

Physicians Are No. 1 Source for Drug Law Info

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WASHINGTON — Older patients are choosing their physician over the phone or using electronic resources to help them understand the complexities of the new prescription drug law.

Many beneficiaries don't understand what the new law does, and many are not comfortable looking for information online, Drew Altman, president and CEO of

the Kaiser Family Foundation, said during the annual conference of the National Academy of Social Insurance.

In a Kaiser Family Foundation poll of more than 1,200 adults, only 13% said they understood the new law very well. More than half (53%) said they didn't have enough information about the law to understand how it would impact them personally.

The poll was conducted in December 2004 and included responses from 237

adults aged 65 years and older and 953 adults aged 18-64.

In a question specifically addressed to seniors, respondents were asked what sources they would turn to for help. The majority (38%) said they'd ask for their physician's counsel when deciding whether or not to enroll in a Medicare drug plan, Mr. Altman said.

Seniors also cited Medicare offices, Web sites, or phone number (31%); pharmacists (30%); and health insurance companies (25%) as consultation sources for the new drug benefit.

Upon closer look, however, it doesn't seem as if the Internet or the phone are popular venues to get information. Forty-three percent of the seniors who responded to the poll said they'd never heard of the 1-800 Medicare number, and 42% were aware of it but have never used it.

Only 6% of the respondents said they had heard of Medicare.gov, and 39% said they'd never heard of the Web site. For those aged 65 and older, 73% said they have never gone online, and 85% said they've never gotten assistance from a friend or family member to visit an Internet site on their behalf to get information about Medicare.

Most of the information isn't access friendly to the average beneficiary, Roslyn Taylor, M.D., a family physician in Savannah, Ga., said in an interview. "Many of the seniors do not have or know how to use computers." Those patients who did "told me that even if they went on the Web site they still were confused."

Tackling Health Illiteracy Key in Managing Chronic Disease Patients

WASHINGTON — Physicians are experimenting with better ways to communicate with patients with low health literacy, Joanne Schwartzberg, M.D., said at a conference on health literacy sponsored by the American College of Physicians.

"It's right in the lap of every physician," said Dr. Schwartzberg, director of aging and community health at the American Medical Association. "Physicians can't say it's someone else's problem."

Using simple language, distributing patient education materials, speaking slowly, reading instructions aloud, using teach-back techniques, and drawing pictures are some of the ways health care providers say they are trying to do a better job of reaching out to patients with low health literacy, Dr. Schwartzberg said.

The AMA has developed a health literacy kit with a video and manual for clinicians. The group has also started a train-the-trainer program. To date, the group has trained 11 teams from state and specialty societies. In 6 months, the first 5 teams have conducted 57 trainings and reached more than 1,500 physicians, she said.

Preliminary results show that after the training, a majority of the physicians changed their communication with patients.

For example, many reported that they

Thirty-seven percent of the seniors who responded to the survey said they would prefer to get their Medicare information from mailings, and 25% said they would not mind obtaining the information in person from Medicare or Social Security offices. Only 18% cited toll-free telephone hotlines as a preferred method.

Physicians themselves may need a quick tutorial on the new benefits. "I think that a lot of physicians are not aware of the details regarding what new things Medicare is covering—and under what specific rules," said Colette Willins, M.D., a professor at Case Western Reserve University in Westlake, Ohio.

Older beneficiaries seemed more aware of specific benefits. Respectively, 86% and 67% of beneficiaries aged 65 and older knew about the discount drug card and a \$600 subsidy on the costs of drugs for low-income people. Only 27% of beneficiaries aged 18-64 were aware of the subsidy.

Senior respondents seemed divided on their reported plans to enroll in the drug benefit in 2006. Nineteen percent said they would, 37% said they would not, and another 37% said they hadn't heard enough about the new benefit to decide.

Seniors who responded to the Kaiser survey thought low-income people on Medicare would benefit the most from the new law, although fewer respondents thought it would help the typical Medicare beneficiary. Only 34% thought it would be very or somewhat helpful to them, personally. "It does seem like a pretty difficult program to explain," Dr. Farley said. ■

