1997 Annual Meeting of the American Medical Association

Reports of the Council on Scientific Affairs

EDITOR'S NOTE: *The Recommendations in these report summaries reflect AMA policy at the time the reports were adopted by the AMA House of Delegates. Consult the AMA PolicyFinder for the most recent AMA policy and directives.*

1997 AMA Annual Meeting

Summaries and Recommendations of Council on Scientific Affairs Reports

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Guide to Clinical Preventive Services (CSA Rep. 1, A-97)

SUMMARY

A resolution, introduced by the American College of Preventive Medicine at the 1996 American Medical Association (AMA) Annual Meeting, asked the AMA to recommend to physicians the use of the United States Preventive Services Task Force's Guide to Clinical Preventive Services, Second Edition. In response to that resolution, the Council on Scientific Affairs has reviewed and evaluated this publication in this report.

RECOMMENDATIONS

The following statements, recommended by the Council on Scientific Affairs, were adopted by the AMA House of Delegates as AMA policy at the 1997 AMA Annual Meeting. The AMA:

1. Recommends the US Preventive Services Task Force (USPSTF) Guide to Clinical Preventive Services, Second Edition, to clinicians and medical educators as one resource for guiding the delivery of clinical preventive services. The Guide should not be construed as AMA policy on screening procedures and should not take the place of clinical judgment and the need for individualizing care with patients; physicians should weigh the utility of individual recommendations within the context of their scope of practice and the situation presented by each clinical encounter;
2. Will continue to encourage the adoption of practice guidelines as they are developed based on the best scientific evidence and methodology available; and
3. Will continue to promote discussion, collaboration, and consensus among expert groups and medical specialty societies involved in preparation of practice guidelines.

NOTE: The full text of this report has been published: Houston TP, Elster AB, Davis RM, Deitchman SD, for the Council on Scientific Affairs: The US Preventive Task Force Guide to Clinical Preventive Services, Second Edition. *American Journal of Preventive Medicine.* 1998;14:364-376.

Immunization of Health Care Workers With Varicella Vaccine (CSA Rep. 2, A-97)

SUMMARY

Varicella-zoster virus (VZV) is the etiologic agent of two common diseases: varicella (chickenpox) and herpes zoster (shingles). Groups such as infants under 1 year of age, the immunocompromised, and adults are at increased risk of developing complications from VZV infection. The transmission of VZV within health care facilities from contact with infected patients, staff, and visitors is a potentially serious problem. Nosocomial outbreaks of varicella can result in significant morbidity and mortality in high-risk patients, particularly in pediatric wards. VZV transmission to susceptible individuals is difficult to prevent because exposures may occur before appropriate infection control procedures can be implemented.

In 1995, a varicella vaccine was approved for use in the United States. The vaccine has been shown to be fairly effective in preventing varicella in adults and very effective in preventing severe disease. While current data indicate that the vaccine is safe and poses minimal risks, more research is needed to address concerns about the long-term safety, efficacy, and epidemiological impact of more widespread use of the vaccine.

It is important for health care workers, especially those working with high-risk groups, to know their VZV immune status. Unless contraindicated, health care workers who have no history of VZV infection and are serologically negative should be considered a priority for immunization with the varicella vaccine. Administration of the vaccine to health care workers could reduce nosocomial transmission of VZV. Furthermore, significant cost and labor savings could be realized by avoiding expensive and potentially disruptive infection control measures.

RECOMMENDATIONS

The following statements, recommended by the Council on Scientific Affairs, were adopted by the AMA House of Delegates as AMA policy at the 1997 AMA Annual Meeting. The AMA:

1. Advocates that, unless contraindicated, all susceptible health care workers, including students working in health care facilities, should receive the varicella vaccine. Whereas individuals with a definite history of VZV infection can be considered immune, those with a negative or uncertain history should undergo serologic testing and, if seronegative, should be immunized.
2. Urges health care facilities to incorporate guidelines for use of the varicella vaccine into infection control programs to prevent nosocomial transmission of VZV. Such guidelines should address the management of vaccinated individuals who are exposed to VZV as well as those who develop a varicella-like rash or breakthrough varicella subsequent to vaccination.
3. Encourages appropriate federal agencies to support research to determine the long-term safety and efficacy of the varicella vaccine and closely monitor the impact of widespread use of the vaccine on the epidemiology of varicella and herpes zoster.

NOTE: The full text of this report has been published: Lyznicki JM, Bezman RJ, Genel M, for the Council on Scientific Affairs. Immunization of healthcare workers with varicella vaccine. *Infection Control and Hospital Epidemiology*. 1998;19:348-353.

Unlabeled Indications of FDA-approved Drugs (CSA Rep. 3, A-97)

SUMMARY

This Council on Scientific Affairs (CSA) report responds to referred Resolution 508 (A-96) by reviewing the subject of unlabeled (also called off-label) indications (uses) of Food and Drug Administration (FDA)-approved drugs. Unlabeled uses are defined as the use of a drug product for indications or in patient populations, doses, or routes of administration that are not included in FDA-approved labeling.

