7D. OSHA and Laboratory Screening

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INTRODUCTION

The Occupational Safety and Health Administration (OSHA) directs and enforces the Occupational Safety and Health Act, which went into effect in 1971. The purpose of this law is to protect employees and reduce workplace injuries and illnesses by mandating certain safety and health standards. OSHA has promulgated the blood-borne pathogens standard, which is applicable in any workplace environment where the employees are at some risk for exposure to blood-borne pathogens. This standard applies to all "occupational exposure" to blood and/or "other potentially infectious materials." A typical hair transplant practice certainly falls into the purview of OSHA standards because any employee involved in the surgical portion of the procedure is at risk for exposure (1).

There are numerous record-keeping, vaccination, hazard communication, information, and training requirements mandated by OSHA. Familiarity and compliance with these requirements are important because there are penalties imposed for not following them. A detailed presentation of these requirements is beyond the scope of this chapter. However, there are numerous private and government organizations that provide OSHA education and training to employees of medical practices and that help ensure that a practice is compliant with OSHA regulations. It is difficult for a busy practicing physician to stay up to date with these various rules and regulations. Therefore, it is helpful to use one of these resources and to have a delegated staff member who is specifically trained in OSHA standards. The first part of this chapter briefly addresses the very basic requirements and standards put forth by OSHA with respect to blood-borne pathogens. The second topic addressed in this chapter relates to the laboratory screening for diseases that are life threatening or those that can cause a serious illness as a result of exposure in the workplace environment. As an extension of this topic, there is a brief discussion concerning the controversy of obtaining screening laboratory tests for routine hair transplant patients.

Epidemiology

The three potentially most dangerous blood-borne pathogens are the human immunodeficiency virus (HIV), hepatitis B virus (HBV), and hepatitis C virus (HCV). The following is a brief overview of the epidemiology of these entities.

Hepatitis B Virus (2,3)

Chronic hepatitis B is a major global health care problem. Five percent of the world's population, or approximately 300 million persons, are estimated to be carriers worldwide. In the United States, about 120,000 to 300,000 new cases of acute HBV are reported to the Centers for Disease Control each year. Of these, about 5% develop chronic hepatitis B (patients remain positive for hepatitis B surface antigen [HBeAg]). This is significantly less than the rate of development of chronic hepatitis after exposure to HCV, which occurs in about 85% of people infected with the HCV virus. The prevalence of chronic hepatitis B in the United States is 0.2% to 0.5% of the general population. In subpopulations, such as intravenous drug abusers and homosexual men, the prevalence may be five to ten times higher. The incidence of HBV infection in the United States is declining with the effective use of vaccination against HBV. The antibody to HBV (anti-HBs) confers immunity to hepatitis B.

Hepatitis C Virus (2,3)

Currently, HVC virus is the most common of all blood-borne infections in the United States. It is estimated that there are about 30,000 to 180,000 new cases of acute HCV infections each year. Of these, about 85% develop chronic HCV infection. This higher rate of conversion to a chronic disease that occurs with HCV rather than HBV makes chronic HCV infection more prevalent in the general population than HBV (1.8% versus. 0.2% to 0.5%). Chronic HCV infection is the second most common cause of chronic liver disease (alcohol is the first). Before the advent of tests capable of screening for HCV and thus helping to eliminate this virus from the blood supply, HCV was the most common cause of posttransfusion hepatitis. Since the introduction of second-generation immunoassays for the virus in 1992, the risk of posttransfusion hepatitis C has declined and is estimated to be about .01% to 0.001% per unit transfused. The risk of inoculation from a single needle stick accident from a known positive patient is estimated to be approximately 1.8% in prospective studies (range 0% to 7%).

