REDUCING RISK WHEN PRESCRIBING FOR CHILDREN AND ADOLESCENTS

This article is based on a PRMS seminar presentation given by Kim Masters, MD

Introduction

Psychotropic medications have long been a centerpiece of psychiatric treatment but they are not without controversy, especially when prescribed "off-label" for children. Any prescription that involves at least one factor not supported by the clinical trials leading to FDA labeling constitutes an off-label use. Off-label use of medications is a widespread and well-accepted part of medical practice and is not, in and of itself, a professional liability risk and can range from that which is clearly controversial to use that is considered the established standard of care. However, because of the lack of large-scale systematic studies and the limited proven efficacy of many psychotropic medications for children, the specter of irresponsible or poorly justified psychoactive medication prescribing has been raised by many including clinicians, politicians, the media and plaintiffs' attorneys.

When it comes to prescribing for children, psychiatrists may find themselves caught between the proverbial "rock and a hard place" wanting to provide the best care to their young patients but lacking all of the research findings and information they would like to have to support the use of certain medications and recognizing the potential professional liability risk for whatever treatment decision is made. The following is a discussion of risk management strategies that may be utilized to aid in the decision process and help to insulate the psychiatrist against potential liability exposure.

Risk Management Strategies

Information gathering

Information gathering includes staying current with the scientific and policy issues related to the medications that a physician wants to prescribe as well as ascertaining significant information about the patient, through thorough assessment and evaluation, before and during treatment with psychotropic drugs. The psychiatrist needs to be as knowledgeable as possible about a medication or treatment before recommending its use to a patient. The psychiatrist can draw upon his or her own experience with prescribing a specific medication, the experience of colleagues (for example, through informal and/or formal consultation or a second opinion) as well as various other resources including, among others, professional literature, published research, continuing education, and information from professional organizations and government agencies. Some recent resources related to the use of antidepressants in children include:

FDA

- "*Antidepressant Use in Children, Adolescents, and Adults"* including a *Medication Guide for Antidepressant Drugs*, *Revisions to Product Labeling*, and a *Questions and Answers* section.
- MedWatch, The FDA Safety Information and Adverse Event Reporting Program

NIMH

- *Questions and Answers about the NIMH Treatment for Adolescents with Depression Study* (TADS)
- *Antidepressant Medications for Children and Adolescents: Information for Parents and Caregivers*

APA and AACAP

- Medication guides for parents and for physicians at parentsmedguide.org

The process of information gathering also includes information about the patient and the patient's family and should be part of the ongoing assessment and evaluation of the patient. As this is an ongoing process, the understanding gained over time will inform decisions about modifying treatment planning and recommendations. Use of the "Decision and Discussion Worksheet" can assist in this information gathering.

Significant new information gained through this continuous process of information gathering (for example, about psychotropic medications, other treatments, and/or about the patient's clinical condition) requires the informed consent for treatment to be updated.

Communication of Risk

Physicians have a duty to disclose to patients the information necessary for patients to make informed decisions about treatment recommendations, including psychotropic medications. Although specific disclosure standards may vary from jurisdiction to jurisdiction, the law of informed consent has evolved to establish general agreement on the basic content of the physician's disclosure:

- The nature of the proposed treatment
- The risks and benefits of the proposed treatment
- The alternatives to the proposed treatment
- The risks and benefits of the alternative treatments
- The risks and benefits of doing nothing.

However, if this communication is presented as a recitation of facts in a defensive or legalistic manner it has the potential to be less than effective and may set up barriers to a therapeutic relationship. Because psychiatrists practice medicine, not law, they can use the psychotherapeutic process, which is a part of their practice, and incorporate the informed consent discussion into

that process making it more effective, more beneficial to patients and families, and more likely to support the patient – psychiatrist relationship. (See “Using The Psychotherapeutic Process To Discuss Medications” below).

The informed consent discussion takes on particular importance when prescribing for children due to the issues and concerns about the use of psychotropic medications with this population. Additionally, although informed consent must be obtained from the parent or legal guardian with authority to consent, for all but the youngest children, informed assent from the child is important. The child’s development level, environmental factors, and the ability to see oneself in the future are important factors influencing a child’s competence to be involved in clinical decisions. [Fundudis T. Consent issues in medico-legal procedures: how competent are children to make their own decisions? *Child Adolesc Ment Health* 8:18 -22 (2003); Masters KJ, Melonas JM. Lamotrigine and informed consent (letter). *J Am Acad Child Adolesc Psychiatry* 43:131 (2004).] Additionally, emotions and psychiatric conditions may blur the ability to understand treatment information and affect intellectual capacity. [Carandang CG, Maxwell DJ, Robbins DR. Lamotrigine in adolescent mood disorders (letter). *J Am Acad Child Adolesc Psychiatry* 42:750 (2003).]

Informed consent to treatment is an on-going, continuous process which requires periodic re-evaluation to ensure that it remains relevant and meaningful. Re-evaluation can be prompted by events such as changes in the patient's clinical needs, developments in the risks and benefits of the current treatment (for example, the FDA’s Public Health Advisory on antidepressants), or the appearance of new treatment options. The informed consent discussion should clarify whether the proposed treatment is an off-label use of the medication. Off-label use should not be described as "experimental" or "investigational" as these terms do not accurately reflect the status of medications that have been approved by the FDA and are being prescribed for off-label use.

