

## Closed Claim Abstracts

The following closed claim abstracts vividly illustrate some of the ways in which errors may occur with diagnosing a malignant melanoma.

## Case #1

During a routine office visit, a 38-year-old married woman brought our insured Internist's attention to a "mole" on her left leg that had been there for an uncertain amount of time.

She stated that it was constantly being irritated by shaving and occasionally bled. The doctor noted that the lesion was small, approximately 2 millimeters in diameter, not irregular in shape, round with the appearance of a small wart and of normal skin color. The Internist made the diagnosis of seborrheic keratosis and decided the best treatment was cryotherapy. The patient agreed to this procedure, especially since it was the least invasive treatment. Cryotherapy was applied several times in three to five minutes without complication. The Internist instructed the patient that if the lesion did not disappear she was to call him and he would recommend a dermatologist.

In subsequent visits for other matters, the patient never inquired nor showed him a lesion on her leg again. A little over a year after the initial cryotherapy, the Internist froze the "mole" again. Three months after the second freezing, the mole reoccurred. The Internist referred the patient to a dermatologist who biopsied the lesion, making the diagnosis of melanoma. A month later the patient underwent surgeries to remove the melanoma and also the lymph nodes in the area of her left groin. The melanoma had spread to one of those nodes. The patient attempted a round of chemotherapy with Interferon. However, she was only able to

Early Detection of Melanoma -  
The Best Hope for a Cure

By E. Dan DeLoach, M.D.

The incidence of malignant melanoma has increased in recent years, more than that of any other cancer in the United States. About one in 70 people will develop melanoma during their lifetime<sup>1</sup>. The mortality rate is increasing by 2 percent per year, while survival rates are improving—which tends to confirm the impression of a true increase in incidence rather than simply an increase in detection<sup>2</sup>.



All medical specialties evaluating and treating skin lesions are involved. Of the most prevalent procedures involved in claims submitted to the PIAA's Data Sharing Project in 2003, operative procedures on the skin, excluding skin grafts, were ranked # 12 in terms of frequency. Forty percent of claims filed were paid. The average severity of these claims was seven on a scale of one to nine with nine being the most severe<sup>3</sup>.

In the 2004 Edition of the PIAA Data Sharing project, the most prevalent medical misadventure in pathology claims was diagnostic errors, reported as the primary issue in 60 percent of claims from 1985 through 2004. Of these errors in diagnosis by pathologists, malignant melanoma resulted in the highest percentage of paid claims (55.3%) and had the highest average payment (\$396,336). Regardless of medical specialty, failure to make a timely and correct diagnosis can spell the difference between life and death for the patient.

Several factors may help to determine if a patient is at increased risk of having a melanoma.

Melanomas often show the "ABCD" symptoms:

- **A**symmetry, when one half of the growth has a different shape than the other
- **B**order irregular, when the growth has scalloped or uneven edges
- **C**olor varied, when the growth is more than one color. Melanomas may be black, shades of brown and tan, and even have specks of red, white, and blue
- **D**iameter, when the size, measured edge to edge, is bigger than the diameter of a pencil eraser

View pictures: [www.tustison.com/melanoma\\_images/abcd.shtml](http://www.tustison.com/melanoma_images/abcd.shtml)

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tolerate a week of treatment before becoming very ill. She complained of lymphedema from the lymph node dissection. She was being closely monitored at the time of the mediation.

Plaintiff alleged a delay in diagnosis of melanoma of 21 months. The Internist was advised by the attorneys to settle the case because of the probability that the melanoma would reoccur and spread causing greater damages. The case settled for a large amount.

Some Risk Management thoughts:

- The physician's records lacked thorough documentation and a plan of action concerning the "mole". This resulted in a case of "he said-she said"
- The physician did not place the "mole" on a problem list in the patient's medical record and did not actively track its status upon the patient's return visits for other matters
- Too much time elapsed before a proper and timely referral was made

### Case #2

This case involved a 39-year-old, married, white ER physician who underwent an excision biopsy of a lesion on his right hand. The specimen was sent for pathological examination and interpretation by our insured pathologist. The pathologist diagnosed the lesion as a pigmented compound nevus. The pathologist sent the specimen to her partner for a second opinion. She stated he concurred with her opinion. However, the partner said he never looked at the slides.