Human Immunodeficiency Virus (2,3)

The first reported cases of AIDS were described in 1981 when previously healthy homosexual men were diagnosed with *Pneumoscystis carinii* pneumonia and Karposi's sarcoma. By 1997, there were an estimated 1.1 million people infected with HIV (a prevalence of 0.4% or 1 in 250). Most of these cases are confined to high-risk groups (e.g., homosexual males, intravenous drug abusers, hemophiliac patients). The prevalence in low-risk groups is much less. The estimated risk of sexual transmission of HIV from a known positive source is 1 in 300 for male-to-male transmission, 1 in 500 for male-to-female transmission, and 1 in 1000 for female-to-male transmission. The estimated risk of acquiring HIV after a percutaneous encounter with a sharp instrument contaminated with HIV is estimated at being 1 in 300 (0.32%). The risk is increased when the injury involves a hollow-bore needle that has been inside an artery or vein and when it is more severe than a simple needlestick. In a retrospective case-control study, the use of zidovudine after percutaneous exposure was associated with an 80% reduction of HIV transmission. As of June 2000, the Centers for Disease Control had documented 56 cases of confirmed seroconversion after occupational exposure and an additional 138 of possible seroconversion after occupational exposure.

OSHA Blood-Borne Pathogens Standards

The OSHA requirements for blood-borne pathogens can be summarized as follows. OSHA requires that the regulations for safety be posted for all employees to see. The employer has the responsibility to provide masks, safety gloves, gowns, and protective eye wear when there is a "reasonable" risk of exposure to blood-borne pathogens. The employee must be offered

hepatitis B vaccinations at no cost. The proper handling and disposal of sharp materials contaminated with blood and other body fluids is required. The adoption of universal precautions is required. It is this last requirement that is discussed in this chapter at some depth.

Certainly, there are no disputes surrounding the requirement that physicians provide their surgical staffs with items that give adequate physical protection in the form of barriers. What has emerged as a topic of debate centers on the need to presume that all patients are potential carriers of a blood-borne pathogen.

The goal of universal precautions is to treat any particular patient, regardless of the individual's true infection status, as an actual threat. Ideally, the strategy will minimize the risk of infection from exposure to infected patients who test negatively because they have not yet undergone seroconversion. Such patients must be treated with the same caution as those with a proven disease state.

Preoperative Testing for HIV and Hepatitis

Controversy exists over the practice of obtaining routine preoperative screening tests for HIV and hepatitis. The arguments for testing, relating to universal precautions are that if it can be shown that a patient is positive for HIV or hepatitis, "extra special" universal precautions and more careful protection can be afforded to the employees who in turn can take "extra" care to avoid contamination.

Arguments Against Testing

Detractors cite several flaws in this logic. They contend that if universal precautions are in place and if all patients are treated as if they pose risk for exposure, the epitome of caution has been reached . If, in fact, a patient with a positive result is treated differently, routine universal precautions are not being followed. Moreover there is the dilemma of the patient who has been exposed to the HIV virus but who has not yet undergone seroconversion. If this patient is treated with less regard or as a low risk, the staff will be at a higher risk for exposure if anything less than standard universal precautions are followed. There are other arguments made by opponents to routine preoperative testing for HIV and hepatitis. The incidence of a positive test in a preselected *low-risk* group, such as hair transplant patients is low, and the cost of testing is high. It is not considered cost-effective to do routine screening. It is interesting to look at the statistical probability of an employee's contracting HIV if stuck by a needle from an unknown source during a single-hair transplant procedure. Statistical analysis states that the total probability for an event to occur is the product (or multiplication) of the probability of the individual factors that need to occur for the event to take place. This means that the probability of an employee's contracting HIV from a needlestick during a procedure is the product of the probability of a patient's being HIV positive times the probability of a needlestick causing seroconversion. *[Formula: "Prevalence of HIV in normal population" (.4%) x "Incidence of seroconversion from a single needlestick (.33%)] The* math shows this to be as follows:

4% × .33% = .001%, or a in 75,000 probability

Other considerations against testing are the obligation to provide proper counseling and disposition for patients who have a positive test and the high incidence of false-positive tests in groups with low prevalence. It has also been argued that it is more efficient to screen only those patients who appear to be in a high-risk category as revealed by their medical history. There are well-known medicolegal problems associated with such a policy of "profiling."

