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The Psychiatrists’ Program
Medical Professional Liability Insurance
Designed for Psychiatrists

MONITORING GUIDELINES AND THE ADVERSE EFFECTS OF MEDICATION

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Failure to monitor: a source of liability

Many medical malpractice lawsuits against psychiatrists include allegations of negligence involving the use of medications. In addition to negligence in prescribing, administering and obtaining informed consent, medical malpractice actions involving psychopharmacology frequently allege negligence in the monitoring of medication treatment.

Examples of actual allegations from lawsuits about negligence in monitoring psychotropic drugs include:

- Failure to monitor as frequently as required and address side effects of prescribed medication
- Failure to perform and/or monitor necessary laboratory testing (e.g., failing to perform renal function testing prior to prescribing lithium or failing to monitor blood lithium levels)
- Failure to communicate with other healthcare professionals when prescribing psychotropic medications (e.g., not obtaining pertinent data from primary care physician about co-morbid medical condition)
- Failure to test for potential dangerous conditions (e.g., failing to test for diabetes when the physician knew or should have known these dangers could arise)
- Failure to monitor for and address signs and symptoms of tardive dyskinesia; failure to monitor for and address signs and symptoms of neuroleptic malignant syndrome

Liability claims based on alleged failure to properly monitor a patient when prescribing medication may be particularly difficult to defend because of well-established standards and guidelines for the monitoring of many psychotropic medications (e.g., clozapine, lithium, antidepressants, ADHD medications). Ongoing monitoring of drug treatment is a basic tenet of clinical treatment and any failure to monitor will be characterized by a plaintiff’s attorney as a virtual abandonment of the patient’s care.

For some medications and conditions there is authoritative agreement about the need for and value of appropriate monitoring even if monitoring guidelines are not universally standardized, e.g. patients with schizophrenia or bipolar disorder taking second-generation antipsychotics (SGAs), which are linked with the risk of metabolic syndrome. A consensus statement was released in February 2004 by the APA and the American Diabetes Association, and endorsed by the American Association of Clinical Endocrinologists and the North American Association for the Study of Obesity, stating that “[g]iven the serious health risks, patients taking SGAs should receive appropriate baseline screening and ongoing monitoring.”(1)
However, recent studies have indicated that in some cases adequate monitoring of the side-effects of medications is lacking, along with appropriate intervention when problems exist related to prescribed medications.(2)

This set of circumstances provides an opportunity to review monitoring systems and practices, and make them even more effective. Patient care can be improved and professional liability risk decreased by taking such action.

Key sources for monitoring guidelines

Some key sources of guidelines for monitoring the side-effects and effectiveness of drug treatment are:

- FDA-approved drug labels
- Practice guidelines/parameters promulgated by professional organizations
- Peer-reviewed professional journals/published studies
- Other authoritative sources, e.g., 2004 consensus statement from APA, American Diabetes Association, et al., on antipsychotic drugs and obesity and diabetes.

Setting up a monitoring system

It is recommended that clinicians set up a system for regularly monitoring medications prescribed as well as documenting the results of monitoring. A monitoring system might include, but is not limited to, the following:

- Use of authoritative monitoring guidelines to guide the development and implementation of monitoring practices
- List of medications and/or patient conditions that routinely require baseline and ongoing laboratory tests, a schedule for frequency of testing, list of testing to be done, etc.
- Procedures for the timely review and response to results of lab testing
- Documentation of instructions to patients to obtain lab testing and documentation that testing was done. If patients refuse or are unable to obtain lab testing, documentation of response and plan to manage the situation.
- Information and instructions to patients (and families when appropriate) about why monitoring is needed. Documentation of the instruction.
- Periodic review, and documentation, of the efficacy of medications and adjustments made as a result of information obtained (change to dosage, change in routine, change in time of administration of medication, etc.)
- Side-effects and adjustments made as a result of information obtained and documentation of same.
- Periodic communication with other involved healthcare providers about monitoring of side-effects, complementary lab results, etc., and documentation

Implementation of monitoring

There is not always complete agreement about exactly what monitoring should be in place for particular drugs and conditions. For example, the FDA-approved labeling on antidepressants recommends a specific schedule for monitoring and follow-up to observe for clinical worsening, suicidality, and unusual changes in behavior in pediatric patients; and recommends that adults be similarly observed. This recommended schedule includes:
- At least weekly face-to-face contact with patients or their family members or caregivers during the first 4 weeks of treatment;
- Every other week visits for the next 4 weeks;
- Then at 12 weeks; and
- Visits as clinically indicated beyond 12 weeks


At the same time, the American Psychiatric Association, the American Academy of Child and Adolescent Psychiatry, and a coalition of other professional organizations published “PhysiciansMedGuide: The Use of Medication in Treating Childhood and Adolescent Depression” which states “[c]areful monitoring by physicians and parents of children’s mental health and behavioral status upon initiation of antidepressants and changes in medications and/or dosages is critically important.” The PhysiciansMedGuide goes on to say “[t]he APA and AACAP believe that rather than requiring adherence to a prescribed schedule, the frequency and nature of monitoring should be individualized to the needs of child and family.”

(www.physicianmedguide.org/physiciansmedguide.htm#11 – accessed 8/17/06)

In light of the various published guidelines, lack of complete agreement by experts and evolving monitoring standards, the clinician must manage the realities of the practice environment (e.g., reimbursement limitations, scheduling and distance challenges, some patients’ refusal to get blood tests done, difficulties coordinating monitoring with another healthcare professional treating the patient, etc.) and the patient’s clinical needs in establishing a reasonable and effective monitoring system.

When implementing a monitoring system, decide what elements to include that will work best in your practice environment. Then, for specific drugs and conditions, look to any monitoring guidelines on the FDA-approved label for the medication(s) being prescribed. Check authoritative practice parameters/guidelines and other important sources for direction. Then bring monitoring practices into compliance with authoritative guidelines or, if such guidelines are not followed in a particular case, decide on a monitoring plan that is supported by a reasonable clinical basis and that meets the patient’s needs. Document the basis for the monitoring that is being done and reasoning for deviation from authoritative guidelines, if applicable.

Ultimately, the monitoring system must be one that permits adequate assessment of the patient’s clinical status so that treatment can progress. In a lawsuit alleging negligence in monitoring the adverse side-effects of a medication, the clinician’s monitoring practices will be evaluated as to whether they met the standard of care. Developing a reasonable monitoring system that takes into account patient needs and authoritative guidelines will help to establish that the standard of care was met.

Note: For more information about guidelines in litigation, see Case of the Quarter in this issue.

Endnotes

Additional Resources


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For more information please contact:
Risk Management Consultation Service (RMCS)
Phone: (800) 527-9181
8:30 a.m. to 5:30 p.m. ET Monday through Friday
Visit the RMCS Online in the “For Participants Only” section on www.psychprogram.com