2000 Annual Meeting of the American Medical Association

Reports of the Council on Scientific Affairs

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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.

2000 AMA Annual Meeting

Summaries and Recommendations of Council on Scientific Affairs Reports

Preventing Needlestick Injuries in Health Care Settings (CSA Rep. 1, A-00)

SUMMARY

Objective. To assess the epidemiology, scientific and cost-analysis data, and regulatory and legislative actions pertaining to needlestick prevention devices via a review of the scientific literature and current media reports.

Data Sources. Literature searches were conducted in the MEDLINE database for articles published between 1990 to 1999 using the search terms *safety needles* or *needlestick injuries* qualified with the terms *prevention and control* or *prevention*. Lexis/Nexis news databases were searched for current developments using the search term *safety needles*. Additional information was obtained from the Web sites of the Occupational Safety and Health Administration (OSHA), the National Institute for Occupational Safety and Health, and the International Health Care Worker Safety Center. The World Wide Web was searched for information using the search term *safety needles*.

Data Extraction. English-language articles were selected based on ability to provide information directly related to the efficacy, cost, and legislation and regulation of needlestick prevention devices.

Results. Scientific data now appear to indicate that the appropriate use of needlestick prevention devices, especially in comprehensive prevention programs, significantly reduces the incidence of needlestick injuries. Additionally, cost analyses are beginning to indicate that in the long term, the use of needlestick prevention devices will be cost-effective and most importantly, save health care workers the emotional and physical trauma associated with needlestick injuries. Significant national support exists for the increased use of needlestick prevention devices to ensure the safety of health care workers. As a result, OSHA has revised its compliance directive for its bloodborne pathogens standard to emphasize the evaluation and use of needlestick prevention devices in health care facilities. Additionally, OSHA will be revising its injury and illness recordkeeping requirements to require that all injuries resulting from contaminated needles and sharps be recorded on OSHA logs used by employers to record injuries and illnesses. To provide more scientific and cost data on the efficacy of needlestick prevention devices, needlestick injuries must be recorded at a better rate than they are now; as such, the call for comprehensive logging of such injuries with OSHA appears prudent. Finally, significant state- and federal-level legislation requiring the evaluation and appropriate use of needlestick prevention devices in health care facilities is being considered.

Conclusions. Health care employers should evaluate the implementation of needlestick prevention devices with the participation of employees who will use such devices and, where appropriate, introduce such devices accompanied by the necessary education and training, as part of a comprehensive sharps injury prevention and control program. Additionally, health care

employers should record and evaluate staff feedback on newly implemented needlestick prevention devices to continually enhance their introduction, evaluation, and replacement. All needlestick injuries should be reported to the appropriate authorities to assure future preventive and proper therapeutic intervention is provided and more accurate epidemiological data on the efficacy of needlestick prevention devices is obtained. Finally, research and development should be encouraged to provide new technologies that will facilitate reduction and eventual elimination of needlestick injuries in health care facilities.

RECOMMENDATIONS

The following statements, recommended by the Council on Scientific Affairs, were adopted by the AMA House of Delegates as AMA policy at the 2000 AMA Annual Meeting.

- 1. The AMA reaffirms Policy H-20.925(4) and states that the use of needlestick prevention devices does not obviate the necessity for proper techniques, universal precautions, and other important aspects of a comprehensive needlestick prevention program.
- 2. The AMA strongly urges: (a) Health care employers to evaluate the implementation of needlestick prevention devices, with the participation of physicians and other health care workers who will use such devices and, where appropriate, introduce such devices accompanied by the necessary education and training, as part of a comprehensive sharps injury prevention and control program; (b) health care employers to record and evaluate staff feedback on newly implemented needlestick prevention devices; and (c) health care employers to report difficulties associated with the use of newly implemented needlestick program.
- 3. The AMA encourages the reporting of all needlestick injuries to the appropriate authorities in order that the proper therapeutic intervention may be provided and that more accurate epidemiological data on the efficacy of needlestick prevention devices may be obtained.
- 4. The AMA encourages continued research and development of new technologies that will facilitate reduction and eventual elimination of needlestick injuries in health care facilities.
- 5. The AMA will work with state and medical specialty societies to: (a) Disseminate the information in the new Occupational Safety and Health Administration (OSHA) bloodborne pathogens standard compliance directive to physicians; and (b) Assist physicians in implementing the requirements of the OSHA bloodborne pathogens standard that are appropriate for their medical practices.

