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Rx FOR RISK

Addressing risk management issues and concerns in the field of psychiatry

Psychopharmacology: Part II

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Table of Contents

PRESCRIBING CONTROLLED SUBSTANCES: MANAGING THE RISKS

While scrutiny of controlled substance prescribing has increased, there are three proven strategies to manage the risks associated with prescribing controlled substances:

(1) Collecting information

(2) Communicating

(3) Carefully documenting

COLLECTING INFORMATION

About the Patient:

- Perform, and document, a complete initial patient evaluation -- including medication history.
- Review your state's Prescription Monitoring Program (PMP) prior to prescribing.
    - If the report shows prescriptions not reported by the patient, address the issue clinically with the patient.
        - » Do not abandon by terminating without notice.
        - » Do not report the entries to law enforcement.

About the Medications:

- Stay up-to-date with the medications you prescribe.
- Read the labels for the medications you prescribe.
- Subscribe to FDA's MedWatch[1] for notification of medication safety alerts.
- Be familiar with FDA's REMS for the medications you prescribe.[2]

About Treatment / Standard of Care:

- Stay current with and follow:
    - Applicable federal and state laws related to prescribing controlled substances
    - Applicable federal and state regulations
    - Guidance from regulatory agencies such as:
        - » DEA
        - » State licensing board
    - Guidance from others such as:
        - » Federation of State Medical Boards
        - » Professional organizations – APA, AACAP, etc.
- Complete appropriate CME courses related to prescribing controlled substances

- Follow universal precautions when prescribing opioids[3]
    - Make a diagnosis with an appropriate differential.
    - Conduct a patient assessment, including risk for substance abuse disorders.
    - Discuss the proposed treatment plan with the patient and obtain informed consent.
    - Have a written treatment agreement that sets forth the expectations and obligations of both the patient and the treating physician.
    - Initiate an appropriate trial of opioid therapy, with or without adjunctive medications.
    - Perform regular assessment of patient and function.
    - Reassess the patient's pain score and level of function.
    - Regularly evaluate the patient in terms of the "5 A's": Analgesia, Activity, Adverse effects, Aberrant behaviors, and Affect.
    - Periodically review the pain diagnosis and any comorbid conditions, including substance use disorders, and adjust the treatment regimen accordingly.
    - Keep careful and complete records of the initial evaluation and each follow-up visit.

About Abuse and Diversion:

- Recognize the drug abuser – from the DEA[4]:
    - Common characteristics:
        - Unusual behavior in waiting room
        - Assertive personality, often demanding immediate attention
        - Unusual appearance
        - Unusual knowledge of controlled substances and/or textbook symptoms
        - Evasive or vague answers to questions regarding medical history
        - Reluctant or unwilling to answer questions regarding medical history
        - No regular doctor; no health insurance
        - Will request a specific mediation and is reluctant to try a different one
        - No interest in the diagnosis; fails to keep appointments for further diagnostic tests or refuses to see a consultant
        - Exaggerates medical problems and/or simulates symptoms
        - Cutaneous signs of drug abuse
    - Common modus operandi:
        - Must be seen right away
        - Wants an appointment toward end of office hours
        - Calls or comes in after regular business hours
        - Traveling through town, visiting friends or relatives
        - Feigning physical problems
        - Feigning psychological problems
        - States that certain medications do not work or is allergic to them

    - » Lost or stolen prescription
    - » Requests refills more than originally prescribed
    - » Pressures by eliciting sympathy or guilt
    - » Utilizes a child or elderly person when seeking stimulants or narcotics
- Recognize doctor shoppers – red flags (from the Tucson DEA):[5]
    - o Symptom incompatible with reported injury
    - o Visits physician some distance from home
    - o History of problems with no medical records
    - o Multiple accidents
    - o Insists on drug of choice
    - o Loss of prescription or medication
    - o Fails to have testing done
    - o Takes more meds than directed
    - o Requests meds early
    - o Obtains meds from multiple prescribers
    - o Prescriptions are filled at multiple pharmacies
- When confronted by a suspected drug abuser (from the DEA):[4]
    - o DO:
        - » Perform a thorough examination appropriate to the condition.
        - » Document examination results and questions asked of the patient.
        - » Request picture ID.
        - » Confirm telephone number.
        - » Confirm current address at each visit.
        - » Write prescriptions for limited quantities.
    - o DON'T:
        - » Take the patient's word for it if suspicious.
        - » Dispense meds just to get rid of drug-seeking patients.
        - » Prescribe, dispense, or administer controlled substances outside the scope of your professional practice or in the absence of a formal practitioner-patient relationship.

