Preparing an AIDS policy for colleges of osteopathic medicine

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There are currently 1.5 million people in the United States infected with the human immunodeficiency virus. In the next five to ten years, this nation's health care facilities and medical schools could be inundated with staggering numbers of the sick and dying. Unless our osteopathic and allopathic colleges and allied health care centers are adequately prepared for this crisis, many of these people will not receive adequate care. A recent survey conducted by Ohio University College of Osteopathic Medicine (OU-COM) revealed that many osteopathic colleges do not have a formal policy to deal with the multiple complex issues of the AIDS epidemic. This brief article reviews the approach which OU-COM took to correct this deficiency. In addition, the article includes OU-COM's conclusions and recommendations regarding many of the salient issues, with a discussion of the rationale behind those conclusions.

There currently are 1.5 million people infected with human immunodeficiency virus (HIV) in the United States.¹ Although the hypothesis is not confirmed, it appears that all persons now infected with HIV eventually will succumb to AIDS.² In the next five to ten years, this nation's physicians, hospitals, health care centers, and medical training centers will be confronted with a staggering number of sick and dying AIDS patients.

During the coming decade, academic health centers will be at the center of the AIDS epidemic because of research and the volume of patients they

will treat. Concern over this fact is mounting among students and residents. Even attending staff and faculty, as well as medical center and hospital leaders, frequently are reluctant to encourage any expansion of HIV-related cases because of their concern about the infection risk.³ In addition, there is growing uneasiness among health professionals over their own safety and that of their families, especially as the probability of coming into contact with an HIV-positive patient increases.³ Further, according to the Associated Medical Schools of New York,³ "The association of HIV-related illnesses with both homosexuality and intravenous drug users (Fig 1) bring to the fore many preju-

Fig 1. Risk factor analysis of the current AIDS cases in the United States.

dices, from which the health professions are not exempt."

Is the osteopathic medical profession ready to deal with this crisis? Are the nation's osteopathic medical training centers preparing themselves to cope with the multifaceted issues presented by this spreading epidemic? It is imperative that every osteopathic medical school in the nation prepare a plan of action in the form of a carefully considered AIDS policy designed to address the issues particular to their institution.

Response by Ohio University College of Osteopathic Medicine (OU-COM)

Early in 1987, the Office of Health, Education and Wellness (Student Health Services) of Ohio University published a [General Statement on Ohio University's Response to AIDS.] This publication was helpful in providing the general student body and faculty with background information regarding the epidemiology, risk factors, and the university's legal response to the AIDS crisis.

It did not, however, address the multiple and often complex issues particular to a medical school and its allied health care centers, such as OU-COM and the Osteopathic Medical Center (OMC). Therefore, in October 1987, the dean of OU-COM appointed an AIDS Task Force. Its primary mission was to consider the legal, ethical, and medical problems associated with the AIDS epidemic and to formulate a comprehensive AIDS policy for OU-COM and OMC.

Members of the task force were chosen to represent a variety of backgrounds, knowledge, experience, and viewpoints. Seven official members (basic scientist, dentist, epidemiologist, ethicist, family physician, fourth-year medical student, and registered nurse) and one ex officio member (an attorney) were appointed. The AIDS issues were approached in two ways: first, by canvassing the other osteopathic medical schools to ascertain what work had already been accomplished; and, second, by identifying those issues unique to a medical school that had not been previously addressed by Ohio University's general statement.

The task force survey (December 1987) found that of the 15 osteopathic medical schools, only two had prepared an individual, comprehensive, formal AIDS policy. A third school had developed a common policy with the allopathic medical schools in their state. Two colleges were, like OU-COM, "in the process" of developing such a policy, and four more had no current policy or any plans to develop one. Five colleges did not respond to the survey.

Five issues were identified as being particularly

relevant to every osteopathic college; these included mandatory HIV testing, confidentiality, the obligation of student and faculty participation in the care of HIV-positive patients, patient, student, and faculty education, and measures to prevent transmission of HIV.

The policy

In keeping with the format of Ohio University's general statement and to enhance the ease with which the policy could be reviewed, the task force used a question and answer style. The material was categorized into five sections—general, employee, student, and patient guidelines, and HIV testing. In addition, the complete 1st21MMWR supplement, "Recommendations for prevention of HIV transmission in health-care settings,"⁴ was included as an appendix.

Copies of the entire policy are made available to every department and departmental section of OU-COM and OMC on the Athens campus. Additional copies are given to all individual personnel requesting them.