Two years later the lesion reoccurred. This time the biopsy revealed malignant melanoma with metastasis, Clark's Level IV. The prior pathology was reviewed, and it was discovered that the prior diagnosis should have been malignant melanoma. The patient continued to have reoccurrences and his prognosis was poor. The plaintiff alleged a 20-month delay in diagnosis of malignant melanoma. The case was settled for a very large amount.

Some Risk Management thoughts:

- The pathology group had no formal, documented quality control program in place.

## A High Index of Suspicion for Melanoma

*Continued from page one*

**Table 1: Risk Factors for Melanoma<sup>4</sup>**

Risk Factor	Relative Risk*
History of a changing mole	400
With a family history of melanoma	148
With a personal and family history of melanoma	500
Large congenital nevus (15 cm or more in diameter)	17
White race	10 to 12
Personal history of melanoma	9
History of melanoma before age 40	23
Regular tanning bed use before age 30	7.7
Multiple nevi	5 to 12
Atypical nevi	7 to 27
Immunosuppression	4 to 8
Family history (first-degree) of melanoma	3 to 8
Nonmelanoma skin cancer	3 to 5
Sun sensitivity (tendency to sunburn)	2 to 3

\*The relative risk is the increase in risk for melanoma with the risk factor present versus when the risk factor is absent.

There are several types of pigmented skin lesions that may mimic melanomas: melanocytic nevi, seborrheic keratoses, dysplastic nevi and blue nevi are the more common ones. View pictures: [www.tustison.com/melanoma\\_images/skin.shtml](http://www.tustison.com/melanoma_images/skin.shtml). Ultimately, the diagnosis rests on the shoulders of the physician. A higher index of suspicion is indicated for any pigmented lesion.

- The lesion should be examined under adequate lighting
- A magnifying lens may be of benefit
- Digital image analysis and dermoscopy seem to hold promise for a more accurate diagnosis
- If there is any doubt whatsoever, perform a biopsy
  - If the lesion is small, the biopsy can be excisional, extending into the subcutaneous tissue with a 2 or 3 mm margin around the lesion, and then closed with sutures
  - If the lesion is larger, one or several punch biopsies can be taken, preferably in the thickest portion of the lesion
  - If there are variations of color within the lesion, multiple biopsies may be indicated
  - A shave biopsy is not usually done for a pigmented lesion, as it may destroy the ability of the pathologist to diagnose the depth of invasion of the melanoma accurately. This is particularly important given that the deeper the invasion, in general, the more aggressive the treatment and the poorer the prognosis
  - The lymph node basin draining the location of the lesion should also be assessed

In most cases, excision of the lesion with several millimeter margins extending into the subcutaneous tissue is adequate. If the lymph node basin is involved, a node dissection may be indicated and surgical consultation should be obtained. Biopsy should be utilized if there is any question of the diagnosis.

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Maintaining a high index of suspicion for melanoma is the best hope for a timely diagnosis and cure.

<sup>1</sup>AM Fam Physician 2001;63:1359-68,1374

<sup>2</sup>Dennis LK. Analysis of the melanoma epidemic, both apparent and real: data from the 1973 through 1994 surveillance, epidemiology and end results program registry. Arch Dermatol 1999;135:275-80.

<sup>3</sup>PIAA Data Sharing Project 2003, Report # 42

<sup>4</sup>Adapted from Rhodes AR, Weinstock MA, Fitzpatrick TB, et al. Risk Factors for Cutaneous Melanoma. JAMA 1987;258:3146-54

## Pain Management: Consider Using Clinical Pharmacy Expertise

By Georgette Samaritan, Senior Risk Management Consultant

Jo Anne strained her back. Before long her physician was prescribing about \$10,000 a month in medications. Jo Anne's case illustrates how physicians may prescribe large amounts of drugs to manage a non-surgical condition. Quality of patient care and safety are risk management issues in pain management.

In this case, Jo Anne's physician appears to have been trying to control her pain by adding drugs as her symptoms evolved. By the time she was terminated from the practice for "drug-seeking," Jo Anne was taking 18 different medications. These medications included six different narcotics, two different strengths of Actiq lozenges, one muscle relaxant, one non-steroidal anti-inflammatory drug (NSAID), one medication for insomnia, one medication to combat daytime drowsiness, three antidepressants, one drug to combat decreased mental ability, one antihypertensive, and one drug for acid reflux.