COMMUNICATING

With the Patient:

- Ensure adequate on-going monitoring of the patient and progress toward treatment goals.
- Consider standardized assessment tool:
    - o Especially for pain management[6]
    - o Especially for buprenorphine treatment[7]
- Ensure adequate on-going monitoring of the medications – efficacy, side-effects, etc.

- Obtain informed consent by discussing:
    - Nature of proposed medication
    - Risks and benefits of proposed medication, including:
        - Severe risks, even if infrequent
        - Frequent risks, even if not severe
        - Potential for tolerance, dependence, addiction, overdose
        - Potential for driving impairment
    - Alternatives to proposed medication
    - Risks and benefits of alternative treatments
    - Risks and benefits of doing nothing
    - Prescribing policies
    - Reasons for which medication may be changed or stopped
- Use resources to assist with patient understanding:
    - Medication guides
        - FDA[8]
        - Professional organizations, such as AACAP[9]
    - FDA's "Patient Counseling Document for Opioids"[10]
- Create office policies related to prescribing controlled substances, such as:
    - Only one prescriber
    - Only one pharmacy
    - No replacement of lost or stolen prescriptions
    - Prohibition on dose or frequency increases by patient
    - Use of PMP
    - Random pill counts
    - Random drug screening
    - Etc.
- Consider the use of a treatment agreement, especially for pain management, which could include:
    - Intended benefits / goals of using controlled substances
    - Risks of the treatment, including tolerance, dependence, abuse, addiction
    - Prescription management – how patient can keep medications secure, etc.
    - Office policies
    - Termination for:
        - Non-adherence
        - Aberrant behavior
    - Etc.
- Ensure the security of your prescriptions (from the DEA):[11]

- Use tamper-resistant prescription pads.
- Keep all prescription blanks in a safe place where they cannot be stolen; minimize the number of prescription pads in use.
- Write out the actual amount prescribed in addition to giving a number to discourage alterations.
- Use prescription blanks only for writing a prescription and not for notes.

- Discuss proper disposal of unused medication.

With Others:

- Ensure communication between all involved in the patient's care (such as covering physician, other treaters, etc.).
- Communicate with family members as authorized by the patient.
  - In emergency situations, remember that safety of the patient or others is an exception to confidentiality, so no authorization is required.
  - You can listen to what third parties want to tell you without breaching patient confidentiality, as long as you are not disclosing information.

CAREFULLY DOCUMENTING

- Document your treatment decision-making process.
  - Documentation allows your work to be understood.
- Record should contain:
  - Medication log
  - Evaluation
  - Medical indication for prescribing
  - Treatment plan – initial and updated
  - Informed consent – including patient education materials
  - Ongoing assessment
    - » Adherence to treatment plan
    - » Medication monitoring
    - » Aberrant behavior
  - Referral / consultation, if necessary
  - Treatment agreement, if used
  - Assessment forms, if used

Sources:

1. www.fda.gov/medwatch
2. www.fda.gov/drugs/drugsafety/postmarketdrugsafetyinformationforpatientsandproviders/ucm111350.htm
3. www.fsmb.org/pdf/pain_policy_july2013.pdf
4. www.deadiversion.usdoj.gov/pubs/brochures/pdfs/recognizing_drug_abuser_trifold.pdf
5. www.acponline.org
6. www.ucdenver.edu
7. www.suboxone.com/hcp/pdfs/app_use_checklist.pdf
8. www.fda.gov/drugs/drugsafety/ucm085729.htm
9. www.aacap.org/App_Themes/AACAP/Docs/resource_centers/adhd/adhd_parents_mediation_guide_201305.pdf
10. www.fda.gov/downloads/forindustry/userfees/prescriptiondruguserfee/ucm361110.pdf
11. www.deadiversion.usdoj.gov/pubs/manuals/pract/

