



Office of Ombudsman for Mental Health and Developmental Disabilities



Reporting Medications – Key to Client Safety



This Medical Alert is based on the work of the Medical Review Subcommittee and should be posted prominently. The Office of Ombudsman for Mental Health and Developmental Disabilities works to improve the services provided to people with disabilities by communicating important information found in the Medical Review Subcommittee's reviews of deaths and serious injuries. Thank you for promptly reporting deaths and serious injuries. You are helping us to meet our mission.

The Medical Review Subcommittee reviewed the unexpected death of a client with mental illness and developmental disabilities. After reviewing the case and supporting documentation, the MRS recommended the development of this Medical Alert.

The MRS recommends that residential staff routinely provide all health care providers with a complete list of all medications prescribed for their clients at all appointments, ER visits, and urgent care visits.

The MRS further recommends that residential providers give a copy of a complete list of the client's medications to the client and/or to responsible family members for use while the client is away from the residential facility.

Case Study – Could this happen to your client?

Unexpected death of a client with mental illness and developmental disabilities, who was **prescribed Humira for psoriasis**. This 24-year-old man, with bipolar disorder, schizoaffective disorder, autistic disorder, mild mental retardation, chronic obstructive pulmonary disease, obesity, psoriasis, sleep apnea, and other medical conditions, died on his second day of hospitalization for respiratory difficulties. The client's death was not reported to the medical examiner, and no autopsy was performed. His death certificate was signed by the physician who had attended him during his hospitalization. His manner of death was natural, and his immediate cause of death was attributed to **pneumonia secondary to blastomycosis**.

Prior to his death, the client had lived in an adult foster home for over two years. He had received supervised living services and case management services. He had attended a day treatment and habilitation program. The client was under the guardianship of family members.

The client did not feel well at the end of December. He was taken to see his physician, but no new orders were received. In mid-January, he returned from work with a fever. He was seen by his physician, diagnosed with bronchitis, and prescribed an antibiotic. A few days later, while on pass with his family, he was seen in an emergency room. He was diagnosed with pneumonia and was given another antibiotic as well as a steroid. He was seen three days later by his primary physician. At some point, a nebulizer treatment was ordered.

Three days later, the client was noted to be disoriented and markedly short of breath. He was evaluated by the RN at his adult foster home, and 911 was called. He was hospitalized with significant pneumonia. Despite aggressive efforts, the client experienced a cardiopulmonary arrest and was unable to be resuscitated. Of note, the client had been on Humira since 2008 for psoriasis unresponsive to other treatments.

At its meeting on 2/03/2012, the MRS reviewed and closed this case with the following comments and recommendations:

1. The MRS recommends that residential staff routinely provide all health care providers with a complete list of all medications prescribed for their client at all appointments, ER visits, and urgent care visits.

It is possible that in this case, some of the health care providers were unaware of the risk of infection posed by Humira which was used to treat the client's psoriasis.

The medical record of the client's ER visit shortly before his death lists only lithium as one of the client's medications. Given the client's on-going problem with "pneumonia," it is possible that given the information that the client was taking Humira for his psoriasis, the clinician may have ordered additional testing at that time.

Humira carries the following black-box warning, of which the client, his family members, and staff who administer the medication and who monitor the client should be aware:

WARNINGS: SERIOUS INFECTIONS AND MALIGNANCY

SERIOUS INFECTIONS

Patients treated with Humira are at increased risk for developing serious infections that may lead to hospitalization or death

Humira should be discontinued if a patient develops a serious infection or sepsis.

Reported infections include:

- **Active tuberculosis (TB), including reactivation of latent TB. Patients with TB have frequently presented with disseminated or extrapulmonary disease. Patients should be tested for latent TB before Humira use and during therapy. Treatment for latent TB should be initiated prior to Humira use.**
- **Invasive fungal infections, including histoplasmosis, coccidioidomycosis, candidiasis, aspergillosis, **blastomycosis**, and pneumocystosis. Patients with histoplasmosis or other invasive fungal infections may present with disseminated, rather than localized, disease. Antigen and antibody testing for histoplasmosis may be negative in some patients with active infection. Empiric anti-fungal therapy should be considered in patients at risk for invasive fungal infections who develop severe systemic illness.**
- **Bacterial, viral and other infections due to opportunistic pathogens, including Legionella and Listeria.**

The risks and benefits of treatment with Humira should be carefully considered prior to initiating therapy in patients with chronic or recurrent infection.

Patients should be closely monitored for the development of signs and symptoms of infection during and after treatment with Humira, including the possible development of TB in patients who tested negative for latent TB infection prior to initiating therapy....

[From http://www.drugs.com/pro/humira.html#section_5.1]

2. In addition, the MRS recommends that the residential provider give a copy of a complete list of the client's medications to the client and/or to responsible family members for use while the client is away from the residential facility.
3. The MRS recommended the development of a Medical Alert addressing the importance of residential staff providing all health care providers with complete lists of all medications prescribed for their clients at appointments, ER visits, and urgent care visits.
4. At the closure of this case, the Medical Review Coordinator reported this Humira-related death to the FDA's MedWatch program.

Further information – The residential provider in this case has made it a practice to provide all health care providers with a copy of the client's Medication Administration Record. They have added a line to their **MEDICAL APPOINTMENT FORM** directing staff to have the provider initial the form to indicate that they have received a list of the client's current medications.

In addition, it has been their practice to provide the client and/or person with whom the client is going on a pass away from the home with a copy of the client's Medication Administration Record. The residential provider is now asking the client/responsible person to sign a document stating they have received a copy of the client's Medication Administration Record.