with moderately to severely active rheumatoid arthritis and Crohn's disease treated with REMICADE in clinical trials with a median of 1.1 years of follow-up, 3 patients developed lymphomas, for a rate of 0.07 cases per 100 patient-years of follow-up in patients with rheumatoid arthritis and 0.12 cases per 100 patient-years of follow-up in the combined clinical trial data for rheumatoid arthritis and Crohn's disease patients. This is approximately 3-fold higher in the RA clinical trial population and 6-fold higher in the overall clinical trial population than expected in an age-, gender-, and race-matched general population based on the Surveillance, Epidemiology and End Results Database. Rates in clinical trials for REMICADE cannot be compared to rates of clinical trials of other TNF blockers and may not predict rates observed in a broader patient population. An increased rate of lymphoma up to several fold has been reported in the Crohn's disease and rheumatoid arthritis patient populations, and may be further increased in patients with more severe disease activity. Other than lymphoma, 13 patients developed malignancies, which was similar in number to what would be expected in the general population. Of these, the most common malignancies were breast, colorectal, and melanoma. (See **WARNINGS, Malignancies.**) Malignancies, including non-Hodgkin's lymphoma and Hodgkin's disease, have also been reported in patients receiving REMICADE during post-approval use. **Patients with Heart Failure** In a randomized study evaluating REMICADE in moderate to severe heart failure (NYHA Class III/IV; left ventricular ejection fraction $\leq 35\%$), 150 patients were randomized to receive treatment with 3 infusions of REMICADE 10 mg/kg, 5 mg/kg, or placebo, at 0, 2, and 6 weeks. Higher incidences of mortality and hospitalization due to worsening heart failure were observed in patients receiving the 10 mg/kg REMICADE dose. At 1 year, 8 patients in the 10 mg/kg REMICADE group had died compared with 4 deaths each in the 5 mg/kg REMICADE and the placebo groups. There were trends towards increased dyspnea, hypotension, angina, and dizziness in both the 10 mg/kg and 5 mg/kg REMICADE treatment groups, versus placebo. REMICADE has not been studied in patients with mild heart failure (NYHA Class I/II) (see **CONTRAINDICATIONS** and **WARNINGS, Patients with Heart Failure**). **Immunogenicity** Treatment with REMICADE can be associated with the development of antibodies to infliximab. The incidence of antibodies to infliximab in patients given a 3-dose induction regimen followed by maintenance dosing was approximately 10% as assessed through one to two years of REMICADE treatment. A higher incidence of antibodies to infliximab was observed in Crohn's disease patients receiving REMICADE after drug-free intervals >16 weeks. The majority of antibody-positive patients had low titers. Patients who were antibody-positive were more likely to have higher rates of clearance, reduced efficacy and to experience an infusion reaction (see **ADVERSE REACTIONS, Infusion-related Reactions**) than were patients who were antibody negative. Antibody development was lower among rheumatoid arthritis and Crohn's disease patients receiving immunosuppressant therapies such as 6-MP/AZA or MTX. The data reflect the percentage of patients whose test results were positive for antibodies to infliximab in an ELISA assay, and are highly dependent on the sensitivity and specificity of the assay. Additionally, the observed incidence of antibody positivity in an assay may be influenced by several factors including sample handling, timing of sample collection, concomitant medication, and underlying disease. For these reasons, comparison of the incidence of antibodies to infliximab with the incidence of antibodies to other products may be misleading. **Hepatotoxicity** Severe liver injury, including acute liver failure and autoimmune hepatitis, has been reported rarely in patients receiving REMICADE (see **WARNINGS, Hepatotoxicity**). Reactivation of hepatitis B has occurred in patients receiving REMICADE who are chronic carriers of this virus (i.e., surface antigen positive) (see **WARNINGS, Hepatotoxicity**). In clinical trials in RA, Crohn's disease and ankylosing spondylitis, elevations of aminotransferases were observed (ALT more common than AST) in a greater proportion of patients receiving REMICADE than in controls, both when REMICADE was given as monotherapy and when it was used in combination with other immunosuppressive agents. In general, patients who developed ALT and AST elevations were asymptomatic, and the abnormalities decreased or resolved with either continuation or discontinuation of REMICADE, or modification of concomitant medications. ALT elevations ≥ 5 times the upper limit of normal were observed in 1% of patients receiving REMICADE. In rheumatoid arthritis clinical trials, 34% of patients who received REMICADE + MTX experienced transient mild (<2 times the upper limit of normal) or moderate (≥ 2 but <3 times the upper limit of normal) elevations in ALT compared to 24% of patients treated with placebo + MTX. ALT elevations ≥ 3 times the upper limit of normal were observed in 3.9% of patients who received REMICADE + MTX compared with 3.2% of patients who received MTX alone (median follow up approximately 1 year). In Crohn's disease clinical trials (median follow up 54 weeks), 39% of patients receiving