Further, a shortened version (summary) has been distributed to all OU-COM medical students prior to their initial clinical rotations. Beginning with the first year class of 1988, the summary also is provided to every incoming first-year student. Finally, an AIDS question and answer session has been scheduled as a regular feature of the phase III (preclinical) curriculum. This allows students an opportunity to comprehend the nature of the current crisis, their roles as medical students in the delivery of health care to AIDS, ARC, and HIV-positive patients, and the critical importance of practicing preventive measures to reduce their own risk and that of their patients.

Recommendations

The conclusions and recommendations of the OU-COM AIDS Task Force regarding some of the salient issues follow. In addition, the rationale behind a decision, where the issue may be controversial or require further explanation, also is provided. (The AIDS policy in its entirety is available upon request.)

(1) *Medical faculty, residents, medical students, and all health care workers associated with OU-COM or OMC will accept as their most fundamental responsibility the care of all patients who come before them.* (In this regard, OU-COM is in full and absolute agreement with the 1987 statement published by the Associated Medical Schools of New York³: "The treatment of AIDS is the function of the doctor's mission; the doctor's mission cannot

be changed because of the small but real dangers inherent in treating AIDS. Communicable diseases have traditionally called for sacrifice and courage from the medical community. In addition, medical schools and academic health centers have a special duty to fight not only the disease itself but the fear and misinformation surrounding the disease.”)

(2) *Mandatory HIV testing of students and employees shall not be required.* (The specificity of the combined ELISA and Western Blot tests is about 99%.⁵ This means that for each 500 persons tested, three would be labeled falsely as HIV positive. Minimally, these persons would suffer severe psychological trauma and might face loss of educational opportunities, health insurance, family support, job, or housing. HIV is transmitted by the transfer of infectious material from the bodily fluids of an infected individual into the body of a susceptible individual. Health care workers frequently are exposed to body fluids of patients. The converse, exposure of a patient to body fluids of a health care worker, seldom occurs. While we are unaware of any statistics based on observations of patients exposed to HIV-positive care givers, there are extensive data on health care workers exposed to HIV-positive patients and their body fluids. To date, over 61,000 cases of AIDS have been diagnosed, and approximately 25,000 AIDS patients have died. These patients have received care from thousands of health care workers over the past 10 years—care that frequently exposed these providers to infectious body fluids. Out of these thousands of person-years of exposure, only a half-dozen health care workers are documented to have acquired HIV infection from patients. The risk, while measurable, is quite small—less than the risk of acquiring a fatal case of hepatitis B, for example. The risk of HIV transmission from an HIV-positive health care worker to a susceptible patient would be even less. The implementation of the recent CDC “Guidelines for preventive AIDS in health care workers” will reduce the risk even further for patients as well as for health care workers themselves.⁴ These guidelines already have been adopted by OU-COM/OMC. The task force concluded, therefore, that the risk of a patient acquiring an infection from an HIV-positive employee of OU-COM/OMC is negligible and would not be altered substantially by a program of mandatory testing.)

(3) *The right to confidentiality is paramount to the person with AIDS.* (When a person with AIDS comes to the attention of OU-COM, whether patient, student, or employee, the Director of Medical Services will conduct a thorough review based

on the best medical and legal information available. Any actions taken will respect the confidentiality and welfare of the individual as well as that of Ohio University, OU-COM/OMC, including its students, patients, and employees, and will be in compliance with all CDC guidelines and state and federal regulations.)

(4) *The fact that a classmate or fellow employee has AIDS or ARC or is HIV positive will not be a legitimate reason for a student or employee to seek reassignment.*

(5) *Employees, faculty, and students working in areas where they can be exposed to body fluids or blood spills should follow general housekeeping procedures and take precautions as recommended by the CDC.* (Equipment or services exposed to blood or other body fluids should be cleansed with a germicidal agent such as SOAK, A-500, or a 1:10 dilution of household bleach. Employees should use protective gloves, surgical masks, eye protectors, and effective barrier gowns as recommended by the CDC⁴ whenever the chance of exposure to open skin or mucous membranes is present.)

