Texas Preventable Disease NEWS

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contents:

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ASTPHLD POSITION STATEMENTS--PART II*

The following ASTPHLD position statments are presented herein for information only. They do not necessarily reflect TDH recommendations or official policy.

HOME TEST KITS FOR DIAGNOSIS OF INFECTIOUS DISEASE

The Association has great concern about the possible relaxation of the Food and Drug Administration's position on approval of home test kits designed for the diagnosis of infectious and communicable disease. Over the past few years, the Food and Drug Administration has approved several laboratory test kits for home use for non-infectious diseases. However, more recently a number of research institutions and manufacturers have succeeded in developing rapid tests for the diagnosis of various infectious and communicable diseases. Examples of such tests are those used to detect group A beta-hemolytic streptococci in children with septic sore throat, to detect sexually transmitted disease agents such as *Neisseria gonorrhea* and chlamydia, and to diagnose a urinary tract infection. Recently, the FDA also licensed a rapid slide latex agglutination test for the detection of human immunodeficiency virus antibody in the blood of individuals. It is only a matter of time before commercial organizations attempt to convince the FDA that approval of these diagnostic kits as home test kits serves a public need.

The Association of State and Territorial Public Health Laboratory Directors opposes the approval of any type of home test kits for the identification and self-diagnosis of infectious or communicable diseases for the following reasons:

1. **Use of home test kits for self-diagnosis of communicable diseases may lead to inadequate and/or inappropriate self-treatment.** This self-treatment could lead to the development of drug-resistant strains of various human pathogenic microorganisms spreading through the community without the knowledge or awareness of public health authorities. Such drug-resistant, disease-producing agents could thwart the prevention efforts of public health officials.

2. **Use of home test kits would bypass mandatory reporting requirements of evidence of communicable diseases to public health authorities and could impede public health control measures designed to prevent the spread of communicable diseases in the community.**

3. **Proficiency in the use of a home test kit by a lay person is a major concern.** A person using a home test kit to detect an infectious disease agent must be capable of performing the test with proficiency the first time it is attempted. Clearly, it is rarely ever possible to be proficient the first time one performs a new test procedure. In most instances home test kits will cost as much or more than conventional tests performed in an approved clinical microbiology laboratory.

4. **Lack of skill on the part of a lay person, coupled with inappropriate or incorrect use of the test, may lead to incorrect interpretation of test results.** This deficiency could give the person an unjustified sense of security, or it could cause the person to overreact to a positive test result.

5. **Elimination of pre- and post-test counseling and the interpretation of test results by a qualified health care provider in the case of a true or false positive test for HIV antibody could cause the patient to adopt life-threatening or self-destructive behavior. On the other hand, a false negative test result could encourage a lifestyle which would transmit the disease to others.**

*Approved by the Executive Committee of the Association of State and Territorial Public Health Laboratory Directors, March 1989.

6. **If a person is symptomatic, he/she should seek medical care from a qualified health professional rather than attempt to utilize a home test for self-diagnosis.**

   Regardless of the results of a home test kit, a person with symptoms should be seen by a physician at which time the test usually would be repeated in a laboratory if the clinical impression would so indicate. Nothing is gained by a patient attempting to self-diagnose his illness by using a home test kit.

In summary, the Association of State and Territorial Public Health Laboratory Directors opposes approval of any type of home test kit for identification and diagnosis of communicable or infectious diseases. The use of such home test kits would not significantly reduce the cost of health care and could lead to a number of adverse reactions including possible crises or life-threatening situations. Significant harm to the individual or patient, as well as to the community, could result from the spread of drug resistant communicable disease agents.

PHYSICIAN OFFICE LABORATORY TESTING

Effective January 1, 1990, the Clinical Laboratory Improvement Amendments of 1988 will require that all laboratories, including physician office labs (POLs) and local public health department clinics which perform laboratory testing, be certified and adhere to personnel standards, proficiency testing, and inspection standards. POLs will have until July 1, 1991, to comply with these requirements. Certification will be waived for labs performing only low-risk testing as defined by regulators.

A provision in the Omnibus Budget Reconciliation Act of 1987 requires POLs performing a minimum of 5,000 tests annually to be certified by HHS, beginning on January 1, 1990, in order to be eligible for Medicare reimbursement. It is anticipated that this provision will be amended to exclude the 5,000 minimum.

Regulation of POLs is important because studies indicate that the quality of laboratory test results from POLs is not comparable to those from hospital and independent laboratories. The volume of testing in POLs is significant and increasing annually by approximately 15%. Currently, about 25% of all outpatient testing is performed in POLs. In states which regulate POLs, performance has been shown to improve.

As POL testing increases, the concern about the quality of such testing has become a serious public health issue. Physicians who perform in-office laboratory tests have a public responsibility to provide reliable results. Often the physician is lulled into a false sense of security that test results are reliable because of the simplicity of test procedures or instrumentation.

