a high volume of studies, with the duration/length of the intervention and number of interventions per client highly variable and not well described in many papers.
	TOTALS		1132	340	

Table 6: Preliminary Analysis of SAMHSA 2000 Monograph Search for Negative Studies

	Topic	Pertinent Trials and Meta-Analyses (unduplicated)	Comment
D1	Prenatal and Perinatal Home Visits	67	Of the 67 unduplicated clinical trials and meta-analyses in this group of papers, 34 showed positive results, one negative results, and 32 were considered non-pertinent to this preliminary analysis—most because they were not home care or were not prenatal/perinatal visits. Of the 34 positive papers, Olds and/or Kitzman and Ramey authored 12. As a result, the number of actual clinical trials is less than the number of papers. In almost every instance, it seemed clear that the home care was part of a more comprehensive package of health and medical services—suggesting that simply adding a home care element to a straight clinical service is unlikely to be effective. Most of the studies could be classified along three general lines: 1. General risk (economically and socially vulnerable groups) 2. Drug/alcohol/tobacco users 3. Children of mentally retarded mothers 4. (A few of the studies dealt with infants with specific disorders or risk profiles) The benefits were mainly long-term social, psychological, and behavioral, rather than health care utilization. The babies were healthier and needed less long-term care. These studies were generally very well designed and showed strong positive benefits. The benefits, however, related to social dependency and issues other than offset of health care costs. While of obvious interest to health care systems serving Medicaid populations and health care providers serving economically vulnerable populations, these studies will be of relatively little interest to health care systems serving more well-to-do clientele.
D2	Tobacco Cessation	26	Of the 26 papers in this set, nine showed positive results, seven showed negative results, four were reviews, and six were not pertinent. The problem is one of getting an intervention that is intense enough to be effective—but not too costly—and then finding some way to extend the benefits beyond the end of the pregnancy.

(table continues...)

Table 6 (continued): Preliminary Analysis of SAMHSA 2000 Monograph Search for Negative Studies

D3	Short-Term MH Therapy	This category was deleted as a discrete category from this 2004 update, with the various interventions distributed to other categories not represented in the 2000 report.	
D4	Self-Care/Self-Help	~100	More than 100 unduplicated papers are included in this self-help/self-care management data set; one negative study (randomized by family) by Moore (1980); and at least six positive studies, of which five used randomization. Most deal with education and training to help patients and family members do a better job of managing a medical chronic disease. The literature on managing chronic mental disorders is an entirely separate body of literature, with remarkably little overlap. Yet a third body of literature relates to the management of mental disorders as an aid to management of chronic medical conditions. This topic was merged into "Psychoeducation."
D5	Presurgical Education	~16	Scanning the literature for relevant studies developed two nonrandomized clinical trials, one RCT, and two meta-analyses that were most relevant. Five were very positive. The large number of publications in this arena represents other and weaker study designs. This area has potential within the area of psychoeducation and the "activated" patient literature.
D6	Brief Education and Counseling To Reduce Alcohol Use	~120	Overall, two studies showed no effect of the intervention, while four were positive with strong results. This large data set includes a single meta-analysis (Poikolainen, 1999). This study concludes "for very brief interventions the change in alcohol consumption (6–12 month follow-up) was not significant among men or women." For "extended brief interventions the reduction was statistically significant, but too small to be of clinical importance." Most of the studies appeared to be more intensive.

Table 7: Topics from SAMHSA 2000 Monograph Reflected in This Monograph (SAMHSA 2004)

	2000 Topic Heading	2004 Topic Heading
D1	Prenatal and Perinatal Home Visits	High-Risk Pregnant Women and Children to Age 5
D2	Tobacco Cessation	Screening: Tobacco; Pregnant Women, Adolescents, and Adults
D3	Short-Term MH Therapy	Psychoeducation for Patients with Chronic Diseases
D4	HRA/Self-Care/Self-Help	Psychoeducation for Patients with Chronic Diseases
D5	Presurgical Education	Psychoeducation for Patients Scheduled for Surgical Procedures
D6	Brief Education and Counseling To Reduce Alcohol Use	Screening: Alcohol; Pregnant Women, Adolescents, and Adults

listing the key studies used by Dorfman in the SAMHSA 2000 report, and then searching what Pub Med lists as "Related Articles." While initially envisioned as a search from 1964 through 1999, the search was expanded through 2002 to eliminate the need for yet additional search exercises. The searches are listed here according to the six categories recommended in the SAMHSA 2000 report, and the results are summarized below:

New topics added as a result of the broader literature review include screening of children and adolescents for evidence of behavioral disorder, screenings for illicit drug use, screening of adolescents for depression, and psychoeducation for persons with somatization.

Life Cycle Convention Used in This Report

After reviewing the literature and trying several alternative approaches, the following life cycle classification was used in this report:

- Pregnant women
- Pregnant women and mother-child dyads, birth to 5 years of age
- Children 5–11 years of age
- Adolescents 12–18 years of age
- Adults 19 years of age and older (including seniors)

This approach compresses what otherwise would have been six or seven age groupings into five because the literature analysis showed that implementation guidelines were similar enough to warrant such compression. Pregnant women appear in two of the five groupings because of a discrete body of literature on the provision of preventive home visitation services to socially and economically vulnerable pregnant women, infants, and preschool children.

The adult population, previously divided into three age ranges (19–44 years; 45–64 years, and 65 years and older), was compressed into a single group after it became clear that the processes for screening, intervention, and follow-up basically were the same across all these age groups.

Although there are vast differences in risk profiles of children and adolescents, as they progress year by year from 5 to 18 years of

age, the entire population in this lifestyle group tends to be neglected by the health care delivery system because of the group's resiliency, generally good physical and mental health, and the ambiguity (which increases year by year into midadolescence) as to whether they or their parents are responsible for addressing risk-related and behavioral issues.

Format for Presentation of Guidelines

A common format is used for presentation of all basic interventions as follows:

- Introduction and conclusions
- Possible interventions
- Review of literature: efficacy-evidence base for the guideline, including assessment of need, proof of efficacy, positive and negative studies, and studies addressing program implementation issues
- Review of literature: effectiveness; program implementation issues; how to manage the intervention so that it succeeds in securing the desired benefits
- Data to be tracked for surveillance, member selection, feasibility assessment, and program evaluation

XIV. Appendix B: Policy and Management Issues and Guidelines

This appendix is intended as a primer for health care administrators, policymakers and fiscal officers—to set the stage for successful implementation of preventive behavioral-related services in health care delivery settings.