The prevalence and clinical importance of prescribing drugs for unlabeled uses are substantial. Unlabeled indications are especially common in oncology, rare diseases, and pediatrics. Thus, the prescribing of drugs for unlabeled uses is often necessary for optimal patient care. The Council recommends that AMA Policy 120.988, which addresses this issue, be reaffirmed.

A practical problem associated with the prescribing of unlabeled uses is that third-party payors frequently deny reimbursement for drug products prescribed for unlabeled uses. The Council recommends that AMA policies 120.988 and 165.896 (#15), which support reimbursement for drugs prescribed appropriately for unlabeled uses, be reaffirmed.

It is imperative that physicians have access to accurate and unbiased information about unlabeled uses of prescription drugs. Currently, physicians obtain this information through a variety of sources, including drug compendia, journal articles, continuing medical education symposia, and professional meetings. However, unless solicited by the physician, pharmaceutical manufacturers currently are prohibited from disseminating information about unlabeled uses to physicians. Dissemination of independently derived scientific information about unlabeled uses by manufacturers to physicians can help physicians have access to the latest, scientifically credible information. However, the independent information should be provided in its entirety, not be edited or altered by the manufacturer, and be clearly distinguished from manufacturer-sponsored materials. Manufacturer-sponsored promotion should remain under FDA regulation. In the recommendations, the Council defines conditions under which manufacturer dissemination of information can be supported. The Council also recommends that manufacturers report to the FDA and share with all physicians any proprietary information that a drug is ineffective or unsafe when used for a specific unlabeled indication.

Physicians should strongly support the addition to FDA-approved labeling those uses of drugs for which safety and efficacy have been demonstrated. Potential problems associated with prescribing the drug correctly, reimbursement, and malpractice liability are likely to be lessened if the use is included in the FDA-approved labeling. Thus, the Council encourages the U.S. Congress, the FDA, pharmaceutical manufacturers, the United States Pharmacopeia, patient organizations, and medical specialty societies to work together to ensure that Supplemental New Drug Applications (SNDAs) for new indications (efficacy supplements), including those for special populations (eg, pediatrics), are submitted and acted upon in a timely manner. Futhermore, the Council makes a number of specific recommendations to improve the SNDA process.

The Council also recommends that pediatric research on investigational drugs be encouraged and suggests ways to facilitate this research.

RECOMMENDATIONS

The following statements, recommended by the Council on Scientific Affairs, were adopted by the AMA House of Delegates as AMA policy at the 1997 AMA Annual Meeting.

Prescribing and Reimbursement for FDA-Approved Drugs for Unlabeled Uses

1. The AMA reaffirms the following policies:
    a. That a physician may lawfully use an FDA-approved drug product for an unlabeled indication when such use is based upon sound scientific evidence and sound medical opinion (Policy 120.988);
    b. That when the prescription of a drug represents safe and effective therapy, third-party payors should consider that drug as reasonable and necessary medical care, irrespective of labeling, and should fulfill their obligation to their beneficiaries by covering such therapy (Policy 120.988); and
    c. That the AMA encourages the use of three compendia (AMA's Drug Evaluations*; United States Pharmacopeia-Drug Information, Volume I*; and American Hospital Formulary Service-Drug Information) and the peer-reviewed literature for determining the medical acceptability of unlabeled uses (Policy 165.896, #15). (*These two compendia currently are being merged as the result of an alliance between the American Medical Association and the United States Pharmacopeia.)

Dissemination of Information about Unlabeled Uses of Drugs by Manufacturers

2. The AMA strongly supports the important need for physicians to have access to accurate and unbiased information about unlabeled uses of drugs, while ensuring that manufacturer-sponsored promotions remain under FDA regulation.
3. The AMA supports the dissemination of independently derived scientific information about unlabeled uses by manufacturers to physicians, if the independent information is provided in its entirety, is not edited or altered by the manufacturer, and is clearly distinguished from manufacturer-sponsored materials. Dissemination of information by manufacturers to physicians about unlabeled uses can be supported under the following conditions:
    a. Reprints of independently derived articles from reputable, peer-reviewed journals that meet the following criteria:
        1. The article should be peer reviewed and published in accordance with the regular peer review procedure of the journal in which it is published.
        2. The reprint should be from a peer-reviewed journal that both has an editorial board and utilizes experts to review and objectively select, reject, or provide comments about proposed articles; such experts should have demonstrated expertise in the subject of the article under review, and be independent from the journal.
        3. The journal is recognized to be of national scope and reputation, as defined by an advisory panel to the FDA; among its members, this advisory panel should have representatives from national medical societies.
        4. The journal must be indexed in the Index Medicus of the National Library of Medicine.
        5. The journal must have and adhere to a publicly stated policy of full disclosure of any conflicts of interest or biases for all authors or contributors.
        6. When the subject of the article is an unlabeled use, or the article contains other information that is different from approved labeling, the industry sponsor disseminating the reprint must disclose that the reprint includes information that has not been approved by the FDA and attach a copy of the FDA-approved professional labeling with the reprint.
        7. If financial support for the study and/or the author(s) was provided by the industry sponsor disseminating the article, and this is not already stated in the article, then this information should be clearly disclosed with the reprint.
    b. Reprints of monographs or chapters from the three compendia (AMA's Drug Evaluations; United States Pharmacopeia-Drug Information, Volume I; and

