Drug Adverse Event System Delivers Mixed Results

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A new national active surveillance system designed to detect adverse drug events is very good at picking up true cases, but not particularly sensitive—especially when it comes to detecting hypoglycemia due to diabetes medications and bleeding associated with anticoagulants, the Centers for Disease Control and Prevention reported.

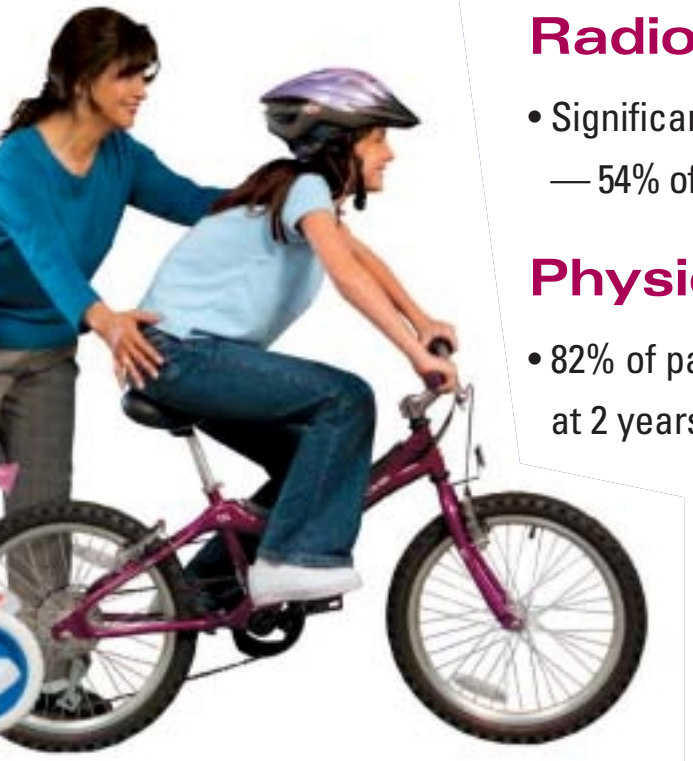
In 2003, the CDC collaborated with the Consumer Product Safety Commission and the Food and Drug Administration in developing the National Electronic Injury Surveillance System–Cooperative Adverse Drug Event Surveillance (NEISS-CADES) project.

Because adverse drug events (ADEs) are often more difficult to identify than other injuries, the CDC conducted an independent chart review in a sample of six NEISS-CADES hospitals, representing a range of sizes and of ADE reporting rates (0.2%-1.7% of emergency department visits).

Of 4,561 ED visit charts reviewed, a total of 68 ADE cases were identified. The patients had a median age of 57 years and 53% were female. Of the 29 ADE cases that had been reported to NEISS-CADES prior to the chart review, 25 were among the 68 cases detected by the reviewers. The remaining four were false-positives in which an injury attributed to a drug in the chief complaint section of the chart was not confirmed elsewhere in the chart, the CDC explained (MMWR 2005;54:380-3).

The estimated sensitivity of the NEISS-CADES for ascertaining ADEs was 0.33, while the estimated positive predictive value of a reported ADE to the system was 0.92. The relatively low sensitivity of the system was attributed to the difficulty in detecting hypoglycemia associated with diabetes agents (just 3 of 16 were detected), and of bleeding associated with anticoagulants such as warfarin and heparin (1 of 9 were detected). ■

Built on Response



Clinical response

• Significant improvement in ACR response rates[2]
—ACR 20, 50, and 70 with HUMIRA/MTX vs placebo/MTX: 65%, 52%, and 24% vs 13%, 7%, and 3% ($P<0.01$)*

Radiographic response

• Significant inhibition of disease progression[2]
— 54% of patients had no progression of structural damage†

Physical function response

• 82% of patients‡ maintained improvements in HAQ-DI at 2 years[2]

HUMIRA® (adalimumab)

CLOSELY. TREATMENT SHOULD BE DISCONTINUED IF A PATIENT DEVELOPS A SERIOUS INFECTION. DO NOT START HUMIRA IN PATIENTS WITH ACTIVE INFECTION (INCLUDING CHRONIC OR LOCALIZED), OR ALLERGY TO HUMIRA OR ITS COMPONENTS. EXERCISE CAUTION IN PATIENTS WITH A HISTORY OF RECURRENT INFECTION OR WITH UNDERLYING CONDITIONS, WHICH MAY PREDISPOSE PATIENTS TO INFECTIONS.

The combination of HUMIRA and anakinra is not recommended. TNF-blocking agents, including HUMIRA, have been associated in rare cases with exacerbation of demyelinating disease. Exercise caution when considering HUMIRA for patients with these disorders. Lymphoma has been observed in patients treated with TNF-blocking agents. The role of TNF-blocking agents in the development of malignancy is not known.

Anaphylaxis has been reported rarely following HUMIRA administration. Rare reports of pancytopenia including aplastic anemia have been reported with TNF-blocking agents. Medically significant cytopenia (e.g. thrombocytopenia, leukopenia) has been infrequently reported with HUMIRA. The causal relationship of these reports to HUMIRA remains unclear. Worsening congestive heart failure (CHF) has been observed with TNF-blocking agents, including HUMIRA, and new onset CHF has been reported with TNF-blocking agents.

Most frequent adverse events vs placebo from placebo-controlled studies were injection site reactions (20% vs 14%), upper respiratory infection (17% vs 13%), injection site pain (12% vs 12%), headache (12% vs 8%), rash (12% vs 6%), and sinusitis (11% vs 9%). Discontinuations due to adverse events were 7% for HUMIRA vs 4% for placebo.

References: 1. Data on file, Abbott Laboratories. **2.** HUMIRA Prescribing Information. Abbott Laboratories. July 2004.

Please see brief summary of prescribing information on adjacent page.

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