Additional guidance on policy and management issues can be found in Appendix D, Implementation and Evaluation of Preventive Services. Appendix C provides guidelines for billing for preventive services. The following issues are addressed here:

Translation of Research Into Practice

- Deciding on benefit packages
- Interpreting the medical literature
- Projecting benefits and desired consequences

Unintended Benefits and Adverse Consequences

- Pareto's Law (the "80/20" rule)
- Perceptions and biases often shared by administrators and physicians
- Time intervals from cost to benefit
- Build versus buy options—disease and demand management

Benefits of Preventive Services

- Member health status and quality of life
- Quality of care
- Employee productivity
- Cost containment
- Image/reputation of health plan

Need

- Incidence and period prevalence
- Case identification
- Severity of illness
- Severity of risk

Efficacy

- Projection and modeling
- Effectiveness and cost-efficiency

Infrastructure

- Surveillance and data systems
- Screening policies and procedures
- Follow-up protocols
- Counseling
- Psychoeducation
- Health education (individual, group, and Web site)
- Case management
- Call centers
- Home visitation

Translating Research Into Practice

Translating preventive behavioral research into health care practice is a complex matter. There are several questions to be addressed at policy, management, and clinical levels as well as perceptions to be addressed—perceptions that historically have limited patient access to behavioral services within health care delivery systems. The major questions can be summarized as follows:

- What preventive behavioral services should be considered for inclusion in benefit packages and why?
- How does a health care plan control the utilization of preventive behavioral services?
- How does a health care plan determine the need for preventive behavioral services?
- How does a health care plan measure the impact of preventive behavioral services on health care costs?
- How does a health care plan manage preventive behavioral services to assure quality, cost-efficiency, and effectiveness?

Deciding on Services and Benefit Packages

Health care plans and managed care organizations are mandated to provide mental health coverage by State and Federal authorities and to meet the National Committee for Quality Assurance's Health Plan Employer Data and Information Set (HEDIS) guidelines. Even if this were not the case, the impact of such preventive services on other health care expenditures for selected preventive behavioral services make investment in such services a wise choice for health care plans and managed care organizations. Systems must be in place, however, to assure the quality and appropriate utilization of such services.

For most preventive behavioral services, there is little question as to the fiscal responsibility of health care plans and managed care organizations. However, some of the services discussed, which clearly are social or educational in nature, are intended to secure social and educational nonmedical benefits. Included are some of the services suggested for economically and socially disadvantaged women and their families. Although the value of these services is firmly established, the question remains as to who should pick up the cost. The answers to these questions will vary by health plan, depending on the public versus private orientation and the needs of membership.

Interpreting the Medical Literature

Randomized controlled trials present the strongest evidence for or against a suggested intervention, but the process of selecting both cases and controls almost always creates a situation in which the cases and controls differ in substantial ways from the enrollment of any given health care system. Cohort and cross-sectional studies usually have more typical patient and control populations, but they are weaker study designs.

When conducting a randomized controlled trial, the research team must carefully select both cases and controls to assure that the differences between these groups after the intervention can be reasonably attributed to the intervention. Health care plans wishing to implement services based on the research can consider the degree to which findings in each paper might or might not apply to their provider panel and membership. One major difference is the willingness of the patient to comply fully with prescribed regimens of care. Research subjects are selected for nearly 100 percent cooperation. Patients in

conventional health care settings are far less compliant. Even with very careful selection of cases and controls, however, even the research studies still must address attrition and noncompliance.

To further complicate matters, real-life patients are likely to deny behavioral problems such as smoking, drinking, substance use disorder, and depression, and primary care practitioners in conventional health care settings are not likely to address these issues because of lack of comfort, desire not to weaken the patient/practitioner relationship, and lack of time.

Another problem is that enrollees might not be similar in demographics, cultural, or clinical profile to the subjects used in the research. Environmental factors also are important, with many patients and health care systems facing economic and administrative barriers that inhibit provider-patient communication (especially between clinic visits) and the high cost of some prescription medications.

Research studies present their results as if a cohort of cases and controls begin the intervention at the same time and are followed for the duration of the study, which then comes to an end. Health plan implementation must take place in the real world, where members are at all stages of illness at all times; where enrollment and processing must take place at all points in time; where concurrent comparable controls are not feasible; and where the intervention is anticipated to extend into the indefinite future. This severely complicates projections of costs and benefits, especially after the initial year of intervention. This set of complications requires establishment of tracking mechanisms that are not traditional in managed care plans—tracking mechanisms that at least initially may have to be structured as small-scale, separate, stand-alone data systems.

"Effectiveness" denotes whether a specified intervention will work under the conditions of a randomized controlled trial. "Efficacy" denotes whether this same intervention will work under conditions of routine health care delivery (Daumit et al., 2001). Depending on how it is managed, a theoretically effective intervention might not be efficacious within a given health care delivery system. The challenge for both health plan administrators and clinicians is how best to manage implementation of the intervention to secure the desired efficacy.

Finally, ethical considerations sometimes make randomization and/or control impossible to implement in research and health care delivery settings. The best example within the scope of this report is identifying the cause of poor pregnancy outcomes among pregnant women using illicit drugs (such as marijuana, cocaine, and heroin). The problem is that one cannot tell the degree to which the low birthweight and other "non-specific" poor pregnancy outcomes are due to the drug or due to the mother's lack of prenatal care, poor nutrition, etc. Since it would not be ethical to treat the substance use disorder without providing prenatal care, or provide prenatal care while ignoring the substance use disorder, randomized controlled studies to differentiate the impact of prenatal care from the impact of substance use disorder counseling never will be done. This being the case, health care systems and individual physicians must establish some health policies and procedures without the benefit of randomized controlled trials.

Projecting Benefits and Desired Consequences

The researchers who generate the published

literature generally avoid fiscal and management issues. The complexity of health care finance, pricing, and billing methodology, bundling and capitation, bad debt and cash flow issues, and annual changes in health plan enrollments all complicate attempts to link provision of preventive services with their impact on other health care expenditures. Although researchers can and often do document changes in health care utilization in response to effective delivery of preventive services, taking the next step and relating these changes to health plan expenditures usually is beyond the scope of their research protocols.