(6) *Any physician or student who has reason to believe that he or she may be a carrier of the HIV virus bears the responsibility of limiting his or her practice to noninvasive care and using appropriate barrier techniques and sterilization procedures in the course of all patient contact.* (This is in keeping with the policy adopted by the Ohio State Medical Board.⁶ The task force slightly modified the MMWR definition⁴ and defined “invasive procedures” as “... any entry into tissue, cavities, or organs, or repair of major traumatic injuries such as (1) in an operating or delivery room, emergency department, or outpatient setting, including both physicians’ and dentists’ offices; (2) drawing blood, starting an intravenous line, or giving an injection; (3) cardiac catheterization and angiographic procedures; (4) a vaginal or cesarean delivery or other invasive obstetric procedure during which bleeding may occur; (5) the manipulation, cutting, or removal of any oral or perioral tissues, including tooth structure, during which bleeding occurs or the potential for bleeding exists; or (6) endoscopy procedures, such as esophagogastroduodenoscopy, bronchoscopy, sigmoidoscopy, etc. Decisions regarding activities of an HIV-infected medical student should be consistent with the established policies governing physicians. If a medical student suspects or confirms that he or she is HIV-positive or has ARC or AIDS, that student should report this information to the Associate Dean for Academic and Clinical Affairs. Whether the medical student reports it, or such knowledge is acquired through

TABLE 1. INFORMED CONSENT FORM FOR HIV ANTIBODY TEST.

I hereby give my consent to have my/my child's blood tested to find out whether or not I/my child have antibodies to HIV in my blood. Doctors think that HIV causes Acquired Immune Deficiency Syndrome (AIDS). The reason my doctor is recommending this test is one or more of the following:

1. I/my child may have been intimate with someone with AIDS.
2. I/my child may have received blood from someone with AIDS.
3. I am pregnant and may have been intimate or received blood from someone with AIDS.
4. Other situations such as tuberculosis, recipient of a skin graft, or _____

(write in reason)

I have been informed that when a person is infected with a virus, his/her body produces antibodies that fight the infection. If I/my child has been infected with HIV, my body may be producing antibodies to this virus. This blood test will determine whether I/my child has HIV antibodies. If these antibodies are present, it means that I/my child might be contagious for others, or, if I am pregnant, my unborn baby could be infected. On the other hand, I have been told that a positive test does not necessarily mean I will get sick with AIDS even though I may be contagious.

I have been informed that sometimes the test result may be negative even though I may have been infected with the virus (false negative). This can happen because it takes time for the body to make antibodies and there may not have been enough time for the antibodies to appear before the test is performed. I have been informed that sometimes the test can indicate that a person has antibodies to the virus when that person is not really infected (false positive). In order to reduce this risk, positive tests will be retested.

I understand that the results of this blood test will become a part of my/my child's permanent medical record and will be released to health practitioners responsible for my/my child's care and treatment. Efforts will be made to keep the results of this test confidential and the University will not release confidential or medical information except as required by law. While I understand that it may be necessary to release this information to others who may pay for my/my child's health care, I further understand that this will require my signature on a separate release form.

The consent form has been explained to me and all questions regarding the nature of the blood test, its expected benefits, its risks, and alternative tests have been answered to my satisfaction. I understand that I may ask additional questions at any time.

Signature: _____ Date: _____

Physician: _____ Date: _____

other means, a thorough and complete evaluation will be conducted by the Associate Dean for Academic and Clinical Affairs and the Committee on Student Progress. This committee, which has as one of its responsibilities approval of alterations and course of study, will consider the effects of removing or excusing the student from direct patient contact involving invasive procedures and will make a recommendation to the dean as to whether the student, if excused, can complete the course of study that will meet the requirements for graduation as an osteopathic physician. The final decision regarding the student's completion of medical school will rest with the dean.)

HIV testing recommendations

Screening. If a faculty member, student, or employee has a concern relative to AIDS, he or she may consult one of the OU-OMC physicians for further information. If a student desires routine screening for HIV antibody but is considered to be at low risk, he/she will be referred to one of several authorized AIDS testing centers for confidential testing and counseling.

Diagnostic evaluation. If a student feels he/she has AIDS or ARC because of symptoms or known exposure and consults an OU-OMC physician, an appropriate medical evaluation will be performed. The OMC Medical Director or other designated physician will provide confidential counseling and any further indicated medical follow-up based on CDC guidelines. The patient's right to confidentiality is paramount. OU-OMC physicians will not release confidential medical information except as required by law or OU-COM policy.

Consent form. An informed consent form (Table 1) is available for any OU-OMC physician who wishes to have a patient tested for the HIV antibody. This form explains the possible reasons for the test and should be signed by both the patient and the physician. The results of this test will become a permanent part of the patient's OU-OMC chart.

Conclusions

The experience of the health care systems in the United States and throughout the world suggest that if there are not sufficient funds, resources, and preparation for treatment and care of persons with AIDS, they will not receive care.¹ Our survey suggests that osteopathic medical schools and their allied health care centers are unprepared to deal with the AIDS crisis. It is the purpose of this article to

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Prescribing Information appears on the next page.

CAUTION: Federal law prohibits dispensing without prescription.