American Hospital Formulary Service-Drug Information) named in federal statutes for determining the medical acceptability of unlabeled uses, provided:

1. The monograph or chapter is reprinted in its entirety by the publisher of the compendia, and the reprints are then sent to the requesting industry sponsor.
2. The reprints are not altered in any way by the industry sponsor.
3. The industry sponsor disseminating the reprint discloses that the reprint includes information that has not been approved by the FDA and attaches a copy of the FDA-approved professional labeling with the reprint.

c. Complete textbooks that meet the following criteria:
   1. The reference text should not have been written, edited, excerpted, or published specifically for, or at the request of, a drug, device, or biologic firm; when financial support is provided by a drug, device, or biologic firm, it should be disclosed clearly in the textbook.
   2. The content of the reference text should not have been edited or significantly influenced by a drug, device, or biologic firm, or agent thereof.
   3. The reference text should be generally available for sale in bookstores or other distribution channels where similar books are normally available and should not be distributed only or primarily through drug, device, or biologic firms.
   4. The reference text should not focus primarily on any particular drug(s), device(s), or biologic(s) of the disseminating company, nor should it have a significant focus on unapproved uses of drug(s), device(s), or biologic(s) marketed or under investigation by the firm supporting the dissemination of the text.
   5. Specific product information (other than the approved package insert) should not be physically appended to the reference text.

d. Manufacturers should report to the FDA and share with all physicians any proprietary information that a drug is ineffective or unsafe when used for a specific unlabeled indication.

e. Continuing medical education (CME) activities:
   1. The FDA should continue to support principles in the FDA Draft Policy Statement on Industry-Supported Scientific and Educational Activities (Fed. Reg. 1992;57:56412-56414), which acknowledges the importance of relying on the professional health-care communities, rather than the Agency, to monitor independent provider activities.
   2. The FDA should continue a policy of regulatory deference for industry-supported CME activities conducted by organizations accredited by the Accreditation Council for Continuing Medical Education (ACCME), state medical societies, specialty societies, and the American Academy of Family Physicians (AAFP), that follow the Essentials and Standards of the ACCME and that may be certified for AMA PRA credit under the auspices of the American Medical Association Physician's Recognition Award program.

4. Physicians have the responsibility to interpret and put into context information received from any source, including pharmaceutical manufacturers, before making clinical decisions (eg, prescribing a drug for an unlabeled use).

Improving the Supplemental New Drug Application (SNDA) Process

5. The AMA strongly supports the addition to FDA-approved labeling those uses of drugs for which safety and efficacy have been demonstrated.
6. The AMA encourages the US Congress, the FDA, pharmaceutical manufacturers, the United States Pharmacopeia, patient organizations, and medical specialty societies to

work together to ensure that Supplemental New Drug Applications (SNDAs) for new indications (efficacy supplements), including those for uses in special populations (eg, pediatrics), are submitted and acted upon in a timely manner. Specific recommendations include:

a. User fee legislation should be reauthorized to ensure that the FDA has the necessary resources to act on all efficacy supplements within 6 months of submission;
b. The SNDA process should be streamlined as much as possible (eg, basing review decisions on already published literature), without compromising the requirements for substantial evidence of efficacy and safety;
c. Legislation should be enacted that provides extensions of marketing exclusivity for the product to manufacturers who submit and gain FDA approval of efficacy supplements, including mechanisms both to provide greater reward when the new indication is for a life-threatening disease (with limited or no alternatives), an orphan disease, or for a special population (eg., pediatrics), and to prevent inappropriate use of the system by manufacturers (eg, place a limit on total length of extended marketing exclusivity);
d. For drugs no longer under patent and for which generic versions are available, the FDA, other governmental agencies (eg, the National Institutes of Health), the pharmaceutical industry, the United States Pharmacopeia, patient organizations, and medical specialty societies should discuss and mutually agree on alternative mechanisms to ensure that efficacy supplements will be submitted to and acted upon by the FDA in a timely manner; and
e. Pharmaceutical manufacturers are urged to seek FDA approval for pediatric uses through the FDA's 1994 regulation that allows approval of pediatric uses based on adult efficacy studies (where the course of the disease and the effects of the drug are sufficiently similar in both populations) and additional information for pediatric use, usually pharmacokinetic studies for determination of dosage (Fed. Reg. 1994:59:64240-64250).

Encouraging Clinical Research in Pediatrics

7. The AMA urges pharmaceutical manufacturers and the FDA to work with the American Academy of Pediatrics and experts in pediatric medicine to identify those investigational drugs that would have pediatric indications and set up a mechanism to ensure that necessary pediatric clinical studies are completed prior to submission of NDAs for approval of these drug products. Legislation should be enacted that provides extensions of marketing exclusivity for the product to manufacturers who complete pediatric studies that lead to pediatric labeling.

NOTE: The full text of this report has been published: Cranston JW, Williams MA, Nielsen NH, Bezman RJ, for the Council on Scientific Affairs. Unlabeled indications of Food and Drug Administration-approved drugs. *Drug Information Journal*. 1998;32:1049-1061.