These fiscal and administrative issues are the issues of greatest importance to health care administrators and fiscal officers. From their perspective, morbidity and health care utilization are but two of many factors affecting the cost of health care delivery. To further complicate matters, fiscal incentives often are perverse in health care delivery, with cost savings for the health plan often being seen as revenue reductions for hospitals and providers.

The most tenuous aspect of documenting the benefit of preventive services is accurately and reliably projecting what would have occurred had the preventive service not been provided. This problem becomes more subjective with every passing year after initiation of the preventive service. Researchers can address this issue by dividing their subjects into cases and controls. This is something a health care system cannot do.

After the first few years of effective delivery of a new preventive service, there will be few differences in outcomes from year to year, as previously secured benefits are maintained on an ongoing basis. This lack of year-to-year improvements can leave the impression that the program has lost its effectiveness and thus lead to elimination of the preventive service. The literature indicates that preventing such premature program demise is best done by establishing baselines, benchmarks, and year-to-year projections prior to initiating the preventive programming, then tracking the programming against these projections. Precautions such as these are rarely taken when new preventive services are initiated. Failure to establish these baselines and benchmarks can lead to premature elimination of the preventive services when additional year-to-year reductions in health care costs cease to occur.

Unintended Benefits and Unanticipated Adverse Consequences

Prevention programming can have unintended benefits and unanticipated adverse consequences more substantial than the direct costs and intended benefits. An example of an unintended benefit would be a health education program to motivate patients to quit smoking, which might also result in lifestyle enhancements such as a more sensible diet or less binge drinking. An example of an unanticipated adverse consequence would be the process by which high-quality depression management programming by a managed care plan might result in physicians urging patients with depression to switch to that plan. In this case, the adverse consequence would be to the health plan and take the form of adverse patient selection. Health plan managers should try to project possible unintended benefits and adverse consequences of preventive services, and plan to measure them for purposes of program planning, program evaluation, and future policy development.

Pareto's Law (The "80/20" Rule)

Pareto was a sixteenth century Italian economist who stated that in any human activity, a small percentage of the participants will account for most of the action. As commonly interpreted, in any given year, approximately 20 percent of the enrollees in a health care plan will be expected to account for approximately 80 percent of the cost, with the top 5 percent accounting for approximately 50 percent of the total health plan expenditures. In this context, the challenge to health care delivery systems is to identify those individuals who are likely to become high-cost patients in the near future, then take the action necessary to reduce the number of individuals at risk of falling into these high-cost groups.

An example appears in the behavioral literature where Simon and Untzer published a study in 1999 (Simon & Unutzer, 1999) presenting health care utilization and costs among patients treated for bipolar disorder in an insured population. Five percent of the patients accounted for approximately 40 percent of costs for (outpatient) specialty mental health and substance abuse services; 90 percent of inpatient costs for specialty mental health and substance abuse services; and 95 percent of out-of-pocket costs for inpatient care.

Health care systems can address both these risk profiles in two ways. One is through the use of the IOM "universal" screening procedures presented in this report, which are to be followed by the "selective" preventive services to confirm or deny the finding of the initial screening and identify those who could benefit from more intensive "indicated" services.

A major key to success in implementing the more expensive and more individualized preventive behavioral services is the ability of the health care delivery systems to successfully target the services to those most at risk, while avoiding provision of the more expensive and more individualized services to members not in need of these more expensive interventions. For most of these interventions, this depends on the skill and level of training of the primary care practitioners.

The second way for health care systems to identify individual and group risk involves data mining and use of predictive modeling software; in other words, skilled manipulation of claims, pharmacy, and other data. Unfortunately, these procedures do not lend themselves to randomized controlled trials. Unlike the screening procedures, the guidelines and software are proprietary and not subject to the scrutiny of peer-reviewed journals. Because of the lack of high-quality peer reviewed literature in this arena, these data mining and predictive modeling interventions were considered outside the scope of this report.

Perceptions and Biases Often Shared by Administrators and Practicing Physicians

Bias against prevention:

There is a widely held belief that prevention sounds good but just does not work.

Bias against behavioral/mental health services:

Behavioral needs and benefits are seen as "soft" since they usually are not verifiable by laboratory testing or physical examination.

Stratification and discrimination:

Stratification of both subpopulations and individuals is critical to cost-efficient provision of selective and indicated preventive services. In this context, "stratification" refers to the process by which a health care

delivery system might identify groups of members to receive specific preventive services not offered to other members. Health care system managers often are uncomfortable with any form of stratification because of their perception that it is not ethical to offer some services to some members, but not others, when all are paying the same premium. They also worry about accusations of discrimination, stereotyping, and inappropriate use of confidential data. This issue and these conflicts can be very carefully explored. Failure to do so may severely inhibit the cost-efficiency of preventive services.

Uncertainty:

Administrators and fiscal officers dislike uncertainty. The inability to directly document what might have occurred had a preventive service not been provided creates a situation where there often is substantial uncertainty about the benefit to be secured by almost any preventive service. The most effective way to address this uncertainty may be by generating epidemiologically sound projections of likely costs and benefits, then measuring the outputs and outcomes so they can be compared with the original projections.

Competition and cost:

Health care systems and health insurance plans are highly cost-competitive. From their perspective, preventive services sometimes are perceived as overhead costs of no benefit to the plan. As a result, some managed care plans may feel that they cannot afford the cost of providing preventive behavioral services unless such services are imposed as a requirement or promise to reduce other health care costs within a year of program implementation. With members frequently switching managed care plans on the basis of premium cost, some health care systems are reluctant to invest in preventive services where they will pick up the cost of the preventive service, but a competing health care system will enjoy the fiscal benefit of the illness prevented. To address this issue at the national level, certifying and regulatory bodies now require the provision of selected preventive services.

Reluctance to develop supplemental data systems:

Supplemental data systems to track individuals and small groups often are required for the cost-efficient implementation of preventive and disease management services. Supplemental systems can be seen as costly, as violations of patient and physician confidentiality, and as an inappropriate use of premium dollars to fund research. Despite this reluctance, supplemental data systems along these lines now are being widely implemented in health care systems to address the overlapping needs of quality assurance, disease management, and preventive service programming.

