Health Agencies Update

ED Visits for Sedatives Increase

Emergency department (ED) visits involving misuse of the sedative alprazolam doubled between 2005 and 2010, according to a new report from the Substance Abuse and Mental Health Services Administration (SAMHSA).

People sometimes abuse alprazolam, a benzodiazepine used to treat anxiety, for its psychoactive effects. Taking too much alprazolam or taking it in combination with other medictions can exacerbate the drug's effects, depress breathing, or lead to overdose. Patients who take the drug regularly for even short periods also may experience symptoms of withdrawal, such as tremors and seizures. Between 2005 and 2010, the estimated number of ED visits involving nonmedical use of alprazolam increased from 57 419 to 124 902 and then plateaued in 2011 at 123 744, according to the SAMHSA report (http://1.usa.gov/1tvn9X3).

Most of the visits involved patients taking other pharmaceuticals, illegal drugs, or alcohol in combination with alprazolam, with 39% of visits involving 1 other drug, 21% involving 2 other drugs, and 21% involving 3 or more drugs. Opioid painkillers and other benzodiazapines were among the pharmaceuticals frequently taken in combination with alprazolam.

FDA Opens Adverse Event Data

The US Food and Drug Administration (FDA) has launched a new initiative to make it easier for researchers, web developers, and others to access and build interactive tools based the FDA's Adverse Events Reporting System data.

The openFDA (http://open.FDA.gov) initiative is part of a larger effort to make Department of Health and Human Services data more accessible. Currently, the adverse event reports are publicly available (with identifying data excluded). Accessing the data, however, requires a time-consuming Freedom of Information Act request. In addition, the FDA typically provides the information in a report that may not be easy to use.

The openFDA project will make the adverse event report data available in a structured, computer-readable format that technologists can use to build interactive applications or visualizations. The project uses an application programming interface to collect the data and make it easy to search. This format will also make it easier for researchers to quickly search and collect FDA data. The agency plans to eventually make product recalls and drug labeling data available as well.

Clinician's Guide for Genomics

The number of physicians ordering genome or exome testing for their patients is expected to increase from several thousand this year to 10 000 next year, with continued growth thereafter, according to National Human Genome Research Institute's Leslie G. Biesecker, MD. Because uptake of this new technology is increasing, Biesecker and Robert C. Green, MD, MPH, of Harvard Medical School, have published a primer to help clinicians implement these technologies (Biesecker LG and Green RC. *N Engl J Med*. 2014;370[25]:2418-2425).

Clinical versions of tools used for the Human Genome Project are rapidly finding their way into practice as technological advances decrease cost and studies reveal their utility. Exome sequencing focuses only on DNA regions that encode proteins (about 20 000 genes or 1%-2% of the genome); genome sequencing is more comprehensive. Computer programs can help physicians compare their patient's DNA to a reference sample, which may help identify genetic variations that might explain the individual's medical condition.

To help physicians learn about the use of these new tools, the guide explains several key issues. For example, because both whole-genome and exome sequencing miss some genetic anomalies, a negative test will not rule out a genetic disease. So far, the authors note these tools are most useful for patients with rare single-gene disorders. Exome sequencing only identifies a genetic cause about one-quarter of the time. Even when a genetic cause is identified, there is often no cure, but a diagnosis may end unnecessary testing or off-target treatments, the authors note.

The US Food and Drug Administration (FDA) has set new ground rules for online marketing of FDA-regulated products.

FDA Sets Social Media Rules

The US Food and Drug Administration (FDA) released its long-awaited guidance for marketing via social media in June.

As part of their efforts to sell medical products, marketers and drug companies have been eager to use social media, including forms of online advertising that involve stringent length constraints. However, lack of clarity about rules for use of social media and how they differed from the rules for traditional print and web marketing led many companies to avoid this venue.

The FDA's guidance documents address 2 issues. One document explains that marketers are required to balance risk and benefit information, even when there are character limits, such as on Twitter, which allows a maximum of 140 characters (http://1.usa.gov/1lvM79F). The document states that marketers should note the most important risk information within the character-limited space and provide a link to detailed information. The other document states that marketers are not required to correct misleading information posted by third parties not under their control but may correct the information if they choose to do so (http://1.usa.gov/1nMdUOX). Many marketers had been concerned that the FDA would require them to police misinformation on the web. **– Bridget M. Kuehn, MSJ**