DESCRIPTION: Lorelco (probucof) film-coated tablets for oral administration.

CLINICAL PHARMACOLOGY: Lorelec lowers total serum cholesterol and has relatively little effect on serum triglycerides. Patients responding to probucol exhibit a decrease in low-density lipoprotein (LDL) cholesterol. Cholesterol is reduced not only in the LDL fraction, but also in the high-density lipoprotein (HDL) fraction with proportionately greater effect on the high-density portion. Epidemiologic studies have shown that both low HDL-cholesterol and high LDL-cholesterol are independent risk factors for coronary heart disease. The risk of lowering HDL-cholesterol while lowering LDL-cholesterol remains unknown. There is little or no effect reported on very low-density lipoprotein (VLDL).

Absorption of Lorelco from the gastrointestinal tract is limited and variable. When it is administered with food, peak blood levels are higher and less variable. With continuous administration in a dosage of 500 mg b.i.d., the blood levels of an individual gradually increase over the first three to four months and thereafter remain fairly constant. In 116 patients treated with Lorelco for periods of three months to one year, the mean blood level was 23.6 ± 17.2 mcg/ml ($\pm$ S.D.) ranging to 78.3 mcg/ml. Levels observed after seven years of treatment in 40 patients yielded an average value of 21.5 ± 16.5 mcg/ml ($\pm$ S.D.) ranging to 62.0 mcg/ml. In a separate study in eight patients, blood levels averaged 19.0 mcg/ml at the end of 12 months of treatment. Six weeks after cessation of therapy, the average had fallen by 60%. After six months, the average had fallen by 80%.

INDICATIONS AND USAGE: Serious animal toxicity has been encountered with probucol. See **WARNINGS** and **ANIMAL PHARMACOLOGY AND TOXICOLOGY** sections. Probucol is not an innocuous drug and strict attention should be paid to the **INDICATIONS, CONTRAINDICATIONS, AND WARNINGS**.

The selection of patients for cholesterol-lowering drug therapy should take into account other important coronary risk factors such as smoking, hypertension, and diabetes mellitus. Consideration should be given to the efficacy, safety, and compliance factors for each of the cholesterol-lowering drugs prior to selecting the one most appropriate for an individual patient.

$$\text{LDL-cholesterol} = \text{Total cholesterol} - [(0.16 \times \text{triglycerides}) + \text{HDL-cholesterol}]$$

It is not always possible to predict from the lipoprotein type or other factors which patients will exhibit favorable results. Lipid levels, including HDL-cholesterol, should be periodically assessed.

CONTRAINDICATIONS: (See also **WARNINGS** and **PRECAUTIONS**.) Lorelec is contraindicated in patients who are known to have a hypersensitivity to it. Lorelec is contraindicated in patients with evidence of recent or progressive myocardial damage or findings suggestive of serious ventricular arrhythmias or with unexplained syncope or syncope of cardiovascular origin.

Prolongation of the QT interval can occur in patients on Lorelco. Serious arrhythmias have been seen in association with an abnormally long QT interval in patients on Lorelco alone and in patients on Lorelco and a concomitant antiarrhythmic drug. The following precautions are deemed prudent:

Lorelco therapy should be discontinued or not started if the QT interval at an observed heart rate on a resting ECG is persistently more than one of the values listed below:

*Values calculated from Burch GE, Winsor T. A primer of electrocardiography. Philadelphia, PA: Lea and Febiger; 1958; p. 272 (Table 6).

4. Drugs that prolong the QT interval are more likely to be associated with ventricular tachycardia after:

- An increase in the dose of the drug.

The use of Lorelco in patients receiving any of these drugs should be based on the conclusion that alternate methods of hypocholesterolemic therapy are either ineffective or not tolerated, and the potential benefits of cholesterol lowering outweigh the risk of serious arrhythmia.

PRECAUTIONS
General: Before instituting therapy with Lorelco, adequate baseline studies should be performed to determine that the patient

General: Before instituting therapy with Lorelco, adequate baseline studies should be performed to determine that the patient has persistently elevated total and LDL-cholesterol levels representing a primary lipid disorder, and that the increased cholesterol is not due to secondary conditions such as hypothyroidism, peripheral vascular disease, diabetes mellitus, or other obstruction.

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Laboratory Tests: The physician should schedule periodic blood lipid determinations and periodic ECGs. (See WARNINGS.)

Drug Interactions: The addition of clofibrate to Lorelco is not recommended, since the lowering effect on mean serum levels of either LDL or total cholesterol is generally not significantly additive and, in some patients, there may be a pronounced lowering of HDL-cholesterol.