The supplemental information systems often can be developed and initially managed on desktop computers using off-the-shelf spreadsheet or database software until such time as the data can be incorporated into larger claims-based or electronic medical record (EMR) systems.

The perceptions and biases noted above often may be best addressed directly within individual health care delivery systems if preventive services and therapeutic behavioral services are to be effectively and efficiently implemented with full accountability for costs and outcomes.

Time Intervals From Cost to Benefit

Changes in a health care system's client base can dramatically alter both costs and perceptions of benefit. To track both costs and benefits, the possibility of such changes can be considered in the initial design of the systems used to track costs and benefits. Since there is little published literature on the time-related issues noted above, guidelines may be based on personal/professional opinion until such time as the needed research can be done.

Time-related issues are critically important given the need for administrators and fiscal officers to look at costs and benefits by calendar-quarter and fiscal year. There is a time delay between the decision to initiate the service and the time the preventive program comes online. There are options concerning how quickly the plan or medical center will saturate the initial need for the service in question, with rapid coverage usually requiring an intensity of staffing that need not be maintained in future years. There also are delays between the provision of the service and reduction in subsequent health care costs that must be well understood.

Build vs. Buy Options: Disease and Demand Management

Health plans may wish to carefully consider whether they wish to build their own disease management systems in-house, purchase the services from disease management and data system vendors, or pursue a hybrid approach. As a rule of thumb, one can generally expect a system purchased from an outside vendor to cost more than it would cost to provide the service in-house. In return for this higher cost, the purchase option offers the advantages of very little, if any, development time, access to well-developed and debugged systems, and a much greater chance to secure health care savings in excess of program cost within 12 months of initial program implementation. Vendors also offer expertise not otherwise available to many health care delivery systems.

Once developed, the health plan can plan to maintain the preventive/disease management program on a long-term basis. Even with vendored programs, much work is required to get the patients and physicians into the program and used to the system. Initially, the tracking systems will be the means by which the health care system documents the savings and other investments from the preventive programming, by tracking year-to-year changes in the outcome parameters. Three to 5 years into the program, however, the year-to-year differences will disappear, creating a situation where the tracking system becomes even more important to documenting maintenance of the desired benefit.

A major problem is that the dramatic reductions in health care costs from year to year will phase out over the first 3 to 5 years, as the benefit is achieved and maintained. This creates a situation where the higher costs of fully vendored systems will be harder and harder to justify to financial managers, with each passing year. This problem may be anticipated when such programs are initiated, either in-house, vendored, or hybrid, with understandings reached among program advocates, program staff, the vendor(s) and the financial managers as to how these issues are to be addressed in subsequent years. One possibility is to plan to transition the vendored services in-house over the first 3 to 5 years. If this is to be considered, attention must be paid to the issue of software

licensure at the time the vendored service is initiated.

Benefits of Preventive Services

Member Health Status and Quality of Life

Major depression is one of a number of behavioral health disorders reviewed in this report with major impact on overall health status (especially in members with concurrent major chronic diseases), quality of life, and workplace productivity. The most effective and objective way for a health care system to measure functional health status and overall quality of life is through use of questionnaires, such as the SF-36 (Jordan-Marsh, 2002; Ferguson, Robinson, & Splaine, 2002; deHaan, 2002). The SF-36 is one of a number of currently available health status questionnaires that measures current physical health and mental health status in terms of what a patient is able to do and how the patient feels on a day-to-day basis. Such questionnaires can help the clinician identify undetected illness and depression and can help the health care system track the overall quality of care provided to patients with medical and behavioral chronic diseases.

Quality of Care

"Quality of care" has multiple domains. One domain is physician, nurse, and other health professional compliance with nationally recognized guidelines for the process of care. Another domain is health care system performance, as assessed using industrial-type measures of quality, consistency, and efficiency of administrative, logistical, and support services. Yet other domains include member health outcomes, member and physician satisfaction, employer-as-a-client satisfaction, and financial performance.

Because of the impact of preventive/disease management programming on member outcomes, and the manner in which HEDIS has framed preventive/disease management programming in the name of health care quality, all the guidelines in this report can be seen as quality-control measures. Increasingly, more and more preventive/disease management programming will be required of managed care plans wishing to score well on quality of care "score cards."

Employee Productivity

Most of the commercial market for managed care plans is employer-based. There is ample literature to document that poor health can adversely affect employee productivity, with behavioral problems among the most costly (Williams & Strasser, 1999). Ironically, preventive/disease management programming does not commonly cover these disorders, presumably because they do not result in large numbers of emergency room visits and hospitalizations.

Cost Containment

The overwhelming importance of financial concerns in the management of health care systems has resulted in almost single-minded focus on "return on investment," which usually is calculated on the basis of program costs and reductions in other health care costs within each 12-month period after program initiation. As noted above, these calculations can be very problematic.

With behavioral health services, favorable cost-effectiveness, as calculated above, can be reliably secured for services related to tobacco, drugs, and alcohol for pregnant women, and for early detection and treatment of depression in patients with diabetes, asthma, congestive heart failure, and other major chronic illnesses. The

services to pregnant women reduce the need for costly newborn intensive care unit (NICU) services. The services to persons with chronic illness reduce emergency room and hospital use. Another service that the literature shows would almost certainly be cost-effective within 12 months of program initiation is psychoeducation for patients scheduled for surgery.

Image/Reputation of Health Care System

The image/reputation of the health care system is important for recruiting employers, members, and medical staff. Voluntary certifying agencies, such as the National Committee for Quality Assurance (NCQA), the Joint Commission on Accreditation of Healthcare Organizations (JCAHO), and the Utilization Review Accreditation Commission, track preventive programming and selected health outcomes as measures of health care quality. Thus, preventive programming that does not offer immediate cost-effectiveness still can have substantial favorable fiscal impact by virtue of its value for health plan marketing.

Need

Incidence and Period Prevalence

For practical purposes, in a managed care setting, incidence can be considered the rate of new cases per 100 or per 1,000 members per year. New cases can arise from initial diagnosis/onset of new illness in previously enrolled members, and through enrollment of persons with preexisting illness. Period prevalence is the percentage of members known to have a specified disease within any given year. There is interplay among incidence, prevalence, and severity of illness that needs to be understood.