Using the Psychotherapeutic Process to Discuss Medications

The discussion about the use of medications as part of the treatment plan takes place in the context of the doctor-patient relationship and should be a therapeutic encounter like any other issue in therapy. Consider using a worksheet or other resource/tool when gathering patient information because this creates an assessment process that is reliable and standardized. We have learned from lawsuits as well as from patient safety research that such standardization reduces error. Use of a worksheet, such as the one below, can help guide the discussion and avoid the omission of significant information that should be gathered and shared during patient assessment/evaluation and the informed consent process. This proposed worksheet does not address every possible point that could be significant in making decisions about and talking to patients about prescribing psychotropic medications. It is meant to be a tool that is dynamic and can be modified and customized by practitioners to meet their particular practice needs and situation. [See “Decision and Discussion Worksheet: Talking with Patients and Families about Medications” at the end of this article. See also “FDA Medication Guide for Antidepressant Drugs” and other resource documents at www.fda.gov. Medication Guides for specific drugs can be obtained at www.fda.gov/Drugs/DrugSafety/ucm085729.htm (accessed 10/8/2015).

Documentation

Whether the outcome of the process of talking to a patient and his/her family about medications is a decision to prescribe or not to prescribe, the clinical basis for the decision-making must be documented. Such documentation supports the patient's clinical care and is invaluable for defending the psychiatrist's position, should it be questioned. The worksheet referenced above can be a useful template for documentation.

If medication is prescribed, documentation should include the name of the medication; the dosage and size of the prescription; instructions given to the patient; known medication allergies or sensitivities; and notations of refills and follow-ups on effectiveness and side-effects of the drug. Documentation should also include applicable baseline laboratory testing, a comprehensive patient history, and any necessary physical examinations that were completed before medications were prescribed. Document ongoing laboratory testing and other patient monitoring actions that are taken. Copies of all written instructions or informational materials provided to the patient should be maintained in the patient's record.

The informed consent process should be documented and include the elements which the physician has a duty to disclose, as indicated earlier in this article. A signed consent form may be useful for documenting informed consent but is not a substitute for the full discussion with a patient and family. In some jurisdictions, a statute will specify that a written form must be used to document consent to certain medical treatments. If so, the benefits and protections of the statute will attach only if the statutory form is followed.

Conclusion

Some medical decisions may be unduly influenced by controversy about certain medications, lack of information and concerns about professional liability risks when prescribing psychotropic medications for children. Quality of patient care can be improved and liability risks can be reduced by using a psychotherapeutic approach when talking to patients and families about medications and by employing the risk management strategies of information gathering, communication, and documentation.

Working through the categories on the "Decision and Discussion Worksheet" can help the psychiatrist come to a decision with the patient and family about whether to prescribe, when to prescribe, how to prescribe, and what and how much to prescribe.

Psychiatrists considering prescribing antidepressant medications, or other medications for off-label use children, as well as those reconsidering previous prescriptions should expect increased scrutiny of their decisions. A thorough evaluation of the patient and the medication involved, following the guidelines recommended above, should minimize potential risk of harm related to prescribing decisions.

DECISION AND DISCUSSION WORKSHEET

1. Diagnosis

The allegation of “incorrect diagnosis” is a frequent claim in malpractice lawsuits against psychiatrists. If an incorrect diagnosis is made it follows that the course of treatment ordered might not have been appropriate. It may take some time to establish an accurate diagnosis. The doctor and the patient and the family should discuss this because the certainty of the diagnosis will impact the treatment ordered and subsequent changes in the treatment, including medication therapy.

What is the certainty about this diagnosis?

How likely is it to be accurate?

What types of medications are appropriate for this diagnosis?

How likely is the proposed medication to be used by practitioners to treat this diagnosis?

2. Properties of the medication

What are the unique risks of this medication; is it an off-label use for this medication?

If it is an off-label use, how common is it to be used by other practitioners?

Is there empirical support in the literature for this use?

How likely is the dosage range contemplated to conform to common use for this diagnosis?

What is the likelihood of a therapeutic response? Define.

What is the likelihood of major side effects? Define.

What are the risks of side effects versus potential benefits?

Are there any life-threatening risks? Define

How will the medication be monitored?

3. Experience of the physician with this medication

Is the psychiatrist professionally current and knowledgeable about this specific medication?

Is a professional consultation or referral to physician with specialized training and expertise for a second opinion appropriate in this case?
What is the psychiatrist's experience with ordering this medication?

What have been the therapeutic responses to the drug by the psychiatrist's patients?

4. Patient issues

What are the special concerns of this patient in view of his/her diagnosis? What is his/her familiarity with his/her illness?

Does the patient have co-morbid somatic conditions?

What is the current status of the patient's relationship with the psychiatrist?

Are there trust issues that may impact acceptance or compliance with prescribed medication?

Does the patient have unrealistic expectations about treatment?

About the risks and benefits of the medication?

What is the patient's tolerance for delay in symptom relief or tolerance for side effects?

Are there substance abuse/use issues?

Are there personality issues that will likely affect the use of the medication?

Does the minor patient give assent to the use of the medication?

Has the child's developmental cognitive level been taken into consideration in presenting information to him/her?

5. Family issues

What does the family understand about the patient's diagnosis?

What is the family's view of the medication?

How is the family influencing the patient's assent or consent to take medications?

6. Summary

Is the patient ready for the medication?

Is the family ready for the medication to be prescribed?

What is the psychiatrist's assessment of the patient and family's awareness of the risk versus benefit of using the medication?

Other concerns or issues that need to be addressed?

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