REMICADE-maintenance experienced mild to moderate elevations in ALT, compared to 34% of patients treated with placebo-maintenance. ALT elevations ≥ 3 times the upper limit of normal were observed in 5.0% of patients who received REMICADE-maintenance compared with 4.0% of patients who received placebo-maintenance. In an ankylosing spondylitis clinical trial in which patients were not receiving MTX, 40% of patients who received REMICADE experienced mild to moderate elevations in ALT compared to 13% of patients treated with placebo. ALT elevations ≥ 3 times the upper limit of normal were observed in 12 (6%) REMICADE-treated patients compared to none in placebo-treated patients. **Other Adverse Reactions** Safety data are available from 2629 REMICADE-treated patients, including 1304 with rheumatoid arthritis, 1106 with Crohn's disease, 202 with ankylosing spondylitis and 17 with other conditions. Adverse events reported in $\geq 5\%$ of all patients with rheumatoid arthritis receiving 4 or more infusions are listed below. The types and frequencies of adverse reactions observed were similar in REMICADE-treated rheumatoid arthritis, ankylosing spondylitis and Crohn's disease patients except for abdominal pain, which occurred in 26% of REMICADE-treated patients with Crohn's disease. In the Crohn's disease studies, there were insufficient numbers and duration of follow-up for patients who never received REMICADE to provide meaningful comparisons. The percentages of adverse events for placebo-treated patients (n=350; average weeks of follow-up 59) and REMICADE-treated patients (n=1129; average weeks of follow-up 66), respectively, are: *Gastrointestinal:* Nausea: 20, 21; Abdominal pain: 8, 12; Diarrhea: 12, 12; Dyspepsia: 7, 10. *Respiratory:* Upper respiratory tract infection: 25, 32; Sinusitis: 8, 14; Pharyngitis: 8, 12; Coughing: 8, 12; Bronchitis: 9, 10; Rhinitis: 5, 8; *Skin and appendages disorders:* Rash: 5, 10; Pruritis: 2, 7; *Body as a whole—general disorders:* Fatigue: 7, 9; Pain: 7, 8; *Resistance mechanism disorders:* Fever: 4, 7; Moniliasis: 3, 5; *Central and peripheral nervous system disorders:* Headache: 14, 18; *Musculoskeletal system disorders:* Back pain: 5, 8; Arthralgia: 7, 8; *Urinary system disorders:* Urinary tract infection: 6, 8; *Cardiovascular disorders, general:* Hypertension: 5, 7. Because clinical trials are conducted under widely varying conditions, adverse reaction rates observed in clinical trials of a drug cannot be directly compared to rates in clinical trials of another drug and may not predict the rates observed in broader patient populations in clinical practice. The most common serious adverse events observed in clinical trials were infections (see **ADVERSE REACTIONS, Infections**). Other serious, medically relevant adverse events $\geq 0.2\%$ or clinically significant adverse events by body system were as follows: *Body as a whole:* allergic reaction, diaphragmatic hernia, edema, surgical/procedural sequela; *Blood:* pancytopenia; *Cardiovascular:* circulatory failure, hypotension, syncope; *Gastrointestinal:* constipation, gastrointestinal hemorrhage, ileus, intestinal obstruction, intestinal perforation, intestinal stenosis, pancreatitis, peritonitis, proctalgia; *Central and Peripheral Nervous:* meningitis, neuritis, peripheral neuropathy, dizziness; *Heart Rate and Rhythm:* arrhythmia, bradycardia, cardiac arrest, tachycardia; *Liver and Biliary:* biliary pain, cholecystitis, cholelithiasis, hepatitis; *Metabolic and Nutritional:* dehydration; *Musculoskeletal:* intervertebral disk herniation, tendon disorder; *Myo-, Endo-, Pericardial, and Coronary Valve:* myocardial infarction; *Platelet, Bleeding, and Clotting:* thrombocytopenia; *Neoplasms:* basal cell, breast, lymphoma; *Psychiatric:* confusion, suicide attempt; *Red Blood Cell:* anemia, hemolytic anemia; *Reproductive:* menstrual irregularity; *Resistance Mechanism:* cellulitis, sepsis, serum sickness; *Respiratory:* adult respiratory distress syndrome, lower respiratory tract infection (including pneumonia), pleural effusion, pleurisy, pulmonary edema, respiratory insufficiency; *Skin and Appendages:* increased sweating, ulceration; *Urinary:* renal calculus, renal failure; *Vascular (Extracardiac):* brain infarction, pulmonary embolism, thrombophlebitis; *White Cell and Reticuloendothelial:* leukopenia, lymphadenopathy. The following adverse events have been reported during post-approval use of REMICADE: neutropenia (see **WARNINGS, Hematologic Events**), interstitial pneumonitis/fibrosis, idiopathic thrombocytopenic purpura, thrombotic thrombocytopenic purpura, pericardial effusion, systemic and cutaneous vasculitis, Guillain-Barré syndrome, transverse myelitis, and neuropathies (additional neurologic events have also been observed, see **WARNINGS, Neurologic Events**). Because these events are reported voluntarily from a population of uncertain size, it is not always possible to reliably estimate their frequency or establish a causal relationship to REMICADE exposure. **OVERDOSAGE:** Single doses up to 20 mg/kg have been administered without any direct toxic effect. 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. **REFERENCE:** 1. American Thoracic Society, Centers for Disease Control and Prevention. Targeted tuberculin testing and treatment of latent tuberculosis infection. *Am J Respir Crit Care Med* 2000;161:S221-S247.

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