When dealing with behavioral disorders and major chronic diseases, there always is a hidden burden of illness that has not yet been diagnosed but is present within the enrolled population. For behavioral disorders and diseases such as hypertension and diabetes, the number of not-yet-diagnosed cases may equal or exceed those known to the plan through claims data. The purpose of screening programming is to aid the early diagnosis of these diseases so that they may be inexpensively managed before the progress to a more severe stage of illness. Screening programming increases incidence and prevalence while reducing average severity of illness and future costs. In many cases, the "future" is only 6 to 24 months away, creating a situation where such programming often can pay for itself within 12 to 24 months.

Case Identification

Both individuals and groups with priority needs can be identified in many ways. For some, claims or pharmacy data can be used to identify persons with diabetes, asthma, and other chronic diseases who may need priority screening for depression and other mental illnesses. Others can be identified through chart review. For some, however, identification will be difficult because the member may not be forthright about behaviors seen as stigmatizing, or out of a desire to please the doctor who may be seen as an authority figure. This frequently is seen relative to tobacco use and alcohol and illicit drugs, where less than half of those using these substances may voluntarily admit to their use. Some research protocols have included blood or urine tests. With rare exceptions, blood or urine screening for these substances is not appropriate for routine medical care. As a result, from a health care delivery perspective, there is no easy or complete solution for this problem.

Severity of Illness

Behavioral and chronic medical illnesses have a natural history of progressing from asymptomatic to symptomatic, to more severely ill stages, with or without medical complications. The purpose of both preventive and therapeutic services is to delay or interrupt this progression—perhaps delaying it for the remainder of the natural life of the person. Given this model of illness, the secret to success is either prevention of the illness or early identification to prevent progression of illness. Tracking onset and severity of illness will require data not found in most claims-based data systems. Some of these data will not even be in the medical record and will require screening and follow-up questionnaires.

Severity of Risk

For purposes of quality assurance and disease management programming, "severity of risk" is a characteristic of each enrolled member separate from severity of illness, and not directly ascertainable from claims data. One major dimension of severity of risk can be defined in terms of a member's willingness and ability to adhere to prescribed regimens of lifestyle and management of current illness. In this context, "high-risk" members are those who do not quit smoking, take their pills, control their diet, etc. Basically, the higher the risk, the more health plan resources need to be invested to encourage and enable the member to do what is needed to prevent future illness and prevent deterioration of current illness. The common practice of developing educational and fitness programming, but not aggressively marketing it to those most in need of such programming, utterly fails to reach the higher risk members. High-quality case management and preventive programs, including psychoeducation, can be very effective in reaching out to these higher risk members, eliminating barriers to their participation, and enabling their participation.

Efficacy

Projection and Modeling

Assessing the efficacy of preventive services involves projecting what would have happened had the service not been provided. In most cases, this is best done by estimating likely outcomes based on the published literature and the experience of others. Projection and modeling does not necessarily imply reliance on elegant mathematical modeling procedures.

The most practical ways involve use of carefully selected baselines and benchmarks. The usual baseline is incidence or prevalence data from within the health plan. Benchmarks can be secured from a variety of sources, including but not limited to HEDIS, Healthy People 2010, the published literature, and databases presenting State and national averages and State and national survey data. Unfortunately, from the perspective of managed care plans, many of the most useful benchmarks are not parameters discernable from claims data. They require special surveys, medical record reviews, or data that might be secured from electronic medical record systems. Much of the ascertainment of HEDIS compliance is based on highly structured reviews of randomly sampled medical records.

It is generally considered best to establish the baseline and define the benchmarks and objectives prior to initiating new preventive services. Running the preventive program first, then trying to reconstruct the baseline

can be difficult and can significantly erode confidence in the results.

Use of fixed baselines and benchmarks is critical to maintaining preventive services after the stage has been reached in which annual differences in process and outcome measures no longer occur, or have been substantially curtailed by the previous success of the preventive programming.

Effectiveness and Cost-Efficiency

Cost-efficiency generally is assessed in two stages. The first is limited to process measures (persons educated, calls, visits, prescriptions filled, etc.) that usually are easy to gather and track on a concurrent basis. These measures will document the activity needed to improve the outcomes.

The second stage focuses on member outcomes (cost-benefit). Given the delays between the delivery of the preventive service and the capture of the benefit in terms of reducing illness and reduction in hospital and emergency room utilization, total reliance on outcome data can give distorted pictures of program efficacy, both positive and negative. Both process and outcome measures may be tracked and validly interpreted. Total reliance on cost-effectiveness calculations based on costs of programming and claims-related health care use data can be distorted by changes in membership, delays in submission or processing of health care claims, changes in rate structure, and movement between fee-for-service and capitated billing.

Infrastructure

From a management perspective, similar infrastructure elements are needed for preventive services (both medical and behavioral), disease and demand management programming, quality assurance, and utilization review.

A review of the literature indicates the following four major components as most promising for a health plan to develop and maintain the best possible quality assurance and preventive/disease management services:

- Medical leadership, preferably with one or more physicians on a full-time or part-time basis, with personnel who are trained and experienced in epidemiology and population-health management
- Management information support services, surveillance and data systems (MIS) for need ascertainment, program management, and program evaluation
- Staff capacity to manage and interpret the quality assurance and preventive/disease management data
- Financial support and staffing for screening and survey work, provider and patient health education, prevention-oriented case management, and prevention-oriented outreach and home visitation.

Research strongly suggests that universal preventive services, both medical and behavioral, will have to be implemented by primary care physicians and their staff assistance. These services represent an additional burden for them to carry and must be recognized in terms of clinical productivity expectations and reimbursement if such services are to be effectively and universally implemented. In the case of the universal preventive behavioral screening procedures, depending on the type of patient and whether one is dealing with an initial or follow-up visit, such screening can be expected to lengthen the clinical encounter between 30 seconds and approximately 2 or 3 minutes. A percentage of the patients will give positive

responses to the screening questions and will then require between 2 and 10 minutes of additional time for patient interview and in some cases to arrange follow-up referrals to other programs and professionals.

Quality assurance (QA) and preventive/disease management (DM) services both require the same population-based approach and same types of data systems. Since they both contribute to member outcomes, and since NCQA, JCAHO, and peer-review organizations consider them together, it is probably best to address them with a combined initiative.