NOTE: The full text of this report has been published: Tan L, Hawk JC III, Sterling ML, for the Council on Scientific Affairs. Preventing needlestick injuries in health care settings. *Arch Intern Med.* 2001;161:929-936. (April 9)

Use of Antimicrobials in Consumer Products (CSA Rep. 2, A-00)

SUMMARY

Objective. To summarize the available data on the effectiveness of antimicrobial ingredients in consumer products such as hand lotions and soaps, and discuss the implications of such use on antimicrobial resistance.

Data Sources. Literature searches were conducted in the MEDLINE database for articles published between 1966 to 1999 using the search term *resistance* qualified with the terms *consumer product(s)*, or *soap*, or *lotion*, or *triclosan*. Lexis/Nexis news databases were searched for current developments using the search strategy *antimicrobial resistance* AND *consumer product*. The World Wide Web was searched for information using the search strategy *antimicrobial resistance* AND *consumer product*.

Data Extraction. English-language articles were selected based on ability to provide information relevant to use of antimicrobial ingredients in consumer products and the impact of such use on antimicrobial resistance.

Results. Despite their recent proliferation in consumer products, the use of antimicrobial agents such as triclosan in consumer products has not been studied extensively. No data exist to support their efficacy when used in such products or any need for them, but increasing data now suggest growing acquired resistance to these commonly used antimicrobial agents. Studies also suggest that acquired resistance to these antimicrobials in bacteria may also predispose these organisms to resistance against therapeutic antibiotics, but further research is needed. In light of these findings, there is little evidence to support the use of antimicrobials in consumer products such as topical hand lotions and soaps. However, there is also little evidence to link the use of these antibiotics. Considering the available data and the critical nature of the antibiotic resistance problem, it may be prudent to avoid the use of antimicrobial agents in consumer products. Ultimately, antibiotic resistance is a major public health concern that has to be controlled through judicious use of antibiotics by health care practitioners.

Conclusions. The use of common antimicrobials for which acquired resistance has been demonstrated in bacteria as ingredients in consumer products should be discontinued, unless data emerge to conclusively show that such resistance has no impact on public health and that such products are effective at preventing infection. Scientific research on the issue of antimicrobial resistance must continue to elucidate gaps in knowledge, particularly with respect to the use of common antimicrobials as ingredients in consumer products and its impact on the major public health problem of antibiotic resistance.

RECOMMENDATIONS

The following statements, recommended by the Council on Scientific Affairs, were adopted by the AMA House of Delegates as AMA policy at the 2000 AMA Annual Meeting:

- 1. The AMA encourages the Food and Drug Administration (FDA) to expedite its regulation of the use in consumer products of antimicrobials for which acquired resistance has been demonstrated.
- The AMA will monitor the progress of the current FDA evaluation of the safety and effectiveness of antimicrobials for consumer use in over-the-counter (OTC) hand and body washes.

3. The AMA encourages continued research on the use of common antimicrobials as ingredients in consumer products and its impact on the major public health problem of antimicrobial resistance.

NOTE: The full text of this report has been published: Tan L, Nielsen NH, Young DC, Trizna Z, for the Council on Scientific Affairs. Use of antimicrobial agents in consumer products. *Arch Dermatol*. 2002;138:1082-1086.

Combating Antibiotic Resistance Via Physician Action and Education: AMA Activities (CSA Rep 3, A-00)

SUMMARY

Objective. To describe the problem of antibiotic resistance and report previous and current American Medical Association (AMA) activities on this issue.

Data Sources. Literature searches were conducted in the MEDLINE database for articles published between 1990 to 1999 using the search term *antibiotic resistance* qualified with the terms *prevention strategies*, or *prevention policies*, or *control strategies*, or *control policies*.

Data Extraction. English-language articles were selected based on ability to provide information on relevant strategies to prevent and control antibiotic resistance in the United States and globally.

Results. Antibiotic resistance continues to be a major public health concern. Resistance in bacteria is due to complicated interactions that involve not only the microbe but also the environment, the patient, and the physician. New data concerning the impact of transposons and integrons on antibiotic resistance support the need for new prevention and control strategies that rely on a multidisciplinary education base with a cooperative approach to management of antibiotic resistance. Previous AMA actions to combat antibiotic resistance include the publication of AMA recommendations as part of the World Medical Association's statement on antibiotic resistance, the publication of a *JAMA* Patient Page on antibiotic resistance, and a Science Reporters Conference highlighting antibiotic resistance as a media issue. Current AMA activities include collaborations with federal agencies on important issues of antibiotic resistance, such as the use of antibiotics in animal feed; with medical specialty societies; and with the National Health Council.