DOCUMENTATION OF INFORMED CONSENT: WHEN SHOULD USE OF A FORM BE CONSIDERED

The informed consent is an important communication process between the patient and the psychiatrist. Patients should always receive and understand the following basic information: the nature of the proposed treatment, the risks and benefits of the proposed treatment, alternatives to the proposed treatment, the risks and benefits of alternative treatments, and the risks and benefits of doing nothing.

As with all aspects of treatment, the informed consent process should be documented. Without a written record of the informed consent discussion, in the event there is later a conflict regarding consent, it may be difficult to prove that the appropriate information was disclosed and that the patient understood the ramifications of his or her decision. Or in other words, that the patient's consent was truly informed. A written record of the process is the best evidence that the standard of care was met.

With some aspects of patient care (such as prescribing practices) being subjected to greater scrutiny, psychiatrists may be wondering if they should have patients sign a consent form as proof that the informed consent process took place. In considering this, psychiatrists should keep in mind that the use of a signed form may not be necessary in all cases and also that there are several methods for documenting consent.

OPTIONS FOR DOCUMENTING INFORMED CONSENT

Verbal consent documented only in the record

If only verbal consent is obtained, the psychiatrist should write an entry in the record indicating what the patient was told, the patient's understanding of the disclosure, and the patient's consent to treatment. Psychiatrists may want to personalize the entry in the record with specific issues and/or questions addressed with the particular patient. As discussed below, documentation in the chart of verbal consent alone may or may not be sufficient depending on the nature of the treatment being discussed.

Consent documented only by a form

Signed forms can play a role in the documentation of informed consent, but they cannot replace the psychiatrist-patient discussion. Moreover, a form merely stating that consent was obtained may not be sufficient. It may be necessary to document more details of the informed consent discussion.

Consent documented in the record *and* by a form

Optimal documentation of the informed consent process would consist of a thorough informed consent discussion documented on a signed consent form (perhaps incorporating patient information sheets, as discussed below), along with a brief entry in the patient record. However, this may not be necessary in all cases, particularly if the treatment being discussed is low risk.

ADVANTAGES AND DISADVANTAGES OF USING A CONSENT FORM

Advantages of incorporating a signed form into the consent process

Enhanced communication: The primary purpose of informed consent discussions is to help patients understand the treatment being contemplated. Using a consent form as a basis for your consent discussions, and personalizing the form by adding specific issues discussed with that particular patient, may enhance the patient's understanding as well as demonstrate that informed consent was obtained.

Patients' focus on consent: The formality of the process may force a patient to focus on what he/she is consenting to, making it less likely that he/she will later believe that the informed consent was not adequate.

Proof of consent: The signed form supports the assertion that the consent process took place and establishes at least some of what was disclosed. Also, under some states' laws, having the patient sign an informed consent form may create a rebuttable presumption that a patient's written consent is an informed consent. For example, Indiana's code provision 16-36-1.5-7 (*Rebuttable presumption of informed consent*) states the following:

> "Sec. 7. If a patient's written consent is:
>
> (1) signed by the patient or the patient's authorized representative;
>
> (2) witnessed by an individual who is at least eighteen (18) years of age; and
>
> (3) explained, orally or in the written consent, to the patient or the patient's authorized representative before a treatment, procedure, examination or test; a rebuttable presumption is created that the consent is an informed consent."

Disadvantages of incorporating a signed form into the consent process

The disadvantages of using consent forms derive from the difficulty in knowing what information to include. If the content of the form is non-specific, then a patient could allege that certain pieces of material information were withheld by the psychiatrist. On the other hand, if the form is very specific in listing all of the possible complications, any complication not listed could be presumed to have not been disclosed.