Use of Restraints for Patients in Nursing Homes (CSA Rep. 4, A-97)

SUMMARY

Studies reveal that restraint use for patients in nursing homes imposes more risk of falls and other undesirable outcomes than it prevents and, that in response to legislative initiatives and regulatory activities, and by implementation of alternatives, restraint use has decreased by 50% in recent years. In all states, facilities have achieved restraint-free environments or have in place restraint-free policies and goals. The Council on Scientific Affairs (CSA) finds that current federal and state regulations regarding the use of restraints have benefited the vast majority of nursing home patients.

While guidelines are in place for the use of restraints when clinically necessary, the CSA recommends increased research to determine when the use of restraints results in desirable outcomes. Extra-regulatory initiatives such as widespread educational programs are needed for professionals, paraprofessionals, and consumers to improve awareness regarding the risks and benefits of restraints, as well as the rights of residents with respect to restraint use. Because of the constraints and limitations imposed on facilities, as well as the nonspecific guidelines and fear of penalty related to excessive enthusiasm on the part of surveyors, there has been an exaggerated move toward nonuse of restraints even when they are permissible and clinically indicated. Thus there is a need for clearer definitions, particularly regarding "medical necessity," of why and when restraints might be beneficial, as well as on-going education of long-term care personnel in the use and acceptance of restraint alternatives.

RECOMMENDATIONS

The following statements, recommended by the Council on Scientific Affairs, were adopted by the AMA House of Delegates as AMA policy at the 1997 AMA Annual Meeting. The AMA:

1. Recommends further research to support or refute the findings that physical restraints in nursing homes tend to be more harmful than beneficial;
2. Supports the position that there must be compelling reasons to justify the use of restraints and urges the Health Care Financing Administration (HCFA) to expand the Omnibus Budget Reconciliation Act (OBRA) Requirements of Participation for Long-Term Care Nursing Facilities to include specific examples and definitions of what constitutes "medical necessity" for which restraint use is justified.;
3. Encourages widespread dissemination of information and educational initiatives for the public as well as health care professionals on the risks and uncertain benefits of restraints;
4. Encourages physicians to communicate the consequences, risks, and potential benefits of restraint use with family members of residents who ask for restraints;
5. Encourages research to determine precisely when the use of restraints results in improved outcomes; and
6. Encourages the long-term evaluation of effects of restraint regulations on the health and well-being of nursing home residents.

NOTE: The full text of this report has been published: Guttman R, Altman RA, Karlan MS, for the Council on Scientific Affairs. Use of restraints for patients in nursing homes. *Archives of Family Medicine*. 1999;8:101-105. (March/April)

Diagnosis and Treatment of Attention Deficit Hyperactivity Disorder (CSA Rep. 5, A-97)

SUMMARY

This report examines the issue of the increasing number of diagnoses of attention deficit hyperactivity disorder (ADHD) and addresses public concerns regarding possible overprescription of ADHD medications. The report reviews the diagnosis and treatment of ADHD as well as the epidemiologic literature pertaining to ADHD prevalence and prescribing patterns.

ADHD is a commonly seen neuropsychiatric syndrome that has been extensively studied over the past four decades. It is a condition with onset in childhood, most commonly becoming apparent (and thus coming to medical attention) during the first few years of grade school. ADHD may be associated with a number of co-morbid psychiatric conditions as well as with impaired academic performance and with both patient and family emotional distress. The disorder typically persists throughout childhood and into adolescence. While it was previously thought that the disorder remitted before or during adolescence, it has become well-established that many patients will have an illness course that persists well into adulthood. Pharmacologic treatment, particularly with stimulant medication, is the most-studied aspect of management, although other forms of treatment (eg, behavior therapy, parent training) are important parts of good clinical care.

Although the production and use of methylphenidate has been rising sharply in the United States since 1990, this report finds that overall there is no evidence of overprescribing by physicians. The increased use can be understood in terms of the well-validated expansion of the diagnostic criteria (and thus more children being appreciated as affected and treated), increased physician and public awareness of the condition, and appropriate increases in the duration of treatment of affected youth. There is no significant evidence of increased abuse of methylphenidate in the US population, particularly among those with ADHD.

RECOMMENDATIONS

The following statements, recommended by the Council on Scientific Affairs, were adopted by the AMA House of Delegates as AMA policy at the 1997 AMA Annual Meeting. The AMA:

1. Encourages physicians to utilize standardized diagnostic criteria in making the diagnosis of ADHD, such as the American Psychiatric Association's Diagnositic and Statistical Manual of Mental Disorders (DSM)-IV, as part of a comprehensive evaluation of children and adolescents presenting with attentional or hyperactivity complaints;
2. Encourages the creation and dissemination of practice guidelines for ADHD by appropriate specialty societies and their use by practicing physicians and will assist in making physicians aware of their availability;
3. Encourages efforts by medical schools, residency programs, medical societies, and continuing medical education programs to increase physician knowledge about ADHD and its treatment;
4. Encourages the use of individualized therapeutic approaches for children diagnosed with ADHD, which may include pharmacotherapy, psychoeducation, behavioral therapy, school-based and other environmental interventions, and psychotherapy as indicated by clinical circumstances and family preferences; and
5. Encourages physicians and medical groups to work with schools to improve teachers' abilities to recognize ADHD and appropriately recommend that parents seek medical evaluation of potentially affected children.