Conclusions. Ultimately, antibiotic resistance must be controlled through judicious use of antibiotics by health care practitioners. The AMA should continue to encourage the federal government, the World Health Organization, the World Medical Association, and the International Federation of Pharmacists to promote more effective education on the appropriate use of antibiotics. Physicians should continue to educate their patients about their antimicrobial therapy, the importance of compliance with the prescribed regimen, and the problem of antimicrobial resistance. The AMA should also continue to educate physicians and physicians-in-training about the appropriate prescribing of antimicrobial agents while encouraging the implementation of antibiotic resistance management programs. These education-based programs should be multidisciplinary and cooperative (ie, including infectious disease physicians, infection-control specialists, microbiology laboratory personnel, and clinical pharmacists).

RECOMMENDATIONS

The following statements, recommended by the Council on Scientific Affairs, were adopted by the AMA House of Delegates as AMA policy at the 2000 AMA Annual Meeting:

1. The AMA amends Policy H-100.973 to read as follows:

The AMA: (a) Encourages the federal government, the World Health Organization, the World Medical Association, and the International Federation of Pharmacists to promote more effective education concerning the appropriate use of antibiotics, (b) strongly urges physicians to educate their patients about their antimicrobial therapy, the importance of compliance with the prescribed regimen, and the problem of antimicrobial resistance; (c) will continue to educate physicians and physicians-in-training about the appropriate prescribing of antimicrobial agents; (d) encourages the use of antibiotic resistance management programs; these education-based programs should be multidisciplinary and

cooperative (ie, including infectious disease physicians, infection-control specialists, microbiology laboratory personnel, and clinical pharmacists); and (e) encourages continued scientific research on the issue of antibiotic resistance.

- 2. The title of Policy H-100.973 is changed to read as follows: Combating Antimicrobial Resistance through Education
- 3. The AMA will continue to collaborate with the appropriate federal agencies, other medical specialty societies, and other appropriate public health organizations to address the urgent problem of increasing antimicrobial resistance and its impact on public health.

Use of Wireless Radiofrequency Devices in Hospitals (CSA Rep. 4, A-00)

SUMMARY

Objective. To review the risks of electromagnetic interference (EMI) from wireless radiofrequency (RF) transmitting devices in hospitals and identify national organizations that have developed information and guidance to assist hospital personnel in assessing these risks and making informed risk management decisions.

Data Sources. MEDLINE was searched for English-language articles published from 1980 to 2000. Additional information was derived from review of references cited in relevant journal articles and reports, and from communication with experts in biomedical engineering and physics.

Data Synthesis. The wide variety of RF sources, medical devices, and hospital use environments makes it difficult to reliably predict EMI patterns and characteristics. It is difficult to identify which devices may interact adversely and what specific power levels are necessary to cause interference. While experimental studies indicate that the potential risk of EMI in hospitals is great, clinical reports (albeit anecdotal) suggest that serious EMI-related malfunctions are rare in hospital settings. Reasonable steps for managing EMI include: increasing the distance between RF sources and susceptible devices; lowering the power of RF sources when possible; educating patients, staff, and visitors about EMI risks; purchasing medical devices that have been designed and tested for electromagnetic compatibility; and reporting actual or suspected EMI problems to appropriate personnel.

Conclusions. Wireless RF transmitting devices such as cellular telephones and two-way radios can interfere with medical devices and present a real risk when used in close proximity to sensitive equipment. The diversity of RF sources operating over a broad spectrum of frequencies (both in and around hospital settings) makes it is difficult to predict EMI risks, particularly in critical care units where patients are connected to a range of sophisticated electronic medical equipment. Various organizations have developed information and guidance to assist hospital personnel in assessing and managing EMI risks in their facilities. International standards can guide US manufacturers in the design and testing of medical equipment and devices for EMI immunity. Comprehensive and collaborative approaches are needed to address EMI in hospitals including education, risk assessment and management, guideline and policy development, regulation, and 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 2000 AMA Annual Meeting:

- 1. The AMA encourages collaborative efforts of the Food and Drug Administration, American Hospital Association, American Society for Healthcare Engineering, Association for the Advancement of Medical Instrumentation, Emergency Care Research Institute, and other appropriate organizations to develop consistent guidelines for the use of wireless radio-frequency transmitters (e.g., cellular telephones, two-way radios) in hospitals and standards for medical equipment and device manufacturers to ensure electromagnetic compatibility between radio-frequency transmitters and medical devices; and the AMA will work with these organizations to increase awareness among physicians and patients about electromagnetic compatibility and electromagnetic interference in hospital environments.
- 2. The AMA encourages hospital administrators to work with their clinical/biomedical engineering staff, safety committees, and other appropriate personnel to adopt and

implement informed policies and procedures for (a) managing the use of wireless radiofrequency sources in the hospital, particularly in critical patient care areas; (b) educating staff, patients, and visitors about risks of electromagnetic interference (EMI); (c) reporting actual or suspected EMI problems; and (d) testing medical devices for susceptibility to EMI when electromagnetic compatibility information is lacking.

- 3. The AMA encourages medical device and electronic product manufacturers to design and test their products in conformance with current electromagnetic immunity standards and inform users about possible symptoms of electromagnetic interference (EMI). If a possibility of EMI problems affecting medical devices exists, steps should be taken to ensure that all sources of electromagnetic energy are kept at sufficient distance.
- 4. The AMA encourages physicians to become knowledgeable about electromagnetic compatibility and electromagnetic interference (EMI), recognize EMI as a potential problem in hospital environments, and report suspected EMI problems to the Food and Drug Administration MedWatch program or appropriate hospital personnel.

NOTE: The full text of this report has been published: Lyznicki JM, Altman RD, Williams MA, for the Council on Scientific Affairs. Report of the American Medical Association (AMA) Council on Scientific Affairs and AMA recommendations to medical professional staff on the use of wireless radio-frequency equipment in hospitals. *Biomedical Instrumentation & Technology*. 2001;35:189-195. (May/June)

Evaluation of the Federal Abstinence-only Education Programs (CSA Rep. 5, A-00)

SUMMARY

At the American Medical Association (AMA) House of Delegates 1999 Interim Meeting, Council on Scientific Affairs (CSA) Report 7, "Sexuality Education, Abstinence, and Distribution of Condoms in Schools," was presented; the recommendations were adopted as amended in lieu of Resolution 416 (A-98) and the remainder of the report was filed. The report included five recommendations that addressed: family life education in the family and in schools; comprehensive, developmentally appropriate sexuality education programs; the importance of monitoring future research findings; consolidation of several AMA policies; and working with the United States Surgeon General to address the needs of specific communities. Although CSA Report 7 recommends tracking future research efforts relating to educational program outcomes, it is important to describe the federal process for evaluating state-administered, abstinence-only education programs due to its potential impact on our understanding of programs that may change the sexual risk-taking behavior of adolescents.

Methods

The Combined Health Index Database and MEDLINE were searched to identify articles that described the evaluation process for federal abstinence-only education programs. Although limited sources were identified, two organizations are currently tracking the state funding process and its related activities. Consultations with the U.S. Department of Health and Human Services (DHHS) Assistant Secretary for Planning and Evaluation's Director for Human Services Policy who supervises this effort and the federal contractor's director provided additional information about their goals for and approach to the evaluation process.

RECOMMENDATIONS

Because this is an informational report, it does not contain Recommendations.

The Physician's Role in Organ Donation (CSA Rep. 6, A-00)

SUMMARY

Substitute Resolution 519 (I-99), introduced by the Georgia Delegation, asked the AMA to: "Evaluate the Health Care Financing Administration's (HCFA) recent clarification of 42CFR482.45, Hospital Conditions of Participation Regulations on Organ, Tissue and Eye Procurement, to ensure that there is no prohibition of physician involvement in the organ donation process, and disseminate this information to State Medical and Hospital Associations and Specialty Medical Societies."

Background. The number of *potential* organ donors in the United States is 8,000 to 15,000 annually; however, the number of organs procured for transplantation is insufficient. Two major problems account for most of the unrealized donor potential in hospitals: (1) An estimated 25% of the families of eligible donors are not given the option of donation; and (2) the consent rate--more than half of families decline donation when it is offered.

Families' hospital experiences significantly affect their decisions to donate organs. The structure, process, sequence, timing and coordination of the donation process are vital to obtaining consent for donation. Higher rates of consent follow better consent practices. Many physicians and nurses are underskilled or poorly trained in the skills of communication and problem resolution that are required to broach these decisions with patients and their families.