According to pharmacists, this pain management scenario is not uncommon. The following cycle of pain management is observed in many practices:

- Prescribing several pain drugs designed to provide immediate relief in order to address the patient's 24-hour pain management experience
- Adding extended-release pain medication follows this regimen
- Actiq delivered by lollipop is given at the next stage to provide on-the-spot relief from pain spikes. Although this technique is reserved for severe cases, Jo Anne's experts doubted its necessity in her case
- New drugs become necessary to combat the side effects of the existing drugs like insomnia, daytime drowsiness and depression

The goal of pain management should be to reduce pain, maximize function and improve the patient's quality of life. Consider these **risk management suggestions** when practicing pain management:

- Ask the patient to complete a pain questionnaire
- Probe to find out if the patient is highly functional in activities of daily living, such as driving, shopping and recreation
- Determine how and when pharmacy expertise should be utilized
- Determine at what point the patient should be referred to a pain management specialist or other specialist for evaluation/second opinion or treatment

### Case #3

This case involves a 44-year-old male referred to a MAG Mutual insured plastic surgeon for removal of a nevus that the patient discovered on his neck. The surgeon removed the nevus and sent it to pathology. The pathology report indicated that the nevus was malignant melanoma in situ and that the margins of the incision were involved in the melanoma. For unknown reasons, the surgeon never saw this lab report and never followed up. The referring dermatologist did not receive a copy of the lab report or a consultative report from the plastic surgeon. The patient did not return to the referring dermatologist's office.

Approximately one year after the nevus removal, the patient returned to the plastic surgeon for treatment of seborrheic keratosis. The records of that visit do not reflect any further discussion of the nevus removed the prior year. Four years after the original nevus removal, the patient had a sudden onset of seizures. He was admitted to the hospital where he was ultimately diagnosed with malignant melanoma and extensive metastasis involving the brain, lung and adrenal glands. He was admitted to a hospice for palliative care and died within a few weeks. The case settled for a large amount.

Some Risk Management thoughts:

- Neither the dermatologist nor the surgeon had tracking systems in place. If the dermatologist had a referral tracking system in place, he may have realized that he hadn't received a call or report from the surgeon. At that point he could have called, prompting the surgeon to follow-up with the lab results
- More importantly, the surgeon did not have an internal lab tracking system in place, which would have alerted him to the fact that the report had not been received. Unfortunately, neither physician had a patient recall system in place

# Limiting Risk with Sound Employee Record Keeping

By Joe Deroko, Manager Training & Development

Creating and properly maintaining personnel files and records should be a key part of any medical practice's business in today's workplace. Federal and State mandates regulate the inquiring, obtaining and maintaining of employee information. An employer must have policies and procedures in place to ensure that the maintenance of employee records meets these rules & regulations and to limit the practice's liability should a governmental audit take place or legal action be incurred.

## Step One: Setting Policy

The first logical step for an employer is to create a written policy on how records will be kept, accessed and where they will be housed. This will ensure consistency in record keeping practices. The most important aspect of a written policy is that it complies with applicable laws. The policy should also define what specific records will be kept and in what files. One of the common mistakes employers make is keeping all of an employee's records (general employment information, medical records, I-9 etc.) in the same file. Your policy should also set forth who will have access and to what information, procedures on how an employee can request access to their own records and where those records will be housed. Lastly, it is wise to include a timetable on when your records will be reviewed. It is good practice to periodically review files to correct or in some cases even remove outdated, inaccurate or irrelevant information.

## Step Two: Your Files

One of the most common pitfalls for employers is not separating out employee information. A "personnel file" should not be a catch-all for any information that you have pertaining to an employee. Your basic personnel file should include:

- Employment application and resume
- Employee actions (hiring, promotions, transfers, rate changes etc.)
- Performance appraisals
- Disciplinary actions and termination records

This information is helpful for employers, your HR staff and the employees' direct supervisor. However, this is not the only file you should keep.

**Medical Records** - The American with Disabilities Act requires employers to keep all medical records separate. Access to this file should be heavily restricted. The only time a non-HR supervisor should be privy to any of this information is when setting up a reasonable accommodation.

**Immigration Forms (I-9) and Equal Employment Opportunity** - Any documents that identify the employee's race or sex should be kept separately and restricted to those with HR responsibilities. This is to minimize any possible claim of discrimination. It is also good practice to maintain I-9 forms chronologically by year.

## Step Three: Stay Informed

It is critical that you stay aware of any federal or state laws regulating your obtaining, maintenance and employee access to personnel files. This article acts as a primer to setting policy and giving tips on maintaining records. However, you need to make sure you know which federal and state laws impact your individual practice.

For more information on this subject, go to [www.dol.gov](http://www.dol.gov).

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