The AMA also reaffirms Policy 100.975, to work with the FDA and the DEA to help ensure that appropriate amounts of methylphenidate and other Schedule II drugs are available for clinically warranted patient use.

NOTE: The full text of this report has been published: Goldman LS, Genel M, Bezman RJ, for the Council on Scientific Affairs. Diagnosis and treatment of attention-deficit hyperactivity disorder in children and adolescents. *JAMA*. 1998;279:1100-1107. (April 8, 1998)

Calcium Supplementation, Hormone Replacement Therapy, and Osteoporosis (CSA Rep. 6, A-97)

SUMMARY

This report reviews and evaluates the supportive evidence for the utility of calcium supplementation along with standard pharmacologic therapy for the prevention and treatment of osteoporosis.

The data suggest that in growing children, in premenopausal women, and in postmenopausal women, increasing lifelong calcium intake to between 1000 and 1500 mg/day will have positive effects on bone mass and will presumably reduce the risk of fractures. Since fractures of the hip account for the majority of costs associated with osteoporosis, the effects of calcium on bone mass are likely to be both clinically meaningful and economically important.

RECOMMENDATIONS

The following statements, recommended by the Council on Scientific Affairs, were adopted by the AMA House of Delegates as AMA policy at the 1997 AMA Annual Meeting.

1. That Policy 525.997 be amended to read: "Estrogens are effective in the treatment and/or prevention of cardiovascular disorders, vasomotor flushes, atrophic urogenital conditions, and probably osteoporosis."
2. Adequate calcium intake is essential in the prevention of osteoporosis during growth years. Maintenance of adequate calcium intake during the growth years, perimenopausal years, and post-menopausal years is extremely important. The effects of estrogen on bone density can be improved significantly by calcium supplementation, particularly for cortical bone such as in the femoral neck.
3. In the late postmenopausal period, increased calcium intake will improve bone density in those patients with calcium deficiency or poor absorption of calcium. Therefore, it follows that increasing dietary calcium, if necessary by calcium supplementation in proper doses, may be expected to decrease the risk of osteoporosis and fractures in the aging population. Increasing calcium intake also appears to potentiate the positive effects of estrogen on bone mass. Therefore, increased intake, including appropriate supplementation, is also important in patients on such osteoporosis therapies.

Silicone Elastomer Cerebrospinal Fluid Shunt Systems (CSA Rep. 7, A-97)

SUMMARY

This report describes the different types of medical grade silicone used in medical devices, the incidence of hydrocephalus and its causes and treatment, and the use of cerebrospinal fluid (CSF) shunt systems made of silicone elastomer. Published case reports of possible immunologic disease in patients who have had silicone elastomer CSF shunt systems implanted also are reviewed.

The Council on Scientific Affairs has concluded that the evidence presented does not support the occurrence of immune-mediated systemic reactions to implanted silicone elastomer CSF shunt systems. The local granulomatous or inflammatory responses seen in some patients with silicone shunt systems have not been shown to be immunologically mediated; similar reactions have been described with other implanted foreign bodies.

RECOMMENDATIONS

The following statements, recommended by the Council on Scientific Affairs, were adopted by the AMA House of Delegates as AMA policy at the 1997 AMA Annual Meeting.

1. Scientific data currently available do not suggest a specific systemic immune response to the silicone elastomer components of cerebrospinal fluid shunt systems. Further, no suitable replacement materials exist at this time. Consequently, there is no empirical basis on which to call for a restriction of the use of silicone elastomer cerebrospinal fluid shunt systems at this time.
2. The AMA supports continued research and development to identify and evaluate new materials, designs, or procedures that may become the treatment of choice for subsets of patients who now receive silicone elastomer cerebrospinal fluid shunts.
3. The AMA supports the continued efforts of the Food and Drug Administration to monitor adverse reactions to devices such as cerebrospinal fluid shunt systems, so that appropriate research can be conducted where necessary.

NOTE: The full text of this report has been published:. Kalousdian S, Karlan MS, Williams MA, for the Council on Scientific Affairs. Silicone elastomer cerebrospinal fluid shunt systems. *Neurosurgery*. 1998;42.887-892. (April 1998)

Reduction of the Medical and Public Health Consequences of Drug Abuse (CSA Rep. 8, A-97)

SUMMARY

This report reviews the scientific literature on the approach to drug addiction known as harm reduction. For the purposes of this report, harm reduction is defined as those practices that are employed to reduce the medical and/or public health consequences associated with drug abuse.

The report addresses present American Medical Association (AMA) policy on the subject, the usual goals of harm reduction strategies, and the criticisms of harm reduction. The Council on Scientific Affairs concludes that harm reduction may involve various strategies directed toward diminishing the risks of psychoactive drug use.