Federal Conditions of Participation (COP). Federal COP from HCFA and many state laws now require that all families be presented with the option of organ and tissue donation when death is imminent. The COP have created an unintended misconception that the term "designated requestor" implies that only Organ Procurement Organization (OPO) staff may approach families. In fact, the COP require that the OPO and the hospital collaborate to develop a process by which "the family of each potential donor is informed of its options to donate organs, tissues or eyes, or to decline to donate." The COP requirements do not act as a "gag order" prohibiting discussion of organ donation by physicians; rather, the requirements strictly apply to those who initiate the dialogue with the potential donor family COP require than any persons *initiating* a discussion about organ donation with a family be trained and skilled in doing so.

Physicians. Physicians play an important role in caring for patients and families in these circumstances, and the care they provide is enhanced through training and attention to the special issues involved. The Federal COP do not prohibit physician involvement in initiating organ donation requests (provided they are properly trained). In fact, they encourage increased involvement of the medical community.

RECOMMENDATIONS

The following statements, recommended by the Council on Scientific Affairs, were adopted by the AMA House of Delegates as AMA policy at the 2000 AMA Annual Meeting.

- 1. AMA policies H-370.977, H-370.980, H-370.981, H-370.982, H-370.983, H-370.986, H-370.995, H-370.996, and H-370.998 are reaffirmed.
- 2. The AMA will continue to support the "Live and Then Give" promote organ donation awareness campaigns, a partnership between the AMA and state and specialty medical societies and that this report be disseminated as part of that campaign.
- 3. The AMA encourages the Department of Health and Human Services to widely distribute the "Roles and Training for the Donation Process: A Resource Guide."
- 4. The AMA will work with members of the Federation, the transplant community, and the Department of Health and Human Services to convene a workshop to develop the best

practices for medical management of potential organ donors, which respect honoring of advance directives by physicians.

- 5. The AMA encourages physicians to be aware of the important issues involved in discussing brain death and organ donation with families, and encourages physicians to participate in training to work effectively with Organ Procurement Organization coordinators to present the option of organ donation to families.
- 6. The AMA will work to amend HCFA 42CFR482.45 to include language directing the designated organ donation requestor to contact the attending physician prior to organ donation requests, to include the attending physician in the discussion with the family if he or she desires.

NOTE: A revised version of this report has been published: Williams MA, Lipsett PA, Rushton CH, et al. The physician's role in discussing organ donation with families. *Critical Care Medicine*. 2003;31:1568-1573.

Decade of the Brain (CSA Rep. 7, A-00)

SUMMARY

Objective. To review and highlight some of the significant findings in basic neuroscience research and advances in clinical practice emanating from the Decade of the Brain initiative.

Data Sources. Literature searches were conducted in the MEDLINE (PubMed) database and Lexis/Nexis GenMed library for articles between 1990 and December 1999 using the terms *decade* and *brain*. Articles that featured discussion on the Decade of the Brain or that reviewed advances in neuroscience were exploded using the related-article feature. The webpages of the National Institutes of Mental Health (www.nimh.nih.gov) and the Library of Congress (www.lcweb.loc.gov/brain) devoted to their joint "Project on the Decade of the Brain"; the Dana Alliance for Brain Initiatives (www. dana.org); the National Foundation for Brain Research (www.brainnet.org); the National Alliance for the Mentally III (www.nami.org); the Society for Neuroscience (www.sfn.org); and *Science* (www.science.org) were also searched for summary information relating to the Decade of the Brain initiative.

Data Synthesis. A working template highlighting some significant advances that occurred during the Decade of the Brain in the understanding of brain structure and function and in the clinical treatment of brain diseases was created and offered to several specialty societies, and the Food and Drug Administration, National Institutes of Health, National Institute of Neurologic Diseases and Stroke, National Institute on Drug Abuse, National Institute on Alcohol Abuse and Alcoholism, and the National Institute of Mental Health for review and comment, which were incorporated into the final draft.

Conclusion. Significant advances have been made in understanding the basic brain anatomy of cognitive functions. In particular, advances in neurogenetics and neuroimaging have advanced our understanding of both normal brain function and dysfunction in disease. Delineation of the pathways of brain development and degeneration hold great promise for targeted manipulations.