The Association of State and Territorial Public Health Laboratory Directors recommends the following guidelines for regulating the physician office laboratory.

1. **Physician office laboratories should be regulated based on the complexity of the tests performed, not on test volume or whether the physician personally performs the tests on his own patients.**

2. **A tiered system of POL testing should be used to group these laboratories as to the extent of regulatory compliance required.** For example, those POLs performing only low-risk tests would be required to register, meet quality control standards, and participate in a proficiency testing (PT) program for those tests where PT is available. All other POLs would be required to meet licensure/certification requirements for personnel, quality assurance, proficiency testing, and physical facilities, and be subject to inspection.

3. **An advisory committee should be established for the purpose of reviewing tests to determine which have a low-risk for the patient if performed incorrectly.** This review process must be ongoing because of the rapid changes in test procedures and instrumentation.

4. **Physician office labortories should meet the basic requirements of performing laboratory tests with accuracy and precision and provide reliable reporting of test results.** To accomplish these objectives, the POLs should comply with the following generally accepted standards.

a. Only adequately trained personnel, consistent with the complexity of test procedures, should be permitted to conduct the laboratory testing.

b. A quality assurance program designed to assure the reliability and medical usefulness of the laboratory data must be a component of laboratory testing. It should include a quality control program to monitor precision of laboratory performance, an instrument maintenance program, a procedures manual, a continuing education program for laboratory staff, and written documentation of all these activities. As part of an external quality assurance program, the laboratory must participate in an approved proficiency testing program.

c. The POL must have adequate facilities and equipment to perform its scope of testing in a safe and reliable manner.

5. **Annual on-site inspection of the estimated 100,000 physician office laboratories in the US is not economically feasible.** It is recommended that on-site inspection of a minimum of 5% of randomly selected POLs be conducted annually. In addition, unannounced inspections should be conducted as a result of complaints, poor performance in proficiency testing, questions raised by the survey questionnaire submitted by the POL, or suspicion of fraud.

State and territorial public health laboratories have an important public health responsibility to ensure that clinical laboratory services provided to its residents are performed in an accurate and reliable manner. When the quality of laboratory services declines, the failure of preventive health services and patient care may occur, as evidenced by the problem with PAP smear screening for cervical cancer. Compliance with good laboratory practices can no longer be left to voluntary initiatives.

In the POL, inadequate training, lack of knowledge concerning internal quality control/quality assurance processes, and the use of incorrect laboratory procedures are the most common causes of erroneous laboratory results. Therefore, in addition to mandatory compliance with regulations, state and territorial public health laboratories have a major responsibility to provide training and guidance to physician office lab personnel, as there are few reliable sources of such assistance.

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MEFLOQUINE APPROVED FOR MALARIA*

Mefloquine (Lariam) has been approved for the treatment and prevention of infection with two malaria parasites, *Plasmodium falciparum* and *Plasmodium vivax*, including those strains of *P. falciparum* resistant to other anti-malaria drugs.

Mefloquine, which is a designated orphan drug, was developed and tested by the Walter Reed Army Institute of Research, Hoffmann-La Roche, and the World Health Organization.

In many areas of the world, including southeast Asia, Africa, and South and Central America, many strains of *P. falciparum* parasites have become resistant to chloroquine, the mainstay of treatment and prevention of malaria.

Mefloquine has been shown to kill *P. falciparum* and *P. vivax* parasites in red blood cells. In clinical trials carried out in South America and southeast Asia involving more than 1,000 patients, the drug was found to be highly effective in destroying the parasites in infected individuals with mild to moderate illness.

Patients with severe malaria should be treated initially with an intravenous antimalarial drug. In patients with *P. vivax* infection, after initial treatment with mefloquine, primaquine must be used to clear the liver phase infection and prevent relapse.

In addition to these studies demonstrating effectiveness in treatment of malaria, separate studies showed mefloquine to be effective in preventing malarial infections. It is recommended for travelers to areas where malaria is endemic,

*DHHS. FDA Drug Bulletin 1989;19(2):17.

particularly where *P. falciparum* is resistant to other antimalarial drugs. Oral prophylaxis should be started 1 week before visiting the area, continued while there, and for 4 additional weeks after returning to this country. The recommended dosage regimen is one 250-mg tablet once a week for 4 weeks, then 1 tablet every other week.

The drug must be used carefully in patients taking beta blockers, quinidine, and quinine because of the potential for arrhythmias when given in combination with these other drugs. In patients taking mefloquine in addition to anticonvulsant drugs, blood levels of the anticonvulsant drug(s) should be monitored because breakthrough seizures and unexpectedly low antiepileptic drug blood levels have been reported.

The effects of mefloquine on the fetus are not known. Therefore, women of childbearing potential who are traveling to areas where malaria is endemic [and who plan to take mefloquine] should be warned against becoming pregnant.

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