



## POLICY & PRACTICE

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### Elderly Women Miss Screening

Many women aged 65 and older have never been tested for osteoporosis risk, according to a report from the Centers for Disease Control and Prevention. The agency examined the women's history of bone mass and bone density screening as recommended by the U.S. Preventive Services Task Force for Medicare beneficiaries. Varying by race, large percentages of women 65 and older reported never having received either of the tests. Among black women, 62% said they had never been tested. The figures for Medicare-eligible American Indian/Alaska Native women and white women who were never tested were 54% and 33%, respectively. The report found similar shortcomings in the percentages of elderly people getting other recommended – and often free – preventive services, such as vaccinations or diabetes and cancer screening.

### Drug Injuries Are Up

The number of people treated in hospitals after they took the wrong medicine or an incorrect dose jumped by more than half, from 2004 to 2008, the Agency for Healthcare Research and Quality reported. Pain killers, antibiotics, tranquil-

izers/antidepressants, and corticosteroids/other hormones headed the list of medications for which people were treated in emergency departments and released, the agency said. Corticosteroids, painkillers, blood thinners, drugs to treat cancer and immune system disorders, and heart and blood pressure medicines led to the most people being admitted to hospitals. More than half of people hospitalized were aged 65 years or older; children and teenagers accounted for 22% of the emergency department cases. More women than men suffered injuries and side effects, according to the report.

### NIH Begins Function Study

Researchers at the National Institutes of Health have begun recruiting 9,000 Medicare beneficiaries for a study of how daily function changes with age. The National Health and Aging Trends Study will look specifically at how aging affects walking, dressing, other activities of daily living. Study participants will be interviewed in person in 2011 and then once a year. Researchers also will conduct short tests of physical performance. "The recently observed trend toward decreasing rates of disability identified by the Na-

tional Long Term Care Survey and other national surveys may have leveled off, and this has serious implications," Richard Suzman, Ph.D., director of the division of behavioral and social research at the National Institute on Aging, said in a statement. The National Long Term Care Survey found that physical disability dropped significantly among older people between 1982 and 2005.

### Congress Members Want Help

In a letter, members of the House Energy and Commerce Committee asked 51 physician groups, including the American College of Rheumatology, to help craft a "permanent" and "sustainable" solution to the Medicare physician-payment system. Under the current system, based on the sustainable growth rate (SGR) formula, physicians will face a 29% cut to Medicare payments in 2012. The letter criticized the current formula and asked the physicians to suggest alternatives. The lawmakers said they are seeking payment models that reduce spending, pay providers fairly, and pay for services according to their value to beneficiaries.

### Bill Would Expose Billing

Sen. Ron Wyden (D-Ore.) and Sen. Charles Grassley (R-Iowa) have introduced a bill that would require the government to disclose what physicians earn from Medicare. The Medicare Data Access for Transparency and Accountability

Act would keep patient information blind. "Taxpayers should have a right to see how their hard-earned dollars are being spent," said Sen. Grassley in a statement on the Senate floor. "Also, if doctors know their billing information is public, it might deter some wasteful practices and over-billing." Medicare has been prohibited from making the data public since a 1979 court ruling. Physician organizations, most notably the American Medical Association, have also opposed the release of the data, citing doctors' right to privacy.

### Medical Boards Fail on Discipline

State medical boards failed to discipline more than half of doctors who either lost their clinical privileges or had them restricted by the hospitals where they worked, according to a report from advocacy group Public Citizen. In all, 10,672 physicians were listed in the National Practitioner Data Bank as having restricted or revoked clinical privileges, yet 5,887 (55%) of them did not see any licensing action from their states, the group reported. Of those escaping licensing actions, 1,119 had been otherwise disciplined for incompetence, negligence, or malpractice, and 605 were disciplined for substandard care, the report said. Hospital boards had identified 220 of the otherwise-unsanctioned doctors as "an immediate threat to health or safety," according to Public Citizen.

