

FYI

Native Culture Guide for Providers

The Substance Abuse and Mental Health Services Administration has released a pocket guide to Native American and Alaskan Native culture, history, myths, and facts to help health care providers communicate effectively with members of these communities. The pocket guide can be downloaded at http://download.ncadi.samhsa.gov/enetwork/archive/2009/SAMHSA_cmhs_6_30_09.html, or ordered online through SAMHSA’s National Mental Health Information Center.

Data Available on Discharges

The Substance Abuse and Mental Health Services Administration has issued its 2006 Treatment Episode Data Set (TEDS) report on discharges from treatment for substance use. The report provides data for 42 states, and is broken down into various program and demographic categories. It can be downloaded at www.oas.samhsa.gov/teds2k6highlights/teds2k6high-Web.pdf or ordered by calling 1-877-726-4727 (publication no. SMA-09-4378).

Evidence-Based Practices Registry

The Substance Abuse and Mental Health Services Administration has published information on submitting a program or practice to their National Registry of Evidence-Based Programs and Practices. The NREPP is a searchable database listing proven interventions aimed at preventing or treating mental and substance use disorders. To view the guidance document, go to www.nrepp.samhsa.gov/about-news.asp and choose the Federal Register PDF dated June 23 (scroll to p. 29707).

Health Info for Spanish Speakers

The Agency for Healthcare Research and Quality has expanded its Spanish-language health Web site for patients. The enhanced site includes a monthly health advice column and more than 35 consumer guides on surgery, smoking, cardiac rehabilitation, and health insurance, among other topics. It also includes audio spots on diabetes, osteoarthritis, preventive health, and more. Visit the site at www.ahrq.gov/consumer/espanoix.htm.

Autism Legislation Database

A new online autism database provides up-to-date information about autism legislation introduced in each state and the District of Columbia. The site is maintained by the National

Conference of State Legislators and is designed to allow legislators to see how other states are addressing the needs of autistic patients and their families across a range of issues. The site is at www.ncsl.org/programs/health/autism.cfm.

Tool for Reimbursement

PPS Clinical Optimizer software provides the real-time details and automated data transfer that are necessary to optimize patient care, outcomes, case weight, and reimbursement to ease the adaption to the Medicare prospective payment system algorithm. For more information about this software, call OCS Inc. at 888-325-3396.

Using Methadone Safely

The Food and Drug Administration and the Substance Abuse and Mental Health Services Administration have launched “Follow Directions: How to Use Methadone Safely,” an outreach effort for consumers, health care professionals, and treatment clinics. Visit www.dpt.samhsa.gov/methadone-safety for information.

Software Identifies Preferred CME

iQueue is a Mac and PC desktop application that distributes continuing medical educational activities to health care professionals by automatically gathering CME activities (including live, print, and rich media), based on preselected preferences. The types of activities can be selected in many different ways. To download the software free, visit www.iQueueOnline.com.

DVD Series on Homelessness

The DVD strategic planning tool, “Transformation Through Partnerships: Systems Change to End Chronic Homelessness,” has been released by the Substance Abuse and Mental Health Services Administration. For more details and ordering information, visit download.ncadi.samhsa.gov.

Adjunctive Partial-Onset Seizure Rx

Keppra XR (levetiracetam extended-release tablets) has received approval from the Food and Drug Administration for use as an add-on to other antiepileptic treatments in patients with partial-onset seizures who are at least 16 years old. The medication is available in both 500-mg and 750-mg dosage strengths. Information about a copay support program for the drug is available at 866-822-0068 (press 9). For more information, visit www.KeppraXR.com.

RISPERDAL® CONSTA®
(risperidone) LONG-ACTING INJECTION

Brief Summary

BEFORE PRESCRIBING RISPERDAL® CONSTA®, PLEASE SEE FULL PRESCRIBING INFORMATION, INCLUDING BOXED WARNING.

