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SPECIAL REPORT: Focus on Controlled Substances

Compliance Monitor

Information Mediary Corporation

Risk Management System for Schedule II Controlled Substances

By Allan Wilson, MD, Ph.D.

Opiate analgesics are widely accepted as best practice in the management of chronic pain syndromes. Unfortunately, such medications have high dependence liability, putting them at risk for abuse.

Chronic pain is estimated to affect 35 percent of the population at some point in their lives. Chronic pain has various definitions. Two such definitions are "Pain of three months or six months duration" and "Persistence of pain beyond what is medically expected". The most common etiologies are degenerative joint and disc disease, rheumatoid arthritis and other spondyleomyopathies, hemarthroses, pain associated with chronic illnesses such as cancer and collagen vascular diseases, and diabetic and other neuropathies.

Chronic pain is managed by pharmacological and non-pharmacological methods. The latter include relaxation training, self-hypnosis, hypnosis, imagining, meditation etc. Pharmacotherapy can be divided into analgesic and non-analgesic.

Non-analgesic pharamacotherapy typical involves anxiety-reducing or mood elevating medications. The most widely used such drugs are antidepressants; Neurontin® (gabapentin) also falls into this category.

"Careful monitoring of the patient's compliance early in treatment before the dependence cycle begins may allow the therapist to guide the patient in responsible, non-problematic use of opiate analgesics."

Analgesics, according to the WHO Ladder model, can be categorized into three stages according to increasing order of effectiveness at pain relief:

1. Non-opiate analgesics, such as aspirin (ASA), acetaminophen, non-steroidal anti-inflammatory drugs (NSAIDS) and cox-2 inhibitors. These are all non-addictive – they do not affect central nervous system (CNS) arousal.

2. Low potency opiates such as codeine phosphate, typically combined with ASA or acetaminophen, or barbiturate-containing compounds such as Fiorinal® (butabarbital, ASA, caffeine), Talwin® (pentazocine) and Darvon® (propoxyphene). These have moderate dependence liability and exert a moderate depressant effect on the CNS.

3. High potency opiates such as oxycodone, hydrocodone, meperidine, morphine, fentanyl, and alphaprodine. These all have high dependence liability and are powerful CNS depressants.

Generally, pain patients are motivated to take medication as directed by their physicians and pharmacists. However, it is well known that patients are not terribly compliant with prescriptions, largely due to forgetfulness. Patient non-compliance with prescribed medications in general is widely accepted as costing the U.S. health care system over 100 billion dollars annually.

The situation with respect to compliance is greatly complicated in the case of addictive medications. Approximately 10 percent of the population is at risk for becoming dependent on addictive substances such as alcohol, opiates, benzodiazepines, barbiturates and stimulants. These individuals, due to a complicated set of factors including the inherited biological response of their CNS to the effects of such drugs, personality characteristics, and cultural and environmental factors, are at risk to seek to continue using such drugs for reasons other than the management of physical pain. The addictive potential of such drugs is not deterministic – it is simply a predisposition to dependence.

Careful management of patients with addictive predisposition can reduce the likelihood of the patient becoming dependent. The problem is that the usual high level of non-compliance can lead pain patients to self-medicate – to alter the intervals at which they take their medication. Ideally, narcotic analgesics are taken at equal intervals on a regular schedule. Increasing the inter-dose interval by accidental non-compliance makes it more difficult to regain

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Electronically Monitoring Compliance with Opiate Analgesic