—Mary Ellen Schneider

**Live Vaccines** Live vaccines should not be given concurrently with HUMIRA [see Warnings and Precautions].

#### USE IN SPECIFIC POPULATIONS

**Pregnancy** Pregnancy Category B - There are no adequate and well-controlled studies in pregnant women. Because animal reproduction and developmental studies are not always predictive of human response, HUMIRA should be used during pregnancy only if clearly needed.

**Pregnancy Registry:** To monitor outcomes of pregnant women exposed to HUMIRA, a pregnancy registry has been established. Physicians are encouraged to register patients by calling 1-877-311-8972.

**Nursing Mothers** It is not known whether adalimumab is excreted in human milk or absorbed systemically after ingestion. Because many drugs and immunoglobulins are excreted in human milk, and because of the potential for serious adverse reactions in nursing infants from HUMIRA, a decision should be made whether to discontinue nursing or to discontinue the drug, taking into account the importance of the drug to the mother.

**Pediatric Use** Safety and efficacy of HUMIRA in pediatric patients for uses other than juvenile idiopathic arthritis (JIA) have not been established.

**Juvenile Idiopathic Arthritis** In the JIA trial, HUMIRA was shown to reduce signs and symptoms of active polyarticular JIA in patients 4 to 17 years of age. HUMIRA has not been studied in children less than 4 years of age, and there are limited data on HUMIRA treatment in children with weight <15 kg.

The safety of HUMIRA in pediatric patients in the JIA trial was generally similar to that observed in adults with certain exceptions [see Adverse Reactions].

Post-marketing cases of malignancies, some fatal, have been reported among children, adolescents, and young adults who received treatment with TNF-blockers including HUMIRA [see Warnings and Precautions].

**Geriatric Use** A total of 519 rheumatoid arthritis patients 65 years of age and older, including 107 patients 75 years of age and older, received HUMIRA in clinical studies RA-I through IV. No overall difference in effectiveness was observed between these subjects and younger subjects. The frequency of serious infection

and malignancy among HUMIRA treated subjects over 65 years of age was higher than for those under 65 years of age. Because there is a higher incidence of infections and malignancies in the elderly population in general, caution should be used when treating the elderly.

#### OVERDOSAGE

Doses up to 10 mg/kg have been administered to patients in clinical trials without evidence of dose-limiting toxicities. In case of overdosage, it is recommended that the patient be monitored for any signs or symptoms of adverse reactions or effects and appropriate symptomatic treatment instituted immediately.

#### NONCLINICAL TOXICOLOGY

**Carcinogenesis, Mutagenesis, Impairment of Fertility** Long-term animal studies of HUMIRA have not been conducted to evaluate the carcinogenic potential or its effect on fertility. No clastogenic or mutagenic effects of HUMIRA were observed in the *in vivo* mouse micronucleus test or the *Salmonella-Escherichia coli* (Ames) assay, respectively.

#### PATIENT COUNSELING INFORMATION

Patients or their caregivers should be provided the HUMIRA "Medication Guide" and provided an opportunity to read it and ask questions prior to initiation of therapy. The healthcare provider should ask the patient questions to determine any risk factors for treatment. Patients developing signs and symptoms of infection should seek medical evaluation immediately.

**Patient Counseling** Patients should be advised of the potential benefits and risks of HUMIRA. Physicians should instruct their patients to read the Medication Guide before starting HUMIRA therapy and to reread each time the prescription is renewed.

• **Infections** Inform patients that HUMIRA may lower the ability of their immune system to fight infections. Instruct patients of the importance of contacting their doctor if they develop any symptoms of infection, including tuberculosis, invasive fungal infections, and reactivation of hepatitis B virus infections.

• **Malignancies** Patients should be counseled about the risk of malignancies while receiving HUMIRA.

• **Allergic Reactions** Patients should be advised to seek immediate medical attention if they experience any symptoms of severe allergic reactions. Advise latex-sensitive patients that the needle cap of the prefilled syringe contains latex.

• **Other Medical Conditions** Advise patients to report any signs of new or worsening medical conditions such as congestive heart failure, neurological disease, autoimmune disorders, or cytopenias. Advise patients to report any symptoms suggestive of a cytopenia such as bruising, bleeding, or persistent fever.

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