Monkeys led a high fat, high cholesterol diet admixed with probucol exhibited serious toxicity. (See WARNINGS and ANIMAL PHARMACOLOGY and TOXICOLOGY sections.) Prolongation of the QT interval can occur in patients on Ilorelco and serious

Carcinogenesis, Mutagenesis, Impairment of Fertility
In chronic studies of two years' duration in rats, no toxicity or carcinogenicity was observed. These results are consistent with the lack of any adverse effect on fertility and the negative findings in tests for mutagenic activity in rats.

Pregnancy—Category B: Reproduction studies have been performed in rats and rabbits at doses up to 50 times the human dose, and have revealed no evidence of impaired fertility or harm to the fetus due to probucol. There are, however, no adequate

Labor And Delivery: The effect of Lorelco on human labor and delivery is unknown.

Pediatric Use: Safety and effectiveness in children have not been established.

Cardiovascular
prolongation of the QT interval on ECG, syncope, ventricular arrhythmias (ventricular tachycardia, torsades de pointes)

headache, dizziness, paresthesia, insomnia, tinnitus, peripheral neuritis

Genitourinary
Impotence, gynaecitis

Endocrine
enlargement of multinodular goiter

Other
diminished sense of taste and smell, anorexia, anionneurotic edema

OVERDOSAGE: There is a single report of a 15-kg, three-year-old, male child who ingested 5 g of probucol. Emesis was induced by ipecac. The child remained well, apart from a brief episode of loose stools and flatulence. No specific information

DOSEAGE AND ADMINISTRATION: For adult use only. The recommended and maximal dose is 1000 mg daily given

HOW SUPPLIED: 250 mg: round, white, film-coated tablets imprinted with either the DOW diamond trademark over the code number 51 or LORELCO 250. Bottles of 120 (NDC 0068-0051-52)
500 mg: capsule-shaped, white, film-coated tablets, marked LORELCO 500. Bottles of 100 (NDC 0068-0052-51)

ANIMAL PHARMACOLOGY AND TOXICOLOGY: In rhesus monkeys, administration of probucol in diets containing unusually high amounts of cholesterol and saturated fat resulted in the death of four of eight animals after several months.

20 mcg/mL and not uncommonly reach levels of 40 mcg/mL and higher. Rhesus monkeys fed normal (low fat) chow and receiving probucol three to thirty times the human dose equivalent achieved blood levels only one-third those of many human subjects. No adverse effects were detected in these monkeys over an eight-year period of continuous drug administration. In

observed over the entire one-year treatment period. Regression of gross aortic lesions comparable to that observed in a parallel group of monkeys receiving cholestyramine was seen in animals receiving probucol. It should be emphasized that both HDL cholesterol and LDL cholesterol were markedly reduced in this experimental group. During the one-year treatment period, no

Subsequent experiments have indicated that probucol sensitizes the canine myocardium to epinephrine, resulting in ventricular fibrillation in many dogs. Among the animal species in which probucol has been studied, the dog is peculiar with respect to the phenomenon of sudden death due to the sensitization of the myocardium to catecholamines, as indicated in Figure 1. The dog

In other studies, monkeys were given probucol either before and after, or only after myocardial infarction was induced by coronary artery ligation. In these studies, there was no difference between probucol- and placebo-treated groups with respect to either survival or detailed histologic quantitation of myocardial infarction (measured by histopathological

weight. In chronic studies of two years' duration in rats, no toxicity or carcinogenicity was observed. From studies in rats, dogs, and monkeys, it is known that probucol accumulates slowly in adipose tissue. Approximately 90% of

Myocardial injury was produced in various groups of rats by one of the following procedures: aortic coarctation, coronary ligation, or cobalt or isoproterenol injection. After probucol administration, no deleterious effects related to treatment occurred.

Challenge with epinephrine at the end of 60 days failed to induce ventricular fibrillation in any of the coronary-ligated probucol-treated minipigs.

cholesterol reductions greater than those obtained in the placebo group treated with diet alone. The cumulative seven-year incidence of the primary end point—combined incidence of definite CHD death and/or definite nonfatal myocardial infarction

The subjects included in the study were middle-aged men (35-59 years old) with serum cholesterol levels at least 265 mg/dL and

The bile acid sequestrant, cholestyramine, was used in the above trial. Caution should be exercised in extrapolating these results to Lorelco since it differs from cholestyramine with regard to its mode of action, spectrum of cholesterol-lowering potency

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stimulate renewed resolve of our osteopathic colleges and to encourage them to prepare through the formulation and implementation of their own AIDS policies.

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