Arguments for Testing

Proponents of routine testing counter with the point that, unlike general surgery, hair transplantation is a totally elective procedure, and there is no need to accept any risk, no matter how small, of exposure to blood-borne pathogens. They argue that routine screening for a totally elective procedure in a small, select group such as this should not be looked at in the same light as routine screening for the general public.

Another argument supporting preoperative hepatitis and HIV screening has to do with the clinical and medicolegal situation that exists after an accidental occupational exposure. That is, if the disease status of a patient is unknown, and there is an exposure incident, in all likelihood a request will be made to test the source patient. A problem may occur if the source patient refuses to undergo testing by virtue of the right to privacy, which must be balanced with the exposed health care worker's right to know. Some state and federal laws may address this issue (4). In addition, although studies of preoperative testing do not support this practice, and the probability of finding a significant surgical risk not picked up by history is low, for the one patient who does turn out to be positive, statistics do not matter. A preoperative test would have resolved the issue before there was an exposure incident. In some offices, physicians get around this by asking patients to give permission for an extra tube of blood to be drawn and held until after surgery for testing in the event of an accidental needlestick.

OSHA does not stipulate whether preoperative laboratory tests for blood-borne pathogens should be ordered. This is a medical decision and if, in fact, strict universal precautions are being followed, the operating-room staff is protected regardless of the status of the patient. A small survey of 30 physicians who perform hair transplants around the United States revealed that currently both practices are about equally common (5). The question of whether to perform an elective, cosmetic procedure on a patient who is HIV-positive or hepatitis-positive is outside the scope of this chapter. There are no general guidelines or consensus. It is a decision to be based upon the judgment of the individual physician, the level of competence of the staff, and status of the individual patient. The arguments against performing surgery are the risk to the staff and the potential harm to the patient from undue surgical stress. Physicians who perform surgery on these patients present these arguments. All patients have a right to cosmetic surgery regardless of their infectious disease status. Modern medications contribute to successful management of patients with hepatitis and HIV; therefore, a hair transplant may not present a grave risk to their health.

Dealing with Accidental Exposures

An accidental exposure is defined as a percutaneous injury, a needle stick, or a cut with a sharp object, for example, combined with contact of the injured site with blood, tissue, or other potentially infectious material. Once this occurs, decisions must be

made regarding postexposure management and postexposure prophylaxis (PEP).

The U.S. Public Health Service has published guidelines for the management and PEP of exposure to HBV, HCV, and HIV (6). In addition, a National Clinicians' Postexposure Hotline ([PEP line] 1-888-448-4911) can be used to consult with an expert. These sources can provide details of the protocols and the decision process for the severity of the exposure; however, a brief description of the protocol for each exposure is presented here.

The risk of HBV infection from an occupational exposure is related to the hepatitis B e-antigen (HBeAg) status of the source person. The risk of developing clinical hepatitis when the source is positive for both HBeAg and hepatitis surface antigen is between 22% and 31%. An HBV exposure requires the administration of hepatitis B vaccine, if the person has not been vaccinated previously, as well as hepatitis B immune globulin (HBIG). Employees who have been immunized with hepatitis B vaccine and who have a positive HBV antibody are protected against HBV exposure.

Studies have shown that HCV is not transmitted to any great degree through occupational exposures to blood. The risk of seroconversion after exposure is 1.8%. There have been no studies to assess use of antiviral agents to prevent HCV infection and therefore there is no PEP for HCV. Postexposure management involves early detection of chronic disease and referral for treatment options.

HIV transmission after an exposure has been estimated to be approximately 0.3%. PEP for this exposure consists of a 4-week regimen of either zidovudine (ZDV) and lamivudine (3TC), 3TC and stavudine (d4T), or d4T and didanosine (ddI). When there is an increased risk of transmission, such as an exposure to a larger quantity of blood, a third drug may be added to the regimen. In cases of occupational exposure, strict adherence to OSHA guidelines and prompt (within 2 to 3 hours) evaluation by qualified personnel is recommended.