WARNING: INCREASED MORTALITY IN ELDERLY PATIENTS WITH DEMENTIA-RELATED PSYCHOSIS

Elderly patients with dementia-related psychosis treated with antipsychotic drugs are at an increased risk of death. Analyses of 17 placebo-controlled trials (modal duration of 10 weeks), largely in patients taking atypical antipsychotic drugs, revealed a risk of death in drug-treated patients of between 1.6 to 1.7 times the risk of death in placebo-treated patients. Over the course of a typical 10-week controlled trial, the rate of death in drug-treated patients was about 4.5%, compared to a rate of about 2.6% in the placebo group. Although the causes of death were varied, most of the deaths appeared to be either cardiovascular (e.g., heart failure, sudden death) or infectious (e.g., pneumonia) in nature. Observational studies suggest that, similar to atypical antipsychotic drugs, treatment with conventional antipsychotic drugs may increase mortality. The extent to which the findings of increased mortality in observational studies may be attributed to the antipsychotic drug as opposed to some characteristic(s) of the patients is not clear. RISPERDAL® CONSTA® (risperidone) is not approved for the treatment of patients with dementia-related psychosis. [See Warnings and Precautions]

RISPERDAL® CONSTA® (risperidone) is indicated for the treatment of schizophrenia [see Clinical Studies (14.1) in full PI].

RISPERDAL® CONSTA® is indicated as monotherapy or as adjunctive therapy to lithium or valproate for the maintenance treatment of Bipolar I Disorder [see Clinical Studies (14.2, 14.3) in full PI].

CONTRAINDICATIONS: RISPERDAL® CONSTA® (risperidone) is contraindicated in patients with a known hypersensitivity to the product.

WARNINGS AND PRECAUTIONS: Increased Mortality in Elderly Patients with Dementia-Related Psychosis Elderly patients with dementia-related psychosis treated with antipsychotic drugs are at an increased risk of death. **RISPERDAL® CONSTA® (risperidone) is not approved for the treatment of dementia-related psychosis (see Boxed Warning).**