Surveillance and Data Systems

Surveillance is the process by which health care systems identify those in need of preventive services, then follow up to assess the effectiveness of such services. Depending on the disease, the surveillance system might be entirely claims-based, might include detailed pharmacy and laboratory data, and might be by chart review, by member survey, or a combination of these measures.

Not all health care delivery systems have integrated and computerized claims and medical record systems. Given this circumstance, the literature suggests that the most cost-efficient approach to preventive/disease management data systems may be to have small, separate, dedicated systems that can be developed in-house, using spreadsheet or database software, secured free of charge from selected pharmaceutical manufacturers or purchased from a variety of vendors.

According to the research, the most practical approach in most cases will be to develop a registry of patients to be considered for preventive services for each disease or health condition, then track appropriate health status measures, appointments, etc. This would enable the plan to follow up on missed appointments, cue primary care physicians as to needed periodic diagnostic and treatment procedures, track medication compliance, and flag those who may need special attention due to a deteriorating health or risk profile. Such information systems could be created in-house for a single physician group for a single disease, then, after the bugs have been worked out of the system, expanded to other physician groups and other diseases.

Screening Policies and Procedures

Screening is a process intended to identify preclinical illness so that it can be treated early. Sometimes reviewing claims data or charts can do this. Most of the time, however, it requires direct member participation to collect questionnaire data, x-rays, and/or laboratory specimens. Screening programs and related health fairs are widespread, but many fail to secure desired health benefits and cost savings for lack of adequate follow-up.

Screening for behaviors or disorders with social stigma raises the issue of invasion of privacy and the issue of unwanted intrusiveness into the life of the member. Such behaviors and disorders include use of tobacco, alcohol and drugs, presence of mental illness in the member or their family, AIDS, sexually transmitted diseases, self-inflicted injury, or injury due to criminal behavior. When addressing these issues, some percentage of members voluntarily will provide this information on interview. For those who will not, proceeding with blood or urine testing or other means of investigation may be warranted in selected cases. Such more intrusive screening probably does not appear justified on a

routine basis. This situation, in turn, creates circumstances in which the health care system knowingly will fail to identify a substantial percentage of the cases.

Follow-Up Protocols Postscreening

Research indicates that in the context of preventive and disease management programming, screening without well-established postscreening follow-up protocols is likely to be a waste of time (for anything beyond marketing and community relations). Desired follow-up usually entails more detailed clinical assessment, with treatment in some form initiated for those found to be "positive" for the disease.

Counseling

Counseling, which entails providing objective information and helpful advice, is what every health professional does daily in his or her contact with patients. It is an essential part of the care process. Unfortunately, a quick and cursory explanation by the physician or nurse simply will not suffice, even when accompanied by written instructions. In addition, in most health care systems, if the patient has a question after they reach home, it is difficult, if not impossible, to secure the answer from the provider.

Because the usual practice of physician/nurse counseling often is inadequate to assure patient adherence to prescribed preventive measures and regimens of care, each health care delivery system should consider its needs for health education, psychoeducation, case management, call centers, and home visitation to improve patient adherence to medical recommendations for selected groups of high-risk and chronic disease patients.

Psychoeducation

Psychoeducation is health education combined with behavioral counseling. The counseling component of psychoeducation deals with emotions, perceptions, coping, relaxation, and self-care. Psychoeducation is of value for high users of health care services, those with major chronic diseases, and persons scheduled to undergo major surgical procedures. In the case of surgical patients, psychoeducation can enhance early mobility and control of pain.

Health Education (Individual, Group, and Web Site)

Health education is the least intensive of these ancillary services. Although it is sometimes provided one-on-one, it is more often provided as distribution of written material or in group sessions at the health facility or a community site. The goal of health education is to provide the patient with the information needed to secure and maintain the best of health, and to motivate the participants to adhere to the recommendations.

With each passing year, more and more health education is being provided over the Internet, or by other self-paced electronic means. This can be highly effective and cost-efficient for patients with the computer literacy and motivation to use these modalities.

Seeking health-related information is a major activity on the Internet. The problem from a physician and health-plan perspective is that the information secured may be of dubious quality, may conflict with physician advice, or may simply be wrong. The research indicates that for these reasons, health plans are well advised to develop and maintain their own Web sites, contract with a vendor of such service, and provide health-education pages, with linkage to sources of health information

that they consider to be accurate, reliable, up-to-date, and consistent with what their physicians are advising their members.

Case Management

Case management is a service usually provided by a nurse or social worker to identify the full range of health needs for a given enrollee and to assure that the service package is both complete and cost-efficient. The most common use of case managers is to control the cost of care for persons with exceptionally high health care costs. Case management usually is conducted in inpatient settings or for patients on long-term home care. Prevention-oriented case management, however, frequently is provided on an outpatient basis and consists of an occasional in-depth assessment and relatively light continued contact with the patient and/or family to assure that appointments are being kept, medications are taken, and questions are answered. Such case management usually is reserved for those with very complex or severe illness, or those who need additional assistance and motivation to reasonably comply with prescribed regimens of care.

Call Centers

Call centers provide several types of services. Most commonly, they provide members with 24-hour telephone access for health advice and guidance. Members can call any time of the day or night with questions concerning how to handle current medical situations or issues. These call centers also can be configured to place outgoing calls for purposes of health education, case management, gathering of survey data, etc. Like most of the other components on this list, a health plan or medical center can either set up their own call center or purchase this service from a national vendor who will customize it to meet the needs of the client health plan or medical center.

Home Visitation

Preventive/anticipatory home visitation for high-risk pregnant women and infants was a common practice in many local health departments and some public sector health care delivery systems through the mid-1970s. Since then, it has all but disappeared in the face of cost containment and a lack of peer-reviewed literature demonstrating the efficacy of such services. Over the past 20 years, a new body of literature has been published that clearly demonstrates the value of such home visitation, provided that the mothers and infants are carefully selected, the services are provided in accordance with strict protocols, and the goals of the service are clearly articulated (Eckenrode et al., 2000; Kitzman et al., 1997, 2000; Olds et al., 1986, 1988, 1992, 1993, 1994, 1995, 1997, 1998).