CONSIDERATIONS FOR DETERMINING WHETHER A FORM SHOULD BE UTILIZED AS PART OF THE INFORMED CONSENT PROCESS

Use of an informed consent form may be required by law

Jurisdictions vary with regard to the standards required for the documentation of informed consent. Federal and state laws (statutes and regulations) may require that the patient sign an informed consent form for various clinical activities. For example, federal laws related to **clinical research** require that the subject's written informed consent be documented. And, under some states' laws, patients undergoing **ECT** are required to sign informed consent documents. Some states require written informed consent to be obtained from patients, including from parents of minors, prior to prescribing **psychotropic medications**. If a statute specifies that a written consent form must be used, the benefits and protections of the statute will attach only if the statutory form is followed. If use of a form is not required by law, psychiatrists have discretion

If use of a form is not required by law, psychiatrists have discretion

If use of a consent form is not required by law, psychiatrists can use their own judgment in deciding whether or not to incorporate forms into the informed consent process. The appropriateness of a form may be decided on an individual basis, depending in part on the risks associated with the treatment being discussed. For example, informed consent documentation for psychotherapy patients may be very different than consent documentation for patients considering ECT. Basically, the more risks associated with the treatment, the more consideration should be given to incorporating a form into the informed consent process. When choosing whether or not to utilize a signed informed consent form, psychiatrists may want to consider the following:

Does your state medical board recommend, in policies or guidelines, that written consent be obtained from the patient? In addition to promulgating laws (regulations), your state medical board may also issue guidelines or policy statements relating to informed consent. Psychiatrists should be aware of any such board statements, as they may be indicative of the standard of care.

Is the use of a consent form recommended by authoritative treatment guidelines? Clinical treatment guidelines, developed by authoritative organizations, may also be evidence of the applicable standard of care.

Is the recommended treatment ECT? It is a good risk management strategy to use a consent form for ECT, even if not required by law to do so, because of the prevalence of misinformation about the risks and benefits of this procedure.

Are medications with known serious side effects (such as tardive dyskinesia, lithium toxicity, neuroleptic malignant syndrome, SJS, etc.) being recommended? When medications are recommended that can cause significant injury to patients, psychiatrists may want to enhance the documentation of informed consent by including a signed form. By doing so, the psychiatrist may be able to more effectively communicate the seriousness of the known side effects of the medication to the patient. The form can also be used to document the monitoring that will be required if the medication is prescribed.

Is an off-label use of medication being recommended? 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. Off-label uses range from those that are clearly controversial to those that are considered the established standard of care. Some typical off-label uses include prescribing a medication for a condition not indicated on its FDA-approved label, prescribing at a different dosage than indicated, or prescribing for a different patient population (for example, much prescribing for children is off-label). Education about the nature and risks of the off-label use is a critical part of the informed consent process. Since malpractice allegations related to off-label use of drugs could include insufficient informed consent, psychiatrists may want to expand their consent documentation by incorporating an informed consent form and/or a patient information sheet for the particular medication.

Is the recommended treatment considered controversial, such as experimental or complementary and alternative? For some specific clinical practices, documentation of the informed consent can be crucial in litigation. If a psychiatrist proposes a type of treatment or treatment modality whose application or validity may be controversial, or if complementary and alternative treatments are recommended, then the information disclosed may need to be expanded and a very specific written consent should be obtained. The additional information should include the scientific basis for the treatment, if it is considered the standard of care, and why more conventional therapies are not being used. Without these extra measures, it may be easy for a plaintiff to allege that he/she did not understand the risks and potential outcomes and never would have given consent if he/she had understood. Moreover, it may be difficult to find an expert witness to support the care provided.

IF YOU INCORPORATE SIGNED CONSENT FORMS INTO YOUR INFORMED CONSENT PROCESS...

Do not rely on the forms as a substitute for the informed consent discussion

Having a patient sign a consent form does not constitute informed consent. Signed forms can play an important role in the documentation of informed consent, but they cannot replace the informed consent discussion between the patient and the psychiatrist.

Consider incorporating patient information handouts, such as medication information sheets

Psychiatrists may wish to use patient information handouts in combination with the consent form. For example, the FDA has developed medication guides which are available through their website, www.fda.gov.