Cerebrovascular Adverse Events, Including Stroke, in Elderly Patients with Dementia-Related Psychosis: Cerebrovascular adverse events (e.g., stroke, transient ischemic attack), including fatalities, were reported in patients (mean age 85 years; range 73-97) in trials of oral risperidone in elderly patients with dementia-related psychosis. In placebo-controlled trials, there was a significantly higher incidence of cerebrovascular adverse events in patients treated with oral risperidone compared to patients treated with placebo. RISPERDAL® CONSTA® is not approved for the treatment of patients with dementia-related psychosis [See also Boxed Warning and Warnings and Precautions]. **Neuroleptic Malignant Syndrome (NMS):** A potentially fatal symptom complex sometimes referred to as Neuroleptic Malignant Syndrome (NMS) has been reported in association with antipsychotic drugs. Clinical manifestations of NMS are hyperpyrexia, muscle rigidity, altered mental status, and evidence of autonomic instability (irregular pulse or blood pressure, tachycardia, diaphoresis, and cardiac dysrhythmia). Additional signs may include elevated creatine phosphokinase, myoglobinuria (rhabdomyolysis), and acute renal failure. The diagnostic evaluation of patients with this syndrome is complicated. In arriving at a diagnosis, it is important to identify cases in which the clinical presentation includes both serious medical illness (e.g., pneumonia, systemic infection, etc.) and untreated or inadequately treated extrapyramidal signs and symptoms (EPS). Other important considerations in the differential diagnosis include central anticholinergic toxicity, heat stroke, drug fever, and primary central nervous system pathology. The management of NMS should include: (1) immediate discontinuation of antipsychotic drugs and other drugs not essential to concurrent therapy; (2) intensive symptomatic treatment and medical monitoring; and (3) treatment of any concomitant serious medical problems for which specific treatments are available. There is no general agreement about specific pharmacological treatment regimens for uncomplicated NMS. If a patient requires antipsychotic drug treatment after recovery from NMS, the potential reintroduction of drug therapy should be carefully considered. The patient should be carefully monitored, since recurrences of NMS have been reported. **Tardive Dyskinesia:** A syndrome of potentially irreversible, involuntary, dyskinetic movements may develop in patients treated with antipsychotic drugs. Although the prevalence of the syndrome appears to be highest among the elderly, especially elderly women, it is impossible to rely upon prevalence estimates to predict, at the inception of antipsychotic treatment, which patients are likely to develop the syndrome. Whether antipsychotic drug products differ in their potential to cause tardive dyskinesia is unknown. The risk of developing tardive dyskinesia and the likelihood that it will become irreversible are believed to increase as the duration of treatment and the total cumulative dose of antipsychotic drugs administered to the patient increase. However, the syndrome can develop, although much less commonly, after relatively brief treatment periods at low doses. There is no known treatment for established cases of tardive dyskinesia, although the syndrome may remit, partially or completely, if antipsychotic treatment is withdrawn. Antipsychotic treatment, itself, however, may suppress (or partially suppress) the signs and symptoms of the syndrome and thereby may possibly mask the underlying process. The effect that symptomatic suppression has upon the long-term course of the syndrome is unknown. Given these considerations, RISPERDAL® CONSTA® should be prescribed in a manner that is most likely to minimize the occurrence of tardive dyskinesia. Chronic antipsychotic treatment should generally be reserved for patients who suffer from a chronic illness that: (1) is known to respond to antipsychotic drugs, and (2) for whom alternative, equally effective, but potentially less harmful treatments are not available or appropriate. In patients who do require chronic treatment, the smallest dose and the shortest duration of treatment producing a satisfactory clinical response should be sought. The need for continued treatment should be reassessed periodically. If signs and symptoms of tardive dyskinesia appear in a patient treated with RISPERDAL® CONSTA®, drug discontinuation should be considered. However, some patients may require treatment with RISPERDAL® CONSTA® despite the presence of the syndrome. **Hyperglycemia and Diabetes Mellitus:** Hyperglycemia, in some cases extreme and associated with ketoacidosis or hyperosmolar coma or death, has been reported in patients treated with atypical antipsychotics including RISPERDAL®. Assessment of the relationship between atypical antipsychotic use and glucose abnormalities is complicated by the possibility of an increased background risk of diabetes mellitus in patients with schizophrenia and the increasing incidence of diabetes mellitus in the general population. Given these confounders, the relationship between atypical antipsychotic use and hyperglycemia-related adverse events is not completely understood. However, epidemiological studies suggest an increased risk of treatment-emergent hyperglycemia-related adverse events in patients treated with the atypical antipsychotics. Precise risk estimates for hyperglycemia-related adverse events in patients treated with atypical antipsychotics are not available. Patients with an established diagnosis of diabetes mellitus who are started on atypical antipsychotics should be monitored regularly for worsening of glucose control. Patients with risk factors for diabetes mellitus (e.g., obesity, family history of diabetes) who are starting treatment with atypical antipsychotics should undergo fasting blood glucose testing at the beginning of treatment and periodically during treatment. Any patient treated with atypical antipsychotics should be monitored for symptoms of hyperglycemia including polydipsia, polyuria, polyphagia, and weakness. Patients who develop symptoms of hyperglycemia during treatment with atypical antipsychotics should undergo fasting blood glucose testing. In some cases, hyperglycemia has resolved when the atypical antipsychotic was discontinued; however, some patients required continuation of anti-diabetic treatment despite discontinuation of the suspect drug. **Hyperprolactinemia:** As with other drugs that antagonize dopamine D₂ receptors, risperidone elevates prolactin levels and the elevation persists during chronic administration. Risperidone is associated with higher levels of prolactin elevation than other antipsychotic agents. Hyperprolactinemia may suppress hypothalamic GnRH, resulting in reduced pituitary gonadotropin secretion. This, in turn, may inhibit reproductive function by impairing gonadal steroidogenesis in both female and male patients. Galactorrhea, amenorrhea, gynecomastia, and impotence have been reported in patients receiving prolactin-elevating compounds. Long-standing hyperprolactinemia when associated with hypogonadism may lead to decreased bone density in both female and male subjects. Tissue culture experiments indicate that approximately one-third of human breast cancers are prolactin dependent *in vitro*, a factor of potential importance if the prescription of these drugs is contemplated in a patient with previously detected breast cancer. An increase in pituitary gland, mammary gland, and pancreatic islet cell neoplasia (mammary adenocarcinomas, pituitary and pancreatic adenomas) was observed in the risperidone carcinogenicity studies conducted in mice and rats [see Nonclinical Toxicology]. Neither clinical studies nor epidemiologic studies conducted to date have shown an association between chronic administration of this class of drugs and tumorigenesis in humans; the available evidence is considered too limited to be conclusive at this time. **Orthostatic Hypotension:** RISPERDAL® CONSTA® may induce orthostatic hypotension associated