This report encourages the undertaking of comprehensive research into the potential effects, both positive and adverse, of relaxing existing drug prohibitions and controls. However, until the findings of such research can be adequately assessed, the Council on Scientific Affairs recommends that the AMA reaffirm its opposition to drug legalization

RECOMMENDATIONS

The following statements, recommended by the Council on Scientific Affairs, were adopted by the AMA House of Delegates as AMA policy at the 1997 AMA Annual Meeting.

1. The AMA encourages national policy-makers to pursue an approach to the problem of drug abuse aimed at preventing the initiation of drug use, aiding those who wish to cease drug use, and diminishing the adverse consequences of drug use.
2. The AMA encourages policymakers to recognize the importance of screening for alcohol and other drug use in a variety of settings, and to broaden their concept of addiction treatment to embrace a continuum of modalities and goals, including appropriate measures of harm reduction, which can be made available and accessible to enhance positive treatment outcomes for patients and society.
3. The AMA encourages the expansion of opioid maintenance programs so that opioid maintenance therapy can be available for any individual who applies and for whom the treatment is suitable. Training must be available so that an adequate number of physicians are prepared to provide treatment. Program regulations should be strengthened so that treatment is driven by patient needs, medical judgment, and drug rehabilitation concerns. Treatment goals should acknowledge the benefits of abstinence from drug use, or degrees of relative drug use reduction.
4. The AMA encourages the extensive application of needle and syringe exchange and distribution programs and the modification of restrictive laws and regulations concerning the sale and possession of needles and syringes to maximize the availability of sterile syringes and needles, while ensuring continued reimbursement for medically necessary needles and syringes. The need for such programs and modification of laws and regulations is urgent, considering the contribution of injecting drug use to the epidemic of HIV infection.
5. The AMA encourages the undertaking of comprehensive research into the potential effects, both positive and adverse, of relaxing existing drug prohibitions and controls and, until the findings of such research can be adequately assessed, the AMA reaffirms its opposition to drug legalization.

Advisability of Screening Younger Women for Breast Cancer: Reasons for Continuing Controversy (CSA Rep. 9, A-97)

SUMMARY

Breast cancer is the most frequently diagnosed cancer in women, representing 31% of new cancer cases, and the second most common cause of cancer death in women. Despite major advances in early detection and therapy over the past 60 years, these death rates have been remarkably resistant to change.

Many have argued that breast cancer screening efforts should include younger women, particularly those 40 to 49 years of age. The evidence supporting the effectiveness of screening in this age group, however, has not been as convincing as it is in older women, 50 to 74 years of age. This has led to both widespread uncertainty about such efforts and confusion in the minds of younger women and their physicians about whether or not to participate in screening.

This informational report reviews the reasons for the ongoing controversy about efforts to screen women 40 to 49 years of age for breast cancer, including limitations of the existing randomized controlled trials, possible reasons for lower effectiveness of screening in younger women, and issues in using available data for policy-making.

A younger woman considering mammographic screening should understand: (1) her probability of breast cancer; (2) the potential for a false-positive mammogram requiring further workup; (3) the potential for a false-negative mammogram (and the need not to delay further care if a lump is felt); (4) the potential for overtreatment for ductal carcinoma in situ (DCIS); and (5) the probability of extending her life through mammography. If a woman aged 40 to 49 who is informed of the potential benefits and limitations chooses to undergo mammographic screening, the logic behind screening annually rather than every 2 years should be considered as well.

RECOMMENDATIONS

Because this is an informational report, there are no Recommendations.

Heat-related Illness in Extreme Weather Emergencies (CSA Rep. 10, A-97)

SUMMARY

This report discusses the physiological basis of heat-related illnesses during extreme weather emergencies; describes the continuum of heat-related illnesses from minor (eg, heat cramp) to severe (eg, heat stroke) syndromes; reviews risk factors; and outlines community prevention strategies.

The report also addresses the role of physicians in preventing and treating heat-related illnesses, noting that physicians are an essential component of a multi-pronged effort to identify and educate individuals at risk of heat-related illness. Patients who are at increased risk by virtue of their medical conditions or psychosocial circumstances can be identified by their physicians. Physicians can educate and counsel patients about their risk, including prevention strategies, early signs and symptoms, and strategies for seeking help when they are in trouble. Physicians can also counsel parents of young children and caretakers of the elderly or disabled about how to ensure the safety of their charges. Patients living alone can, with their physician's assistance, identify a support person or agency who will be responsible for assisting the patient when help is needed. Where appropriate, physicians can register at-risk patients with local health departments, to ensure that they are checked during heat crises.

RECOMMENDATIONS

The following statements, recommended by the Council on Scientific Affairs, were adopted by the AMA House of Delegates as AMA policy at the 1997 AMA Annual Meeting.

The AMA recognizes the significant public health threat imposed by heat-related emergencies, and provides the following policy:

1. Physicians should identify patients at risk for extreme heat-related illness such as the elderly, children, individuals with physical or mental disabilities, alcoholics, the chronically ill, and the socially isolated. Patients, family members, friends, and caretakers should be counseled about prevention strategies to avoid such illness. Physicians should provide patients at risk with information about cooling centers and encourage their use during heat emergencies.
2. The AMA encourages patients at risk for heat-related illness to consider wearing appropriate medical identification.

