

A close-up photograph of a man with short brown hair and a light beard, wearing a white lab coat. He is looking through the eyepiece of a black and gold microscope. The background is a blurred laboratory setting.

Beware:

Not All Labs Are Created Equal!

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Your Skin Biopsy.

There is a major epidemic of skin cancer in the world today. In the United States alone, well over 1 million skin cancers will be diagnosed just this year. Furthermore, it is estimated that approximately 1 in 50 individuals born this year will develop malignant melanoma, the most dangerous and often life threatening form of skin cancer in their lifetime. This cancer is the leading cause of death in young women in their 20's. However, skin cancers are most common in older people over the age of 50. Because of the gravity of this problem, it is vitally important that all individuals, especially those in the highest risk groups, understand how to recognize the signs of skin cancer and call it to the attention of their doctor, preferably someone with expertise in skin diseases such as a dermatologist. If there is suspicion that a spot may be skin cancer, a biopsy must be performed to make a diagnosis before treatment is undertaken. Getting an accurate diagnosis from the biopsy is critical as different treatments are used for different skin conditions and if the lesion turns out to be benign, no treatment at all may be required.

What many patients and surprisingly many doctors, especially non-dermatologists, do not understand, however, is that there is significant variation in the accuracy of different pathology labs depending on who is performing the examination of the biopsy. Many doctors try to reassure their patients that they are "sending the specimen to the lab." What you should ask your doctor is, "Which lab and who's going to be reading my biopsy"?

CHANGING TIMES

Years ago and still in many cases today, doctors, especially dermatologists, developed close working relationships with consultants known as dermatopathologists who are specially trained to interpret skin biopsies. With the advent of managed care, however, large laboratory companies made bids to provide laboratory services, mainly blood tests, for managed care plans. Because managed care organizations (MCOs) look at all lab services as a whole, many of the specialized areas of pathology such as dermatopathology, where an expert performs the service, were lumped into the same category as blood tests per-



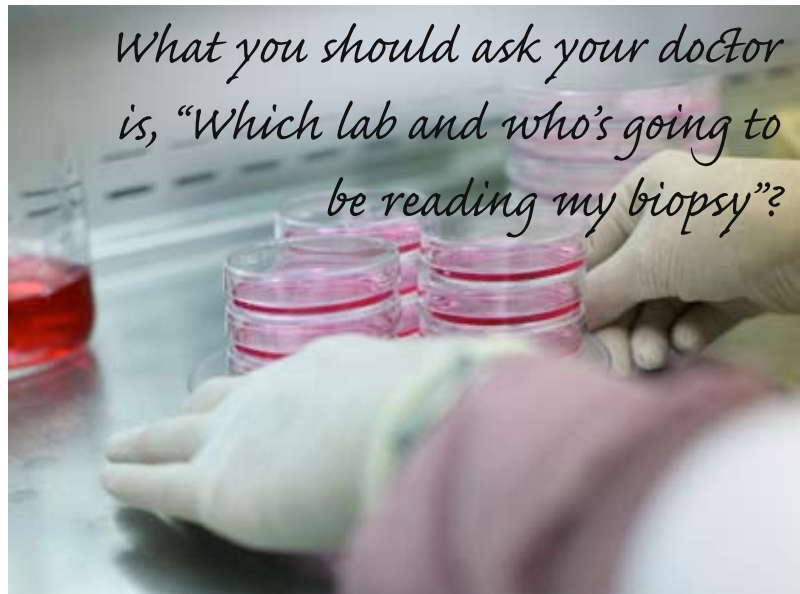
formed by a machine with no need for a physician. Consequently, many skin biopsies are now sent to large organizations in which there is no expert available, which can lead to errors in diagnosis. Furthermore, there are cost pressures that discourage non-experts from seeking second opinions from others.

SERIOUS CONSEQUENCES

A misread specimen can have serious consequences for a patient. Failure to diagnose a skin cancer, especially a melanoma, can result in a disease that can be cured turning into a deadly process. On the other hand, over-diagnosis of something benign as a cancer can lead to loss of insurance or significantly increased insurance premiums, not to mention unnecessary and sometimes disfiguring surgery. In some cases, patients simply go for months, sometimes years with no diagnosis or an erroneous one. In addition to poor patient care, inaccurate lab results can lead to legal liability and increased health care costs.