When using patient information handouts, do not rely exclusively on brochures, pamphlets, or articles to provide information about the treatment, and never assume that patients possess information which you have not provided. Discuss treatments with patients personally and give them a reasonable amount of time to digest the information and respond. They should be given every opportunity to ask questions, but the information disclosed should not be based solely on their questions.

Consent forms must be tailored to meet patient needs and must be kept up-to-date

The consent forms and all patient handouts should be easily understandable by patients and should be reviewed and updated periodically.

Retain copies in the record

Copies of informed consent forms, written instructions, and educational information provided to the patient should also be kept in the patient's record.

DID YOU KNOW?

Many states' prescription monitoring programs are now connected allowing physicians to access the PMPs of multiple states prior to prescribing for patients. The National Association of Boards of Pharmacy (NAPB) InterConnect Hub allows participating states to share data from their respective prescription monitoring programs. It is anticipated that by the end of 2016 approximately 45 states will be either participating in PMP InterConnect or working toward participation.

For more information visit http://www.nabp.net/initiatives/pmp-interconnect/

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MYTHS & MISCONCEPTIONS: PHARMACY BENEFITS

Q: I recently received a letter from a patient's pharmacy benefits manager. The letter listed all prescriptions that the plan has filled for the patient and stated that my prescribing pattern increased the patient's risk for a medication-related hospitalization. I am concerned that my liability will increase if a risk actually materializes and this letter comes to light. Should I ignore this letter? What steps can I take to minimize my potential liability?

A: You appear to have encountered one of the latest tools in healthcare benefits cost containment, and you are right to be concerned. In the event of a lawsuit, one can imagine such a letter blown up to poster size and shown to a jury as the plaintiff's attorney declares indignantly, "See doctor, even the pharmacy warned you that this could happen."

But don't panic. Remember that all psychiatric treatment entails balancing risks and benefits in light of the patient's individual circumstances, and a poor outcome is not in and of itself evidence of malpractice. However, like letting the cat out of the bag, once you become aware of the information contained in the letter, your awareness can never be undone and the information must be dealt with candidly and in a clinically appropriate manner.

The risk management strategies that you can use to reduce your liability risk in this situation are the same strategies that are used anytime treatment decisions are being made - focusing on patient care, obtaining informed consent, and documenting the decision-making process.

The specific steps you should take in response to this letter are:

1. Review and research the information
2. Talk to the patient
3. Document your decision-making process

First, review and research the information cited in the letter. You may wish to take a look at treatment guides from professional organizations as well as any studies or articles cited in the letter. Review the patient's medication for potential adverse interactions, ask your patient about previously undisclosed medications or treatment modalities, and assess for other potential problems.

Second, talk to the patient. Obtain an updated informed consent in light of this new information. Educate the patient about the risks and benefit of the treatment modality in question as well as your recommendations for treatment. The treatment plan may be left as is or it may need to be modified in a way related or unrelated to the letter.

Finally, document your decision-making process in light of the information received from the pharmacy benefits manager. Document your reasons for recommending a specific treatment modality in light of its risks. If the chosen treatment deviates from accepted guidelines, document your reasons for the particular choice. Document the updated informed consent discussions.

The bottom line is that information, wherever it may come from, can always be used productively to support patient care.

MONITORING GUIDELINES & THE ADVERSE EFFECTS OF MEDICATION

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 and 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."

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.

Sources:

1. "Consensus Development Conference on Antipsychotic Drugs and Obesity and Diabetes" Diabetes Care 2004; 27:2.
2. Rosack, J "Clinicians Urged to Better Monitor Drug-Related Side Effects" Psych News 2006; 41:1.

Additional Resources

Cohn TA, Sernyak, M. "Metabolic Monitoring for Patients Treated With Antipsychotic Medications," Can J Psychiatry 2006: 51:492-501.

Moran M, "Treatment is a Delicate Balance Between Efficacy, Side Effects", Psychiatric News 2006: 41: 8, 38.