NOTE: An abbreviated version of this report has been published: Blum LN, Bresolin LB, Williams MA, for the Council on Scientific Affairs: Heat-related illness during extreme weather emergencies. *JAMA*. 1998;279:1514. (May 20)

“Crossover” Use of Donated Blood (CSA Rep. 11, A-97)

This report addresses the concern that much of the blood collected for autologous transfusion is discarded since it is not required for the patients who donated it. Given the frequent shortage of blood for allogeneic transfusion, it is reasonable to examine the potential costs, benefits, and risks of allowing autologous blood that meets established criteria to be relabeled for allogeneic use, a practice called "crossover."

The scientific literature on "crossover" of unused autologous blood for homologous transfusions demonstrates that the benefits associated with this process do not outweigh the costs and risks. Several cost-effectiveness analyses of autologous donation and transfusion conclude that this is an expensive procedure with little increased benefits from a societal perspective, particularly with the advances made during recent years to improve the safety of the allogeneic blood supply.

RECOMMENDATIONS

The following statements, recommended by the Council on Scientific Affairs, were adopted by the AMA House of Delegates as AMA policy at the 1997 AMA Annual Meeting.

1. The AMA does not encourage blood collection programs to "crossover" blood units donated for autologous use to the allogeneic blood supply.
2. Policy 50.990 (AMA Policy Compendium) is amended to read: "That in response to a continuing need for blood for transfusion and decreasing supplies of allogeneic blood, our AMA supports programs that encourage donation of blood to the allogeneic supply by healthy volunteer donors and encourages physicians to participate in promotional efforts to encourage blood donation."

Further,

The AMA will collaborate with the American Association of Blood Banks and other blood collection organizations, medical specialty societies, and other appropriate health care groups to establish and implement practice guidelines that promote optimal use of autologous blood and minimize the collection of autologous units for procedures in which transfusion will not likely be required.

NOTE: The full text of this report has been published: Blum LN, Allen JR, Genel M, Howe JP III, for the Council on Scientific Affairs. Crossover use of donated blood for autologous transfusion: report of the Council on Scientific Affairs. *Transfusion*. 1998;38:891-895. (September)

Alternative Medicine (CSA Rep. 12, A-97)

SUMMARY

The terms "alternative medicine," "complementary medicine," or "unconventional medicine" refer to diagnostic methods, treatments, and therapies that appear not to conform to standard medical practice, or are not generally taught at accredited medical schools. The scope of alternative medicine is broad, with widespread use among the American public of a long list of treatments and practices such as acupuncture, homeopathy, relaxation techniques, and herbal remedies.

This report categorizes and clarifies the alternative medical systems most often used, creates a context to assess their utility (or lack thereof) and discusses how physicians and the medical establishment might deal with issues surrounding these unconventional measures in health and healing.

RECOMMENDATIONS

The following statements, recommended by the Council on Scientific Affairs, were adopted by the AMA House of Delegates as AMA policy at the 1997 AMA Annual Meeting.

1. There is little evidence to confirm the safety or efficacy of most alternative therapies. Much of the information currently known about these therapies makes it clear that many have not been shown to be efficacious. Well-designed, stringently controlled research should be done to evaluate the efficacy of alternative therapies.
2. Physicians should routinely inquire about the use of alternative or unconventional therapy by their patients, and educate themselves and their patients about the state of scientific knowledge with regard to alternative therapy that may be used or contemplated.
3. Patients who choose alternative therapies should be educated as to the hazards that might result from postponing or stopping conventional medical treatment.
4. Courses offered by medical schools on alternative medicine should present the scientific view of unconventional theories, treatments, and practice as well as the potential therapeutic utility, safety, and efficacy of these modalities.

Folk Remedies Among Ethnic Subgroups (CSA Rep. 13, A-97)

SUMMARY

This report reviews what is currently known about the use within ethnic subgroups in the United States of alternative therapies that can be classified as folk remedies and identifies the implications of such practices for physicians.

Increased use of alternative therapies by Americans is related in part to use by immigrants of interventions indigenous to their original cultures. Cultural attitudes toward health, illness, and health care influence the ways in which each person seeks and complies with health care. Few folk remedies have been subjected to clinical trials of their efficacy and safety.

There is very limited scientific evidence about the efficacy or safety of folk remedies. Practicing physicians should routinely ask patients about use of folk remedies for symptom management and inform them of the level of scientific information available about the therapy they are using, as well as proven conventional medicine alternatives.

RECOMMENDATIONS

The following statements, recommended by the Council on Scientific Affairs, were adopted by the AMA House of Delegates as AMA policy at the 1997 AMA Annual Meeting. The AMA:

1. Does not recommend the sole use of unvalidated folk remedies to treat disease without scientific evidence regarding their safety or efficacy;
2. Encourages research to determine the safety and efficacy of folk remedies;
3. Urges that physicians be aware that the use of folk remedies may delay patients from seeking medical attention or receiving conventional therapies with proven benefit for disease treatment and prevention;
4. Urges that practicing physicians routinely ask patients whether they are using folk medicine or family remedies for their symptoms. Physicians can educate patients about the level of scientific information available about the therapy they are using, as well as conventional therapies that are known to be safe and efficacious; and
5. Urges that physicians be aware of folk remedies in use and the level of scientific information available about such remedies, and should include this information when discussing conventional treatments and therapies with their patients.

