MEDICAL PHARMACIES TABLET

Drug information and news for health care providers

November 2013

# INTRODUCTION

Last month the concept of Required Organizational Practices (ROPs) as published by Accreditation Canada in the *Required Organizational Practices Handbook* was introduced. This issue will focus on adverse event assessment, disclosure and reporting as an important component of effective communication among care and service providers, and with the recipients of care and service across the continuum.

# ADVERSE EVENT DEFINITIONS

The term *adverse event* is an umbrella term used to describe an unexpected and undesirable incident (adverse outcome, injury, or complication for the client) directly associated with the care or services provided to the client.[1]

An adverse event that results in the client's death or major and enduring loss of function is known as a sentinel event. An event or situation that is identified before it could have resulted in an accident, injury, or illness is defined as a near miss.

# ADVERSE EVENT ASSESSMENT

A review of a total of 4,740 medication incidents occurring in a long-term care environment found that 2.8% resulted in harm or death. Of those, 88.5% resulted in harm and 11.5% resulted in death. The most common types of medication incidents included incorrect dose (42% of incidents), dose omission (24% of incidents), incorrect drug (12% of incidents), and incorrect patient (6% of incidents).[2]

Medication incidents associated with harm or death followed three main themes:[2]

1. Incidents involving high-alert medications
2. Incidents involving anxiolytic-sedative and/or antipsychotic medications, including incidents leading to falls
3. Incidents involving patient transfers

Practitioners may avoid reporting adverse events due to feelings of guilt and embarrassment; however, no individual should be "blamed" for an adverse event. It is critical that even near misses be reported. Rather, an analysis of the system causes and circumstances that led to the adverse event should take place (i.e., a root cause analysis). The goals of root cause analysis are to determine what happened, why it happened, and actions that can be taken to reduce the risk of a recurrence.[3]

Examples of root causes of adverse drug events include poor drug distribution practices, dose miscalculations, unclear or ambiguous orders, drug and drug device related problems, incorrect drug administration, and failed communication.

# DISCLOSURE OF ADVERSE EVENTS

Disclosure of adverse events in a timely manner is extremely important for the following reasons:

1. Client satisfaction is positively related to formal open disclosure following an adverse event.[1]
2. The adverse event or near miss will be brought to the attention of other practitioners. By sharing the information, other members of the healthcare team will learn how to avoid making the same error.

All healthcare practitioners must be aware of the policy and process in place to report adverse events, sentinel events, and near misses. The goals of the reporting system are to learn from the event, prevent recurrences, and strengthen the culture of safety in the long-term care environment.[1] MPT

1. Accreditation Canada. 2013 Required Organizational Practices Handbook
2. ISMP Canada Safety Bulletin 2010; 10(9)
3. ISMP Canada Safety Bulletin 2005; 5(10)

## Tecfidera® (dimethyl fumarate) 120 mg delayed capsules that contain enteric-coated microtablets

Tecfidera® is a new oral medication for treatment of relapsing-remitting multiple sclerosis. It has been shown to reduce the frequency of exacerbations and slow progression of disability.

### *Dose & Administration*

The recommended initial dose of Tecfidera® is 120 mg twice daily for seven days. The dose should be increased to two capsules (240 mg) twice daily after that. The dose should be reduced back to 120 mg twice daily, if gastrointestinal side effects or flushing are intolerable.

### *Adverse Effects*

Almost 50% of patients receiving Tecfidera® in clinical trials experienced gastrointestinal (GI) side effects such as nausea, abdominal pain, and diarrhea. Flushing occurs in about one-third of patients taking Tecfidera® but usually improves or dissipates with continued use. Flushing may be reduced by premedication with nonenteric-coated ASA about 30 minutes before the Tecfidera® dose. GI side effects and flushing are most often the adverse effects that cause discontinuation of Tecfidera®.

### *Precautions*

Reduced lymphocyte counts may occur in about 30% of patients in the first year of using Tecfidera®. After discontinuation of the drug, lymphocytes begin to increase again within four weeks. A complete blood count (CBC) should be conducted six months before starting Tecfidera® (to identify pre-existing low lymphocyte count), and repeated six months after initiation of the drug, then every six to twelve months, and as clinically indicated. DN

*Please refer to Tecfidera® product monograph for more comprehensive information.*

## Fycompa® (perampanel) tablets

Fycompa® is an oral tablet (available in 2 mg, 4 mg, 6 mg, 8 mg, 10 mg, 12 mg strengths) indicated as adjunctive therapy in the management of partial-onset seizures in adult patients with epilepsy who are not satisfactorily controlled with conventional treatment. There is limited information on the use of Fycompa® in individuals older than 65 years of age. The safety and efficacy of Fycompa® in paediatric patients (less than 18 years of age) has not been established, and its use is not indicated in these individuals.

### *Dose & Administration*

Fycompa® must be dosed and titrated according to individual patient response. It should be administered once daily at bedtime. In the absence of enzyme-inducing antiepileptic drugs (e.g., CYP3A4 enzyme inducers such as carbamazepine, oxcarbazepine, and phenytoin), the dose of Fycompa® should be started at 2 mg per day. The dose may be increased, based on clinical response and tolerability, by increments of 2 mg up to a dose of 8 mg per day. Dose increases should not occur more frequently than every two weeks. The maximum daily dose of Fycompa® is 12 mg per day.

### *Adverse Effects*

Serious or life-threatening psychiatric and behavioural adverse reactions including aggression, hostility, anger, and homicidal ideation and threats have been reported in patients taking Fycompa®. These reactions have occurred in patients with and without prior psychiatric history. Patients taking Fycompa® should be advised against the use of alcohol, as it may exacerbate these effects.

Additional adverse effects occurring in 5% or more of patients in clinical trials included dizziness, somnolence, fatigue, irritability, nausea, ataxia, and falls. DN

*Please refer to Fycompa® product monograph for more comprehensive information.*