Rosack, J, "Better monitoring urged for youth taking newer antipsychotics", Psychiatric News 2006: 41: 15, 1.

Stettin GD, Yao J, Verbrugge, RR, Aubert RE, "Frequency of Follow-up Care for Adult and Pediatric Patients During Initiation of Antidepressant Therapy," Am J Manag Care 2006: 12:453.

Stubbs J, Haw C, Taylor D, "Prescription errors in psychiatry – a multi-centre study", Journal of Psychopharmacology 2006: 20: 4, 553-561.

MEDICATION SAMPLES IN THE OFFICE: UNDERSTAND THE RISKS TO THE PATIENT & TO THE PSYCHIATRIST

Medication samples can be beneficial for many purposes such as starting new prescriptions and assisting patients with financial problems. There are, however, important safety concerns associated with the use of samples. Risks to patient safety include poor instructions, inadequate labeling, and expired samples. Medication samples should not be treated casually – they must be treated with the same formality as any other prescription (e.g., not to be dispensed outside of a treatment relationship). In fact, there are additional requirements put on physicians who choose to add the role of dispenser on top of the role of prescriber.

"Distribution of free samples to patients bypasses the pharmacist and thus skips a crucial safety checkpoint."

Cutrona SL, Woolhandler S, Lasser KE, Bor DH, Himmelstein DU, Shrank WH, LeLeiko NS. Free drug samples in the United States: characteristics of pediatric recipients and safety concerns. Pediatrics 2008;122(4):736-742

UNDERSTAND THE LEGAL REQUIREMENTS FOR DISPENSING SAMPLES

The legal rules governing dispensing of medication samples vary depending on the medication and on the physician's practice setting. In addition to federal law, many states have enacted their own laws regarding physicians and samples.

Federal law: The distribution of medication samples is governed by FDA regulations (21 CFR 203) promulgated under the Prescription Drug Marketing Act of 1987. These regulations cover the physician's written request, receipt, and other record-keeping requirements for the physician to receive samples from the manufacturer. For those physicians utilizing samples of controlled substances, there are additional regulations from the Drug Enforcement Agency. These regulations include requirements for secure storage, qualification of employees having access to the samples, theft reporting, record keeping, inventory, and disposal. More information can be found in the DEA's *Practitioner's Manual*, available online at www.deadiversion.usdoj.gov/pubs/manuals/index.html.

State law: State boards of medicine and/or boards of pharmacy may have regulations, rules, and policies governing dispensing of medication samples. Boards may also have additional requirements for samples of controlled substances. Physicians should contact the medical board and pharmacy board in the state(s) where the physician practices to determine state-specific requirements for dispensing medication samples.

RISK MANAGEMENT RECOMMENDATIONS

In addition to complying with all applicable state and federal laws, the risk management advice related to medication samples is to develop and follow policies and procedures for storing, dispensing, and disposing of medication samples. These policies and procedures should address at least the following:least the following:

Securely storing medication samples

- Maintain a log to track incoming samples. Consider including the following information:
    - Date samples received
    - Drug name and strength
    - Lot numbers
    - Quantity
    - Expiration date
    - Monthly inventory review – date and initials
- Store samples in a secured location – in a locked medication cabinet or storage room.
- Access to samples should be limited to authorized staff only. Employees should not have access to samples for personal use.
- Medications with similar names or similar packages should be separated in storage.
- Store the samples in accordance with the manufacturers' recommendations, such as those related to light and temperature.
- Follow any specific legal requirements, such as those related to samples of controlled substances.
- Perform a monthly inventory of samples.
    - Expired samples should be removed from inventory and disposed of properly (see section below on sample disposal).
    - Recalled medications should be removed from inventory and disposed of properly. To track drug recalls, visit www.fda.gov/Safety/Recalls/EnforcementReports/default.htm.
    - Document when samples have been inventoried.