General Preoperative Laboratory Testing

The need to perform *general* preoperative laboratory testing and screening is another area of controversy. OSHA's standards play no role in this debate. To evaluate the status of a patient's health, physicians obtain these tests. In this field, some of the routine tests ordered are complete blood count (or hematocrit and hemoglobin), electrolyte panel, prothrombin time (PT)/partial thromboplastin time (PTT), and urinalysis. Presumably, these tests evaluate the patient's "fitness" to undergo the procedure in terms of the ability to withstand anesthesia, achieve homeostasis, and withstand the surgical insult. In general, studies evaluating the necessity and value of preoperative testing support the adage that one should not order a laboratory test unless the results of the test will change the course of action.

Studies on electrolyte testing reveal that abnormalities are rare in otherwise healthy individuals, and that the rate of abnormal results increases with increasing age and/or history of hypertension. The effect of abnormal electrolytes on postoperative recovery does not generally seem to increase the risk of postoperative dysrhythmias (7).

Adequate hemoglobin and hematocrit levels have traditionally been set at 10 g and 30%, but the rationale for these values is not explicit in the literature. The National Institutes of Health Consensus Conference in 1988 stated that the available evidence did not support this rule. The literature is somewhat mixed on whether preoperative anemia increases the risk of postoperative complications. Exceptions to this rule are patients who have reached the ninth decade of life and those who are in high-risk categories owing to concurrent medical problems (7).

Screening for coagulopathies usually includes a PT/PTT levels and a platelet count. A bleeding time test is needed to screen for platelet abnormalities. Multiple studies have given evidence that these tests are not usually predictive of postoperative bleeding, nor do the results predict intraoperative bleeding (7).

A preoperative urinalysis in hair transplant patients is probably of limited value. It is undertaken to identify patients with occult renal disease or urinary tract infections. Abnormalities in this test are common, ranging from 5% to 39%, yet only 0% to 6% of abnormalities require further testing or treatment. The chance of a wound infection from a urinary tract infection in this setting approaches 0% (7).

Because of lack of correlation between any "routine" preoperative laboratory studies and postoperative morbidity, our offices have adopted a protocol of using clinical indicators and a medical history to determine the need for laboratory tests. In addition, with the state of managed care and frequent routine physician examinations, many laboratory tests are obtained for routine health maintenance. Often laboratory tests have been done within a year of the proposed hair transplant, and, therefore, use of these results should be adequate. A study by McPherson and colleagues (8). noted that tests repeated within a year showed a 0.4% abnormality rate on retest. Most of these abnormalities could have been found by means of a medical history and physical examination. Therefore, laboratory tests obtained within a year can be reasonably accepted as valid unless there has been a change in the patient's medical history.

In Dr. Harris's office, a medical questionnaire is given to the patient that looks for risk factors that suggest the need for testing. Risk factors for HIV, hepatitis B, and hepatitis C (such as a history of blood transfusion, intravenous drug use, and hypersexual activity), and a history of diabetes mellitus, hypertension, renal or cardiac disease, and current medications are elicited by direct questioning. Dr. Harris has had more than 7 years of experience as a head and neck and facial plastic surgeon in private practice, performing both elective and nonelective procedures. His use of the history and physical examination as a screen has eliminated the need for "routine" laboratory testing. After thousands of cases, not a single incident has occurred when use of this protocol led to an untoward event.

7E. Antibiotic Use in Scalp Surgery

John Karl Randall

INTRODUCTION

This chapter explores the rational administration of antibiotics in the prophylaxis of surgery of the scalp using evidence-based medicine. Evidence-based medicine (Tables 7E-4 and 7E-5) empowers practitioners to make rational, scientifically based decisions about the care of individual patients.

Evidence based medicine is used for grading treatment, diagnosis, prognosis, and other aspects of medical care. The best