DEPENDING ON EXPERT DERMATOPATHOLOGISTS

The most important key to accuracy involves the expertise of the person who is reading your biopsy. While board-certified dermatopathologists are certainly the best trained to read skin biopsies, some general pathologists with interest and experience in dermatopathology can do a good job, especially if he or she has access to consultation with a board-certified dermatopathologist. In the ultimate analysis, it's not the label of the person who evaluates the slide that matters but his or her competence, says A. Bernard Ackerman, M.D., director of the DermPath Diagnostics/Ackerman Academy of Dermatopathology in New York City. As a rule, however, Dr. Ackerman notes that a board-certified dermatopathologist is best equipped to render an accurate diagnosis of a skin lesion that is difficult



to diagnose under the microscope, a phenomenon that is surprisingly common.

While many patients may not know it, some dermatologists are qualified themselves to read slides on skin biopsies they take from their own patients, but they need to make sure they avoid potential conflicts of interest. In order to ensure there is no conflict of interest the patient should know that the dermatologist will charge a fee for both performing and interpreting the biopsy.

CHALLENGING LESIONS

Expertise becomes even more crucial in lesions that are difficult to interpret. Some subtle skin disorders, such as mycosis fungoides, a rare type of skin lymphoma, require very special expertise to make the right diagnosis, says Brian Adams, M.D., associate professor in the Department of Dermatology at the University of Cincinnati Medical Center. Non-cancerous skin diseases due to inflammation such as rashes can be diagnosed accurately only by dermatopathologists. Other challenging diagnoses are diseases that produce blisters such as bullous pemphigoid, pemphigus, and epidermolysis bullosa.

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ON THE "LOW END"

Related to these issues and worrisome to various clinicians are pressures by managed care organizations to use "low end" labs. Some MCOs require physicians to send specimens to a specific lab that may or may not have an individual with expertise in dermatopathology. One organization recently instituted a program to fine physicians who fail to utilize contracted laboratories, a practice that is currently receiving sharp criticism from many major medical

organizations. Many dermatologists choose to opt out of contracts in which the biopsies are “steered” to a “low end” lab. They fear that these labs might not provide complete service for their patients and pose a malpractice risk to them.

Some large labs employ many pathologists that must read a certain number of specimens to meet productivity goals. An overflow of specimens sometimes doesn’t allow

in many regions. Fortunately, many are realizing that it’s penny wise and pound-foolish to alienate dermatologists.

WHAT VOLUME IS APPROPRIATE FOR A PATHOLOGIST TO READ?

Besides the qualifications of the clinician reading the specimens, another concern involves the sheer number of specimens pathologists are called to read. How much is too much for any one pathologist? That depends on a variety of factors including the pathologist’s comfort and confidence as well as the lab’s efficiency and level of automation. Another factor is whether the lab receives specimens from a referral practice, which likely will present more complex cases for interpretation. No benchmark exists beyond which he starts to worry, says the official from the College of American Pathologists. While the number of cases the doctor is expected to read can be a problem, the bottom line is the ability and expertise of the doctor who is performing the interpretation.

If you or your doctor is not happy with the quality of service from a lab, a number of different steps can be taken. Generally, the first step is a letter from your doctor and in some cases from the patient addressed to the MCO expressing complaints.

THE IMPORTANCE OF COMMUNICATION

the “cognitive effort” that a particular case might require. “Low end labs assume a huge liability if it turns into an “industrial mill of pathology,” notes an official from the College of American Pathologists. Although many MCOs are becoming more aware of this issue, it is still a problem

factor in making sure your doctor gets the “right” answer in your skin biopsy. When your doctor, especially a dermatologist, performs a biopsy, he or she is not sending out a simple blood test to a nameless lab. He or she needs to know who the pathologists are and work with them.

TESTS OF THE FUTURE

As science advances, so does the sophistication of tests used to diagnose dermatology specimens. For instance, during the last 10 to 15 years, labs have done immunocytochemistry (ICC), which directs antibodies against a specific cell line. Labs use special ICC stains to determine if a specimen is a melanoma, for example.

In the future, expect to see more use of pharmacopathology (a further expression of ICC). This process involves identifying specific biologic targets by staining tissue. The loop is then closed because researchers will develop specific agents to kill that target.

Recently, pharmacopathology has been used to evaluate breast cancer, identifying a specific biologic target called HER2/neu. It’s just a question of time before this technique is applied to many other conditions, including melanoma.

Applying molecular techniques to specimens will play a large role in this century. Pathologists now are looking at various molecular genetic characteristics of specimens, such as monoclonality in mycosis fungoides with paraffin-embedded tissues. One question looms, however: will MCOs, which are most concerned with the financial bottom line embrace such advances as they become available?