Drivers Impaired By Alcohol (CSA Rep. 14, A-97)

SUMMARY

The AMA was asked to gather injury data from countries that set blood alcohol level limits for drivers at 0.02% or less and to propose national legislation making it per se illegal to drive at any age with a blood alcohol content (BAC) of greater than 0.02%. Current AMA policy supports a BAC of 0.05 g/dL for adults and 0.02% (also known as "zero tolerance") for drivers under the age of 21. All states have set adult driver BAC limits at either 0.10% or 0.08%, with lower limits for commercial drivers. A standard of 0.00% to 0.02% BAC limit for drivers under age 21 is gradually being adopted by most states.

This report found that the research and field literature demonstrate some driving-related impairment for many people at any level of BAC. Substantial and consistent impairment begins at 0.04% to 0.05% BAC. As BAC levels increase, so do individual impairment and the likelihood of impairment across the entire population. The risk of fatal crashes greatly increases at 0.04% to 0.05% BAC, with greatly increased risk at 0.10% BAC. The experience in this nation and others with lower BAC legal limits (0.00% to 0.08%) indicates that crashes, injury, and death are substantially lowered when BAC limits are lowered. The combination of this experience with clinical and experimental research points to the establishment of "zero tolerance" as a goal for adults. However, driving behaviors are complex and require a range of coordinated efforts to successfully reduce the incidence of impaired driving, including but not limited to lower BAC limits. At this time "zero tolerance" polices for adult drivers are not politically feasible and are not supported by the general public's or policy makers' current understanding of the issue.

Thus, the report concludes that the AMA should continue to support lower BAC limits and stronger policy measures to diminish the level of problems related to alcohol-impaired driving, and should educate the public about how alcohol at any level impairs driving.

RECOMMENDATIONS

The following statements, recommended by the Council on Scientific Affairs, were adopted by the AMA House of Delegates as AMA policy at the 1997 AMA Annual Meeting.

1. The AMA acknowledges that all alcohol consumption, even at low levels, has a negative impact on driver skills, perceptions, abilities, and performance and poses significant health and safety risks. The AMA will be involved in efforts to educate physicians, the public, and policy makers about this issue and urges national, state, and local medical associations and societies, together with public health, transportation safety, insurance industry, and alcohol beverage industry professionals to renew and strengthen their commitment to preventing alcohol-impaired driving.
2. The AMA encourages physicians to participate in educating the public about the hazards of chemically impaired driving.
3. The AMA urges public education messages that now use the phrase "drunk driving," or make reference to the amount one might drink without fear of arrest, be replaced with messages that indicate that "all alcohol use, even at low levels, impairs driving performance and poses significant health and safety risks."
4. The AMA urges all states to pass legislation mandating all drivers convicted of first and multiple driving under the influence (DUI) offenses be screened for alcoholism and provided with referral and treatment when indicated.
5. The AMA further recommends the following measures be taken to reduce repeat DUI offenses: (a)aggressive measures be applied to first-time DUI offenders (eg, license suspension and administrative license revocation); (b) stronger penalties be leveled against repeat offenders, including second-time offenders; (c) such legal sanctions must

be linked, for all offenders, to substance abuse assessment and treatment services, to prevent future deaths in alcohol-related crashes and multiple DUI offenses; and (d) the AMA calls upon the states to coordinate law enforcement, court system, and motor vehicle departments to implement forceful and swift penalties for second-time DUI convictions to send the message that those who drink and drive might receive a second chance but not a third.

6. The AMA encourages the National Highway Traffic Safety Administration to investigate the feasibility of technologies that would prevent an automobile from being started or driven by an individual with an excessive blood alcohol level.

HIV Home Blood Collection Kits: Update (CSA Rep. 15, A-97)

SUMMARY

This report addresses issues and responses by researchers and public health officials concerning the use of human immunodeficiency (HIV) home blood collection kits, including preliminary data from manufacturers, evaluation of efficacy, characteristics of HIV test-takers, the use of telephone counseling in HIV testing, and public health responses to the use of HIV test kits.

RECOMMENDATIONS

The following statements, recommended by the Council on Scientific Affairs, were adopted by the AMA House of Delegates as AMA policy at the 1997 AMA Annual Meeting.

The AMA believes that the Food and Drug Administration should not approve HIV home test kits. However, the AMA does not oppose approval of HIV home collection test kits linked with proper laboratory counseling and counseling services, provided their use does not impede public health efforts to control HIV disease.

The AMA encourages:

1. The standardization of data that are collected by HIV home collection test manufacturers and reported to public health agencies;
2. A national study of home collection kit users to evaluate their experiences with telephone counseling; and
3. The development of a national interagency task force, consisting of members from government agencies and the public health community, in order to monitor the marketing and use of HIV home collection kits.