Despite many advances in the basic understanding of brain structure and function, and in the diagnosis and treatment of brain disorders, the 3 conditions (Alzheimer s disease, Parkinson s disease, and stroke) that were the most prevalent causes of morbidity and mortality at the beginning of the Decade, continue to exact a large toll on the health and welfare of the American public. Schizophrenia remains a chronic disorder whose treatment is unsatisfactory in a significant minority of patients. Mood and anxiety disorders remain woefully underdiagnosed and undertreated, and many patients still suffer needlessly from chronic pain, including the pain of terminal illness. Drug addiction remains a significant problem and drain on national resources.

Although the decade ahead offers much promise, particularly for retarding neurodegeneration and stimulating brain repair mechanisms, many scientific lessons have already been learned that require our attention to translate into improved clinical practice.

RECOMMENDATION

The following statement, recommended by the Council on Scientific Affairs, was adopted by the AMA House of Delegates as an AMA Directive at the 2000 AMA Annual Meeting:

That this report be submitted for appropriate dissemination.

Drug Interaction Between Oral Contraceptives and Antibiotics (CSA Rep. 8, A-00)

SUMMARY

Objective. To evaluate the evidence on possible drug interactions between antibiotics and oral contraceptives that may lead to oral contraceptive failure.

Data Sources. Published studies from 1966 through December 1999 were identified through MEDLINE and Lexis/Nexis Medical Library searches using the key word *oral contraceptives*, cross-indexed with the terms *antibiotics*, *adverse effects*, and *pregnancy*. Related articles in the MEDLINE database using the additional MeSH term *drug interactions* also were identified. A total of 167 articles were retrieved for analysis. Another 32 articles were identified by review of the references cited in these publications.

Data Extraction. Articles were selected based on ability to provide information on the relationship between antibiotic therapy and oral contraceptive efficacy in otherwise compliant users. Case reports, surveys, and information from adverse reaction databases were extracted. Additionally, studies that either directly measured the effects of antibiotics on the pharmacokinetics of oral contraceptive components, or that analyzed the effects of antibiotics on measures of ovulation in oral contraceptive users were reviewed.

Results. Several cases have been reported of pregnancies occurring in women taking oral contraceptives and antibiotics, in particular rifampin. Retrospective surveys, primarily from dermatology-based practices, also have reported pregnancies in oral contraceptive users who concomitantly received therapy with antibiotics, most commonly tetracyclines and penicillins. Information from adverse event reporting databases generally mirrors the types of information gleaned from these case reports and clinical surveys. Apparent oral contraceptive failure rates in clinical surveys were within the usual range expected for patterns of typical use.

The disposition of estrogen and progestins is highly variable among individuals. In most studies, oral antibiotics have not affected the disposition of ethinyl estradiol, levonorgestrel, and norethindrone. However, individual patients have been identified who experience significant decreases in plasma concentration of these components of oral contraceptive products.

Conclusion. Drugs like rifampin that induce hepatic drug metabolism may impair the effectiveness of oral contraceptives. Pharmacokinetic studies of other antibiotic studies have failed to show any systematic interaction between antibiotics and oral contraceptive steroids. However, individual patients do show large decreases in the plasma concentrations of ethinyl estradiol when they take certain other antibiotics, notably tetracycline and penicillin derivatives. Because it is not possible to identify these women in advance, a cautious approach is advised.

RECOMMENDATIONS

The following statements, recommended by the Council on Scientific Affairs, were adopted by the AMA House of Delegates as AMA policy at the 2000 AMA Annual Meeting:

The AMA believes that:

- 1. Women who are prescribed rifampin concomitantly with oral contraceptives are faced with a significant risk of oral contraceptive failure and should be counseled about the additional use of nonhormonal contraceptive methods during the course of rifampin therapy.
- 2. Women using combined oral contraceptives should be informed about the small risk of interactions with antibiotics and that it is not possible to identify in advance the women

who may be at risk of oral contraceptive failure. Women who are not comfortable with the small risk of interaction should be counseled about the additional use of nonhormonal contraceptive methods. Women who have had previous oral contraceptive failures or who develop breakthrough bleeding during concomitant use of antibiotics and oral contraceptives should be counseled about the use of alternate methods of contraception if they engage in intercourse during the period of concomitant use, as they may be part of the subset of women at high risk of contraceptive failure.