Home visitation is the most expensive service discussed in this report. Research indicates that to be cost-efficient, it must be reserved for only a small number of patients whose specific needs and risk profiles justify this level of service. Home visitation allows the nurse or social worker to observe the home environment, and by doing so, does a better job of providing counseling, education, and case management to empower and enable that patient and family to better manage their risk profile. Routine home visitation is recommended for low-income, economically and socially vulnerable first-time pregnant women for prenatal and postnatal visits shortly after birth, their newborn infants, and infants born to mentally retarded mothers. Occasional home visits may be helpful to support caregivers in

the home caring for patients with dementia or other serious long-term mental or physical ailments. The home visit option might also be considered for all other classes of patients with extreme risk profiles and/or difficulty adhering to prescribed regimens of care.

The home visitation envisioned herein is very different from the home health services currently provided by most health care systems to facilitate early hospital discharge or to substitute for nursing home placement. Home visitation uses nurses or social workers to provide in-home assessment and guidance in dealing with a wide range of medical, social, financial, psychological, and educational issues. This home visitation may include physical examination and health assessment, but it does not involve giving injections, changing bandages, or any other hands-on therapeutic medical service.

XV. Appendix C: Billing for Preventive Behavioral Services

Multiple sets of billing codes are provided—some for visits completely devoted to preventive services, and some for primary care physician use for mental health diagnosis and patient management. For most visits, the screening will take less than 3 minutes. Follow-up on screening results can then be billed as diagnosis and patient management.

Benefit packages will differ among and between insurance carriers and different policies offered by a single carrier. Practitioners will have to check with the insurance carrier or managed care plan to decide which codes to use to provide specific services to specific patients.

It is important to note that billing codes are expressed in terms of "encounters," and that an outpatient visit may include multiple "encounters." Here again, a provider must inquire with his or her managed care plan or insurance carrier to determine which encounters, within a single outpatient visit, are to be "bundled," and which are to be billed separately.

Coding of diagnoses and medical procedures for billing and for other purposes is a complex matter. International Classification of Disease (ICD-9 and ICD-10) codes are most commonly used for diagnoses. Current Procedural Terminology (CPT) codes are most commonly used for visits, procedures, and billing—but there are at least two other sets of codes in common use. Health Care Common Procedure System (HCPCS) codes are standardized nationally and are used in addition to CPT codes in Medicare and Medicaid Programs. However, there are "Level III HCPC" codes developed by individual States for locally designated services. These are not yet standardized nationally, although government agencies are currently reviewing them to standardize, reduce in number, and streamline. The project to standardize the local Level III HCPC codes is being directed by the U.S. Centers for Medicare and Medicaid Services (CMS) in accordance with the "Administrative Simplification" transactions provisions of the Health Insurance Portability and Accountability Act (HIPAA) of 1996, P.L. 104-191 (see www.cms.gov/hipaa/hipaa2/regulations/transactions/default.asp). Once the HIPAA billing codes become final, providers may bill for mental health services in primary care as well as specialty services in the specialty sector (Tremper, 2003). Our appendix is limited to presentation of the CPT codes

most important to primary care practitioners for preventive behavioral services.

Although psychologists, nurses, and other nonphysicians have a strictly defined scope of practice limitations, physicians do not. A primary care physician may bill for psychiatric services, since CPT code specifications for preventive services do not rule out prevention of mental illness. The limitation, if any, would be based on the interpretation of the State Medicaid office, a regional Medicare intermediary, or the specific benefits offered by a private insurance company. Whether or not mental health specialists can bill for screening for evidence of preclinical mental illness will depend on the benefit packages of the managed care or other health insurance plan, State Medicaid program, or Medicare intermediary. Here again, primary care practitioners are urged to check the resources available to them for patient referral, based on the patients plan membership or insurance policy.

The CPT coding for "Preventive Medicine, Individual Counseling" specifies that this is counseling provided as a separate encounter to promote health and prevent illness and injury for a patient without symptoms, and may be reimbursed using preventive medicine codes (Agency for Healthcare Quality Research, 2003). These codes run consecutively from 99401 for an approximate 15-minute encounter, through 99404 for an approximate 60-minute encounter.

Another possible approach, using general preventive medicine codes, are the codes for preventive medicine evaluation and management of an individual, including a comprehensive history, a comprehensive examination, counseling/anticipatory guidance/risk factor reduction interventions, and ordering appropriate laboratory/diagnostic procedures. There also are preventive medicine codes for counseling and risk factor interventions in group settings, with code 99411 for sessions of approximately 30 minutes, and 99412 for hour-long sessions.

Code 99420 is specific to administration and interpretation of health risk assessment

Table 8: Preventive Medicine, Individual Counseling, and/or Risk Factor Reduction Intervention Provided to an Individual as a Separate Procedure

CPT Code	Approximate Duration of Procedure
99401	15 minutes
99402	30 minutes
99403	45 minutes
99404	60 minutes

Table 9: Preventive Medicine Comprehensive Evaluations

CPT Code for Initial Evaluation of New Patient	CPT Code for Periodic Reevaluation	Age Range
99381	99391	Under 1 year
99382	99392	1–4
99383	99393	5–11
99384	99394	12–17
99385	99395	18–39
99386	99396	40–64
99387	99397	65 and over

instruments. Payers may or may not allow use of this code for behavior-related questionnaires such as the Pediatric Symptom Checklist or one of the longer alcohol- or depression-related questionnaires.

Finally, the last of the preventive medicine codes is 99429, Unlisted Preventive Medicine Service. Practitioners are urged to check with the managed care plan or insurance carrier before using this code.

There are a number of promising psychiatric codes that may be accessible to primary care physicians for follow-up on brief screening tests, especially for depression and any form of substance use. In these cases, the 1- or 2-minute screening interview would not be reimbursed separately. The diagnostic interview, counseling, and development of a treatment plan may be billable in the same manner as billing for diagnosis and management of a purely physical chronic disease.

The major codes of interest here are—

- 90801: Psychiatric interview examination
- 90804: Individual psychotherapy, insight-oriented, behavior modifying and/or supportive, in an office or outpatient facility, approximately 20 to 30 minutes face-to-face with patient
- 90805–90804: With medical evaluation and management services
- 90847: Family psychotherapy (conjoint psychotherapy) (with patient present)
- 90862: Pharmacologic management, including prescription use and review of medication with no more than minimal medical psychotherapy
- 90887: Interpretation or explanation of results of psychiatric, other medical examinations and procedures, or other accumulated data to family or other responsible persons, or advising them how to assist the patient.

