Informed Consent Abandoned; Patient given Contraindicated Drug

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Abstract:
A middle-aged, alcoholic, long term chronic pain patient, presented to his physician for medication management of his alcoholism. Vivitrol, an opiate receptor antagonist, used primarily in the management of alcohol dependence and opioid dependence, was administered to an opiate-dependent patient. This action was determined by experts to be below the standard of care. The patient sustained a severe, acute reaction and required hospitalization.

The Case
This case involves a male in his mid-forties with a history of depression, alcohol abuse and intractable pain syndrome who was prescribed Vivitrol® (naltrexone), a narcotic that blocks the effects of narcotics and alcohol.

The patient began treatment with Methadone 30 mg three times daily in a pain center for intractable pain with good results. Some months later, the patient sought treatment for his depression from a psychiatrist. The psychiatrist treated the patient for the next two years for depression. He then directed that the patient receive a vagal nerve stimulation device to help with the management and treatment of depression. Unfortunately, post insertion of the device, the patient returned to drinking alcohol on a regular basis.

Two years later, the patient sought help with his alcohol problem and the psychiatrist gave the patient an office injection of Vivitrol®. Of note, the patient was still taking Methadone that was prescribed years ago. (Vivitrol® is contraindicated for patients who are taking narcotics.) On the way home, the patient suffered massive seizures, aspirated, became unconscious and unresponsive. He was resuscitated and transported emergently to the hospital where he remained in a coma and on a ventilator. He was left with severe neurological deficits.

In his lawsuit, the plaintiff alleged the psychiatrist failed to meet the standard of care when he gave him an injection of Vivitrol® 380 mg IM. This induced sudden total opiate withdrawal resulting in seizures, coma, and anoxia with subsequent loss of neurological and mental capacity.
This case was settled for a moderate amount of money.

**Risk Management Commentary**

After the incident, the psychiatrist recognized that administering Vivitrol was contraindicated for use in an opiate dependant patient. The physician had office policies and procedures in place to prevent an opiate dependent patient from receiving Vivitrol®. The policy required nursing staff to discuss Vivitrol with the patient and this discussion included certain questions as to whether a patient was dependent upon opioid medications. The patient’s medical record clearly indicated his dependence on Methadone. The physician’s medical assistant testified that she attempted to review the Vivitrol brochure with the patient prior to administering the injection. This brochure included warning for patients taking opioids such as methadone. Unfortunately, the patient refused to listen to the details of the consent. He told the nurse that he had places to go and demanded he receive the injection. The MA should have paused and referred the matter back to the physician. Instead, the medical assistant administered the injection.

We learned two lessons from this case:

1. The value of a formal Informed Consent process when administering / prescribing medications with “material risks”.

   The relevant question is: "What potential results would a person need to know to make an informed decision to consent or refuse consent?" "Material risks" include those that have a high severity or a high frequency. For the less serious risks, a rough rule of thumb could be if the risk event occurs in 3% of the cases. For the more serious risks; 1% would be sufficient to be a material risk.¹

   In addition, there are state regulations with regard to who can provide Informed Consent. In some states, only physicians can conduct Informed Consent; in others, physicians may delegate Informed Consent to staff. In both situations, the physician remains 100% liable for the process.

2. Although the psychiatrist recognized that administering Vivitrol was contraindicated for use in an opiate dependant patient, he left it up to the patient to advise him of that fact.

   A better approach would have been to employ medication reconciliation. Medication reconciliation is the process of comparing a patient's medication orders to all of the medications that the patient has been taking. This reconciliation is done by the provider, in concert with the patient, to avoid medication errors such as omissions, duplications, dosing errors, or drug interactions. It should be done at every transition of care in which new medications are ordered or existing orders are rewritten.
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Related Topics: NPSF, Informed Consent

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1 Malpractice: Your Informed Consent May Not Be Good Enough, Lee J. Johnson, JD, February 10, 2011