

CASE STUDY WITH RISK MANAGEMENT STRATEGIES

Presented by HPSO and CNA

Medical malpractice claims can be asserted against any healthcare provider, including pharmacists. Although there may be a perception that physicians are held responsible for the majority of lawsuits, the reality is that pharmacists are more frequently finding themselves defending the care they provide to patients.

Case Study: Failure to Monitor

Settlement Payment: \$38,625 Legal Expenses: \$30,853

In this case, the defendant pharmacist was employed by a home infusion pharmacy where he was the head pharmacist and also was appointed director of pharmacy. The home infusion company provided home health care to patients, including the dispensing and administration of oral and parenteral medications, nursing care, personal care services and case management.

The plaintiff in the case was a 44-year-old man who noticed bumps developing on his wrist that were beginning to spread. On day one, the man developed a fever. On day two, he was treated by his physician with an injection (medication unknown) to the affected site. The symptoms continued to progress and on day nine, the patient underwent a bone scan. From the bone scan results, the diagnosis of osteomyelitis was determined and the patient was admitted to the hospital on day ten.

During the patient's hospitalization, his physician prescribed a combination of intravenous Vancomycin and Gentamicin to treat the osteomyelitis. The medication dosage and the patient's response to treatment were monitored by the patient's physician and the hospital pharmacist. The patient was discharged on day 21 with physician orders that the intravenous Vancomycin and Gentamicin be continued. The medication was to be dispensed by the defendant pharmacist and administered by the home infusion company's nursing staff.

During the course of the home infusion antibiotic treatment, the defendant pharmacist obtained, reviewed and evaluated the results of laboratory tests ordered by the physician in order to determine the patient's condition and response to treatment. When the defendant pharmacist noted that the laboratory results indicated the need for a change in antibiotic dosage, he contacted the patient's physician who then ordered the appropriate dosage adjustments.

The defendant pharmacist noted that an order to test the patient's creatinine levels was not included in the listing of laboratory tests ordered by the physician. The defendant pharmacist suggested to the physician that the patient's creatinine levels be tested. The physician did not order the creatinine levels and the defendant pharmacist did not insist or pursue the matter further because he did not receive any communication from the physician or home health nurses regarding patient complaints or symptoms that would have indicated problems with the medication as it was being administered.

On day 52, the patient was treated by the physician for complaints of dizziness, nausea and swelling of his ears. The physician maintained the patient on the same medications for twelve more days but neither the physician nor the nurse reported the patient's symptoms to the defendant pharmacist. On day 64, the physician referred the patient to an orthopedist. The orthopedist discontinued Vancomycin and Gentamicin and changed the patient's medication prescription to Zyvox.

The patient was subsequently diagnosed as having developed vestibulopathy (damage to the inner ear), with postural instability (dizziness), gait ataxia (unsteady gait) and oscillopsia (visual disturbance) as a result of long-term intravenous Vancomycin and Gentamicin therapy.

The patient sought damages and sued the defendant pharmacist, the home infusion pharmacy, his physician, the hospital, and the hospital pharmacist. The patient claimed damages for pain and suffering resulting from the permanent side effects from his treatment with Vancomycin and Gentamicin. The claim against the defendant pharmacist alleged that his failure to properly monitor the patient's medications resulted in the plaintiff's injuries.

The defense counsel employed two expert witnesses, a pharmacokineticist and pharmacist to support the case. The experts indicated that the use of Vancomycin and Gentamicin together was appropriate, and they did not believe the defendant pharmacist should have overridden the physician's prescription. The experts did criticize the defendant pharmacist's record keeping, stating they could not determine from his notes if the medication dosage was correct. The experts indicated that the defendant pharmacist should have insisted on the physician's obtaining renal function laboratory tests.

The plaintiff's expert witnesses were critical of the defendant pharmacist's failure to warn the patient's physician that the use of Vancomycin and Gentamicin in combination carried an increased risk for ototoxicity. They stated the defendant pharmacist did question why creatinine levels were not ordered but deviated from the standard of care by failing to insist upon obtaining and monitoring serum creatinine concentrations while the patient was receiving the intravenous Vancomycin and Gentamicin treatment. The plaintiff's experts further stated that the defendant pharmacist should have withheld dispensing the intravenous Vancomycin and Gentamicin pending the physician's order to obtain the creatinine levels.

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Resolution

The claim against the defendant pharmacist in this case closed with a judgment of \$38,625 with an additional \$30,853 in legal expenses. Information regarding the amount of judgments or settlements on behalf of the other defendants is not available.

Risk Management Comments

- ◆ The defendant pharmacist was aware of the well-known risk of ototoxicity with intravenous Vancomycin and Gentamicin therapy and understood the need for monitoring of renal function tests to determine if the patient was adequately clearing the antibiotics or was at risk of reaching toxic levels.
- ◆ The defendant pharmacist failed to insist that the physician order the standard renal function tests needed to evaluate the risk of toxicity to the patient from prolonged Vancomycin and Gentamicin therapy.
- ◆ Experts determined that the defendant pharmacist's documentation failed to demonstrate whether the antibiotic dosages were correct.
- ◆ There is no evidence that the risks, side effects, benefits and alternatives to extended antibiotic therapy with potentially ototoxic drugs were discussed with the patient or that the patient was told to report any discomfort, signs or symptoms related to the medications. Although this is the responsibility of the prescribing physician, it is a sound risk management practice for pharmacists to verify that staff members administering therapies to routinely inquire about patient signs and symptoms that may contribute to an adverse reaction. Of equal importance, staff members should understand the need to timely report such symptoms to the patient's physician and the dispensing pharmacist.

Risk Management Recommendations

- Develop, implement and follow pharmaceutical practice guidelines for medications that are classified as high risk for severe, potentially permanent effects as a result of drug toxicity and/or prolonged use. Include the following recommendations within the practice guidelines:
 - Require documentation that the physician has been made aware of potential toxicity and side effects from the long-term use of specific antibiotics including enhanced toxicity when certain antibiotics are used in combination.
 - Require that the patient's physician order laboratory/diagnostic tests required for the pharmacist to monitor the effectiveness of the medication as well as to identify abnormal test results that require discussion with the physician.
 - If the physician fails to order the necessary laboratory/diagnostic tests the pharmacist should dispense no additional doses of the medication and discuss the need for the testing with the physician and/or the medical director until the matter had been resolved.
 - Require periodic consultations between the home infusion pharmacist and home infusion therapy staff as part of practice guidelines for patients receiving high-risk medications. During the consultations:
 - Verify that the infusion therapy staff has talked with the patient to ensure the patient received information from the physician regarding the risks and potential side effects of long-term antibiotic therapy.
 - Verify that staff has assisted the patient/family with contacting the physician regarding questions related to their treatment and complaints regarding side effects and/or signs or symptoms the patient is experiencing.
 - Discuss and document all pharmacist and infusion staff and physician interactions regarding the patient's medications that have occurred since the prior consultation.
- Document the clinical decision-making process utilized when determining appropriate dosage, the need for additional consultation with the physician, recommended dosage adjustments, additional patient assessments and continued appropriateness of the antibiotic therapy.

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Guide to Sample Risk Management Plan

Risk Management is an integral part of a healthcare professional's standard business practice. Risk management activities include identifying and evaluating risks, followed by implementing the most advantageous methods of reducing or eliminating these risks - A good Risk Management Plan will help you perform these steps quickly and easily!

Visit www.hpsso.com/risktemplate to access the Risk Management plan created by HPSO and CNA. We encourage you to use this as a guide to develop your own risk management plan to meet the specific needs of your healthcare practice.



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