In addition, in the context of psychoeducational interventions, including simple biofeedback training for presurgical patients—

- 90875: Individual psychophysiological therapy incorporating biofeedback

training by any modality (face-to-face with the patient), with psychotherapy (e.g., insight-oriented, behavior modifying, or supportive psychotherapy); approximately 20–30 minutes

- 90901: Biofeedback training by any modality

The material in this appendix was developed from the CPT 2000 Codebook of the American Medical Association (AMA CPT Editorial Panel and AMA CPT Advisory Committee, 1999) and the Ingenix 2003 update (Hopkins & Kachur, 2002). Additional guidance on codes to be used for Medicaid and Medicare can be secured from the U.S. Center for Medicaid and Medicare Services at http://cms.hhs.gov/.

More detailed guidelines for Medicare payments for Part B Mental Health Services can be accessed at http://oig.hhs.gov/oei/reports/oei-03-99-00130.pdf

To secure CPT code books and related materials, a number of products and services may be found on the American Medical Association's Web site at www.ama-assn.org/ama/pub/category/3116.html.

XVI. Appendix D: Procedures for Implementation and Evaluation of Preventive Services

Preventive services, unlike therapeutic services, are provided to persons who currently do not show evidence of disease. As a result, those persons who might benefit from such services often cannot be identified through claims data, but rather by identifying risk and protective factors. This creates a situation where health care delivery systems need policies and procedures for preventive services (both behavioral and medical) and quality assurance services (both behavioral and medical) that rely on data systems other than health care claims. This chapter provides general information regarding the implementation of preventive behavioral services. Additional information appears in Appendix B: Policy and Management Issues Guidelines; and in Appendix C: Billing for Preventive Behavioral Services.

Basic Principles

- Those most in need of preventive behavioral services often are those least likely to volunteer for such services. Addressing this issue requires assertiveness on the part of both the health plan and provider.
- Not all persons provided preventive services will have experienced the disease or complication the service was intended to prevent.
- The literature indicates that interview and counseling-based preventive services are far less than 100 percent effective in securing the desired risk modification or behavior change.
- Most of the preventive behavioral services intended to prevent onset of the behavioral disorder are provided in school and community settings. Preventive behavioral services offered in clinical settings tend to detect those at high risk or those who are in the early stages of illness, and they tend to reduce health care costs of other illnesses.
- As with other preventive services and quality assurance programming, more than claims data are needed to identify those in need of services. Most often, patient interview is required for case finding, and record review and special

physician and patient surveys are needed for program planning and evaluation.

Steps To Be Taken at the Level of the Health Care Delivery System

- Policies, procedures, and quality assurance guidelines can be in place for all clinical preventive behavioral services that are to be implemented within the health care delivery system.
- When dealing with multiple screening procedures for a single age/life-cycle group, it may be helpful to have a single policy statement/document dealing with the entire set of screening procedures for that group.
- These policies and procedures can be summarized in posters and other reminders to cue the clinical staff.
- Physicians, nurses, and other staff as appropriate can be trained in screening, follow-up, and other policies and procedures.
- Printed informational materials specific to preventive services can be distributed to all primary care providers.
- The health care system may wish to have the capability to provide—directly or indirectly—all needed follow-up services.
- Quality assurance programming can be in place to track the provision of each screening, preventive, and follow-up intervention, and the impacts and outcomes of each service on behaviors, clinical outcomes, and use of other health care resources.
- Each preventive service for each age/life-cycle group may be tracked separately. Although the data to be tracked are similar for tobacco, alcohol, and illicit drugs, separate data can be gathered for each substance. Data pooled across multiple substances are of little practical value. The same is true when dealing with screening and other preventive services, as discussed in this report.

The Role of the Primary Care Practitioner

- The physician or other health care provider can briefly screen each person for all the topics for which screening is indicated on the basis of his or her life-cycle group (age and/or pregnancy).
- The initial set of screening questions for each life-cycle group may be organized so that the screening can be completed in less than 3 minutes.
- Follow-up on positive findings may be considered a diagnostic activity and will take as long as required to rule out the problem, treat the disorder, or identify the need for referral to a mental health professional. Initial follow-up can be done by the primary care practitioner. Patients may be referred to mental health practitioners with initial confirmation of the need to do so by the primary care practitioner.
- Primary care practitioners can follow up at subsequent outpatient visits to monitor behavioral change and assure that mental health professionals have provided appropriate services.
- Provisions might be made for the clinician to record the screening, the findings, and the various levels and types of follow-up.
  - In health care systems with electronic medical records, specific fields can be provided.
  - In health care systems without electronic medical records—
    - Dummy billing codes can be developed (to record the provision of the service on the billing form, even though it is not separately reimbursed).

- Specific space can be provided on the medical record to facilitate medical record review.

Assessment of Need for Programming

- Assessment of need may not be required to initiate the preventive behavioral services suggested for universal implementation. The needed data can be secured in the process of identifying the number and percentage of patients who screen positive and require some form of follow-up service.
- Special assessment of needs can be done by contacting the local or State health department and requesting data available on prevalence of substance use disorder within the community(ies) being served by the health care delivery system. All States and some localities will have such data, and some may have data specific to substance use disorder in pregnancy through the Behavioral Risk Factor Surveillance Survey (BRFSS) and locally conducted surveys.
- Claims data can be reviewed for data relating to the prevalence of substance use disorders, depression, and behavioral disorders.
- Claims and medical records data can be reviewed for patients with diabetes, asthma, and other chronic diseases to determine whether it is appropriate to invest in preventive behavioral programming to improve patient compliance with prescribed regimens of care.

Assessment of Program Efficacy

- Number and percentage of patients screened.
- Percentage of those screened with positive findings.
- Percentage of patients counseled.
- Percentage offered post–initial-screening special education, extended counseling, or other follow-up services.
- Documentation of use on each subsequent visit to document changes in behavior, outcomes, quit rates, and relapse rates (medical record reviews).
- Comparison of overall health care utilization, including those who screened positive and participated in follow-up, those who screened positive and did not follow up, and those who screened negative.
- Comparison of utilization data for before-and-after implementation of the new preventive behavioral programming. Medical records can be reviewed and small surveys of both patients and providers can be conducted to assess the preprogram screening for substance use disorder, depression, and behavioral disorders.
- Provider and patient surveys to address behaviors, perceptions, and satisfaction with services.

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