Safely dispensing medication samples

- As with any other prescription:
    - Only dispense medication samples within a bona fide treatment relationship.
    - Obtain the patient's informed consent to use of the medication.
    - Review the patient's drug allergies.
    - Review patient's other medications, supplements, and complementary and alternative substances for potential interactions and contraindications.
- Only physicians and others with prescribing authority should dispense the samples.
- Check the sample's expiration date.
- Document the samples dispensed in a dispensing log. Consider including the following information:
    - Date dispensed
    - Patient name (and possibly another identifier, such as date of birth)
    - Drug name and strength
    - Lot number
    - Quantity dispensed

  - Expiration date
  - Prescriber
  - Dispenser (if different)
- Ensure the patient understands exactly how to take the medication, including dosage and any special instructions.
- Ensure samples are adequately labeled, including at least the following:
  - Patient name
  - Medication name, strength, and quantity
  - Lot number
  - Expiration date
  - Date dispensed
  - How often to take
  - Directions, such as take with food
  - Precautions
- Provide written instructions to the patient. Patients are typically given verbal instructions on the use of samples, but often the medication is not properly labeled and written patient instructions are not provided, thus creating a patient safety issue. Patient-specific written instructions should include the following:
  - Physician's name and contact information
  - Patient's name
  - Date medication dispensed
  - Name and strength of medication
  - Quantity given
  - Lot number(s)
  - Patient instructions
  - Possible side effects
  - Other patient information provided, such as medication information sheets
  - Other relevant information
- The instruction sheet should be signed by the patient and a copy of the sheet should be retained in the patient record.
- Extra caution should be exercised when providing medication samples for use by children.
  - Sample packages may not be child-proof.
  - Preprinted dosing instructions may not be appropriate for children.

Documenting dispensed samples

- Record-keeping is an important key in managing the risk associated with providing medication samples.
- The following logs related to samples should be maintained (see Appendix for specific information to consider including on these logs):

- Log of inventory
- Log of dispensed samples
- Log of destroyed samples

- Documentation for the sample label is discussed in the dispensing section above.
- In terms of documentation in the patient record that samples were dispensed:
  - A copy of the written instructions provided to the patient with the samples (see dispensing section above) should be retained in the patient's chart.
  - Sample medications should be included on the patient's medication list.

Monitoring

- As with any medication prescribed, physicians must:
  - Monitor the patient for medication effectiveness and safety.
  - Stay current with safety information related to the particular medication prescribed. Sources for medication safety information include:
    - FDA's MedWatch – www.fda.gov/safety/MedWatch/.
- Additionally, any medication dispensed which is subsequently recalled must be appropriately disposed of and the patient must be notified.
  - See storage section above for recall resources.
  - Patients with recalled medications samples should be advised regarding stopping the medication and asked to return unused samples to the physician.
  - The patient's chart should reflect this communication with the patient.

Disposing of medication samples

- Expired and recalled samples must be disposed of in accordance with applicable federal, state, and local laws. Resources for determining these laws include:
  - Federal Environmental Protection Agency:
    - http://www.epa.gov/ppcp/basic2.html
    - http://www.epa.gov/osw/hazard/generation/pharmaceuticals.htm
  - State environmental protection agency: www.epa.gov/epawaste/wyl/stateprograms.htm
  - State pharmacy board
- Document the disposal of samples in the log of destroyed samples. Consider including the following information:
  - Date
  - Name and strength of medication
  - Quantity
  - Signature
  - Additional information that may be required for controlled substances, such as a second signature

DISPENSING SAMPLES: IT IS A TWO-STEP PROCESS

Step 1: The first step in dispensing samples is doing what would be done when writing a prescription for any medication, including:

- Only prescribing in the context of a physician-patient treatment relationship, and not dispensing samples casually to family, friends, and employees
- Checking for drug allergies and drug interactions
- Obtaining and documenting informed consent
- Providing patient education
- Monitoring the effectiveness of the medication

Step 2: The second step in dispensing samples is doing what would normally be done by a pharmacist, as a safety check, including:

- Checking (again) for drug interactions
- Providing written instructions on how to take the medication, safety warnings, etc.; also keep in mind that many medications have patient medication guides that are to be provided to patients when the medication is dispensed
- Monitoring for recalled medications that have been dispensed