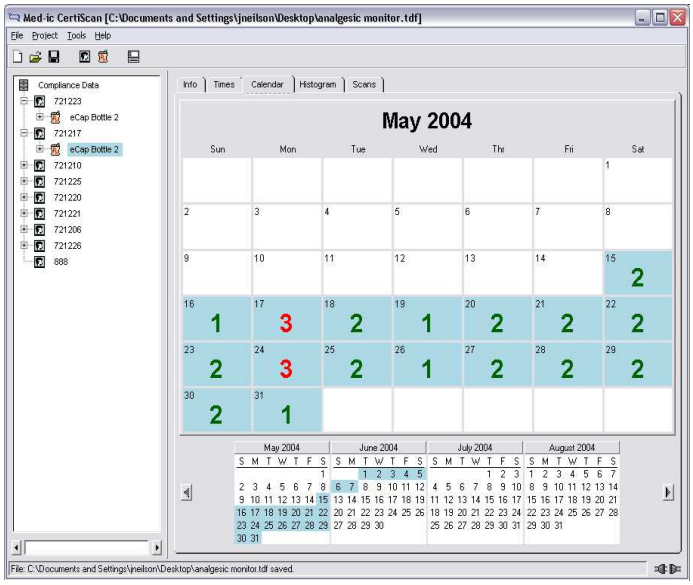
(Continued from page 1)
control of the pain, increasing the patient's anxiety. This leads to anticipatory anxiety as the dosing time approaches, shortening of the inter-dose interval and resulting in escalation of the total amount of medication taken.

By the time the physician or pharmacist recognizes this, the patient may be caught in the addictive cycle, using up a prescription rapidly and perhaps multiple-doctoring or buying medication on the street to avoid breakthrough pain and withdrawal symptoms. Not wanting to leave the patient to withdraw on his own, the physician may engage in this game longer than desirable with the result that the patient becomes seriously opiate dependent.

Careful monitoring of the patient's compliance early in treatment before the dependence cycle begins may allow the therapist to guide the patient in responsible, non-problematic use of opiate analgesics.

Electronically Monitoring Compliance with Opiate Analgesic Therapy

Until recently, compliance monitoring has not been reliable in such situations where patients may have an agenda to deceive the clinician. The Med-ic® ECM™ sheds new light on the careful management of patients who require opiate analgesic therapy. Now, at each follow-up visit, the physician or pharmacist can scan the patient's used medication blister package and see the patient's compliance at a glance. The data can be used to motivate and counsel the patient regarding the responsible use of opiate analgesics.



CertiScan™ Compliance Monitoring Software can provide a physician an "at a glance" view of a patients dosing behavior, quickly identifying problematic use of opiate analgesics.

These data can also be used to motivate the patient to use non-pharmacologic therapies at appropriate points in the procedure, reducing dependence on medication. The Med-ic® ECM™ can even be used to gather information about the patient's perception of pain or other symptoms, which data can be used in the educational process.

Who Benefits

The patient benefits from improved medical care and better pharmacotherapeutic guidance. The Med-ic® ECM™ can drive auditory and visual reminder devices to improve patient compliance with dosing schedules.

The physician and pharmacist both benefit from improved clinician-patient relationships in those cases where patients begin to abuse their medication, this will become apparent early in the process when interrupting the progression of addictive behavior is less difficult. Here, compliance data can be used to guide non-confrontational limit setting.

Likewise, the pharmaceutical company can demonstrate that it has done its best to avoid opiate addiction by equipping its medication packages with a compliance monitoring device, along with instructions to the patient and a system for the prescriber to minimize medication abuse. Further, patients are more likely to persist with a given pharmaceutical opiate if its use does not cause side effects as often occur with abusive self-medication. Cycles of intoxication and withdrawal, characterized by mood swings due to CNS depression (intoxication phase) and CNS stimulation (withdrawal phase) are minimized, encouraging the patient to persist with the therapy as long as it is required. Cognition is not reduced due to the depressant effect of the opiate analgesic.

through knowledge about the actual, not the assumed, use of medication. With the requirement to return the blister package to the clinician for a refill prescription, the patient becomes committed to the therapeutic relationship. In addition, clinicians benefit from both professional and medico-legal perspectives in that they can demonstrate best practice and having done their due diligence in managing patients requiring medications with high dependence liability.

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