NOTE: The full text of this report has been published: Dickinson BDD, Altman RD, Nielsen NN, Sterling ML, for the Council on Scientific Affairs. Drug interactions between oral contraceptives and antibiotics. *Obstet Gynecol.* 2001;98:853-860.

Screening and Early Detection of Prostate Cancer (CSA Rep. 9, A-00)

SUMMARY

Objective. To review the principles of screening and to evaluate the efficacy and potential risks and benefits of screening for prostate cancer with digital rectal examination (DRE) and measurement of prostate specific antigen (PSA).

Data Sources. Published studies from the years 1988 to March 2000 were identified through MEDLINE and Lexis/Nexis Medical Library searches for English-language articles using the key words *prostatic neoplasms*, *palpation*, *prostate-specific antigen*, and *mass screening*, cross-indexed with the additional MeSH terms *prevention and control*, *tumor markers*, *sensitivity and specificity*, and *diagnosis*. A total of 234 articles was retrieved for analysis. Additional articles were identified by review of the references cited in these publications.

Data Synthesis. Prostate cancer is now the most common type of cancer among men. Since the advent of blood tests for measuring PSA, the incidence of prostate cancer increased through 1992, largely based on the detection of moderately differentiated tumors, then declined in conjunction with a stable or slightly declining mortality rate. In asymptomatic patients, cancer detection rates for DRE are 0.2% to 2.2% and for PSA 1.5% to 3.5%. Combination of the two procedures may result in a diagnostic yield of up to 4%. Each procedure detects cancer missed by the other. The majority of tumors that are detected by PSA are organ-confined, but size and pathological characteristics indicate than many of these are clinically significant. The low specificity of PSA results in a number of false-positive tests in men with benign prostatic hyperplasia and a large number of diagnostic biopsies. Specificity is increased by measuring the percent free PSA in serum or the concentration of complexed PSA. Application of adjusted PSA ranges based on age or race to improve specificity is not widely validated at this time.

Conclusions. Measurement of PSA is the most sensitive noninvasive test for prostate cancer and allows for early detection in asymptomatic individuals. Combining the use of PSA and DRE increases the early detection rate of prostate cancer. Indirect measures suggest a benefit to PSA screening but definitive evidence in the form of randomized controlled trials is lacking. The launching of mass screening programs for the early detection of prostate cancer is premature. Physicians should involve patients in the decision to screen for prostate cancer and provide the necessary information to support well-informed decision-making.

RECOMMENDATIONS

The following statements, recommended by the Council on Scientific Affairs, were adopted by the AMA House of Delegates as AMA policy at the 2000 AMA Annual Meeting:

The AMA believes that:

- 1. The launching of mass screening programs for the early detection of prostate cancer is premature at this time.
- All men who would be candidates for and interested in active treatment for prostate cancer should be provided with information regarding their risk of prostate cancer and the potential benefits and harms of prostate cancer screening, sufficient to support wellinformed decision-making.
- 3. Prostate cancer screening, if elected by the informed patient, should include both prostate-specific antigen (PSA) testing and digital rectal examination (DRE).

- 4. Men most likely to benefit from tests for early detection of prostate cancer should have a life expectancy of at least 10 years and include:
 - Men 40 years of age or older of African-American descent
 - Men 40 years of age or older with an affected first-degree relative
 - Men 50 years of age or older

Organized Medicine's Role in the National Response to Terrorism: Update 2 (CSA Rep. 10, A-00)

SUMMARY

Report 4 of the Council on Scientific Affairs, Organized Medicine's Role in the National Response to Terrorism (A-99), recommended: "That the AMA and the Federation of Medicine develop a plan that identifies the specific needs, roles, contributions, and participation of organized medicine and individual physicians in disaster planning, and in responding to terrorist attacks in their states or communities."

This report reviews actions undertaken by the Council on Scientific Affairs (CSA) to implement this recommendation.

RECOMMENDATIONS

The following statements, recommended by the Council on Scientific Affairs, were adopted by the AMA House of Delegates at the 2000 AMA Annual Meeting.

- 1. AMA Policy H-130.949, Organized Medicine s Role in the National Response to Terrorism (AMA Policy Database) is reaffirmed.
- 2. The AMA House of Delegates will consider the Council on Scientific Affairs report to be submitted at the 2000 Interim Meeting in order to arrive at recommendations on how the AMA, members of the Federation, and other medical stakeholders can enhance community preparedness for, and response, to natural disasters and acts of terrorism.