

U.S. Behind on Access, Cost of Health Care

VITALS

Major Finding: The U.S. compares poorly with 10 other industrialized nations when it comes to major indicators of access to care, including cost, difficulty paying medical bills, difficulty accessing needed care, and overall problems with health insurance.

Data Source: Survey of 19,700 adults in 11 countries by the Commonwealth Fund.

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BY JANE ANDERSON

FROM HEALTH AFFAIRS

Adults in the United States are far more likely than those in 10 other countries to go without health care due to cost or have difficulty paying medical bills, according to a new 11-country survey.

The United States lags signifi-

cantly on access, affordability, and problems with health insurance despite spending more than twice as much on average as the other 10 countries included in the annual survey, according to "How Health Insurance Design Affects Access to Care and Costs, by Income, in Eleven Countries."

But some of these disparities could be reversed as provisions

of the Affordable Care Act begin to take effect, Karen Davis, president of the Commonwealth Fund, said in a telephone press briefing. "There could be some effects early on, but the big difference should show up in 2015 or 2016."

The Commonwealth Fund has surveyed adults in these 11 countries for the last 13 years to gain insights into how different coverage and program designs affect access, financial protection, and other health insurance issues. The 2010 edition of the survey involved interviews with 19,700 adults in Australia, Canada, France, Germany, the Netherlands, New Zealand, Norway, Sweden, Switzerland, the United Kingdom, and the United States (10.1377/hlthaff.2010.0862).

The report found significant disparities between the United States and most of the other countries studied.

For example, the report showed one-third of U.S. adults went without necessary care, failed to see a physician when sick, or failed to fill a prescription due to the costs involved. Germany and Australia also scored poorly on those measures – 25% of Germans and 22% of Australians reported going without care due to costs.

About 35% of Americans faced \$1,000 or more in out-of-pocket costs each year, more than any of the other countries studied, the survey found. Twenty-one percent of Australians and 25% of Swiss residents also faced out-of-pocket costs of \$1,000 or more.

One-fifth of U.S. respondents reported a serious problem in paying a health care bill, compared with 9% in France, the next highest on this measure.

"We emerged as the only country in the study where being insured doesn't guarantee you'll be covered when you get sick," said Cathy Schoen, senior vice president at the Commonwealth Fund and lead author of the study.

U.S. adults were significantly less likely than their international peers to have confidence in their ability to afford care, and were less confident than adults everywhere except in Sweden and Norway that they would receive the most effective treatment when needed, according to the study. Only 70% of U.S. adults said they expected they would receive the most effective treatment, including diagnostic tests and drugs.

The Affordable Care Act should begin to reverse some of the disparities between the United States and other industrialized countries, although the changes will take some time to be felt, said Ms. Davis. "The new law will ensure access to affordable health care coverage to 32 million Americans who are uninsured, but just as important are the system reforms in the new law."

However, with health care spending in the United States topping \$7,500 per person, more than twice the average of the other 10 countries in the survey, it will take time to begin to "bend the cost curve," she said, adding that "we see about half a percentage point slowdown" in the annual increase in health care costs as a result of ACA provisions. ■

Postmarketing Experience—The following adverse reactions have been identified during postapproval use of FORTEO. Because these reactions 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 drug exposure.

- **Osteosarcoma:** Cases of bone tumor and osteosarcoma have been reported rarely in the postmarketing period. The causality to FORTEO use is unclear. Long term osteosarcoma surveillance studies are ongoing.
- **Hypercalcemia:** Hypercalcemia greater than 13.0 mg/dL has been reported with FORTEO use.

Adverse events reported since market introduction that were temporally (but not necessarily causally) related to FORTEO therapy include the following:

- **Allergic Reactions:** Anaphylactic reactions, drug hypersensitivity, angioedema, urticaria;
- **Investigations:** Hyperuricemia;
- **Respiratory System:** Acute dyspnea, chest pain;
- **Musculoskeletal:** Muscle spasms of the leg or back;
- **Other:** Injection site reactions including injection site pain, swelling and bruising; oro-facial edema.

USE IN SPECIFIC POPULATIONS: Pregnancy Category C—There are no adequate and well-controlled studies of FORTEO in pregnant women. In animal studies, teriparatide increased skeletal deviations and variations in mouse offspring at doses more than 60 times the equivalent human dose and produced mild growth retardation and reduced motor activity in rat offspring at doses more than 120 times the equivalent human dose. FORTEO should be used during pregnancy only if the potential benefit justifies the potential risk to the fetus.

In animal studies, pregnant mice received teriparatide during organogenesis at subcutaneous doses 8 to 267 times the human dose. At doses \geq 60 times the human dose, the fetuses showed an increased incidence of skeletal deviations or variations (interrupted rib, extra vertebra or rib). When pregnant rats received subcutaneous teriparatide during organogenesis at doses 16 to 540 times the human dose, the fetuses showed no abnormal findings.

In a perinatal/postnatal study, pregnant rats received subcutaneous teriparatide from organogenesis through lactation. Mild growth retardation in female offspring at doses \geq 120 times the human dose (based on surface area, mcg/m²). Mild growth retardation in male offspring and reduced motor activity in both male and female offspring occurred at maternal doses 540 times the human dose. There were no developmental or reproductive effects in mice or rats at doses 8 or 16 times the human dose, respectively.

Exposure multiples were normalized based on body surface area (mcg/m²). Actual animal doses: mice (30 to 1000 mcg/kg/day); rats (30 to 1000 mcg/kg/day).

Nursing Mothers—It is not known whether teriparatide is excreted in human milk. Because of the potential for tumorigenicity shown for teriparatide in animal studies, 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—The safety and efficacy of FORTEO have not been established in any pediatric population. FORTEO should not be prescribed in patients at an increased baseline risk of osteosarcoma which include pediatric and young adult patients with open epiphyses. Therefore, FORTEO is not indicated for use in pediatric or young adult patients with open epiphyses.

Geriatric Use—Of the patients receiving FORTEO in the osteoporosis trial of 1637 postmenopausal women, 75% were 65 years of age and over and 23% were 75 years of age and over. Of the patients receiving FORTEO in the osteoporosis trial of 437 men, 39% were 65 years of age and over and 13% were 75 years of age and over. No overall differences in safety or effectiveness were observed between these subjects and younger subjects, and other reported clinical experience has not identified differences in responses between the elderly and younger patients, but greater sensitivity of some older individuals cannot be ruled out.

Hepatic Impairment—No studies have been performed in patients with hepatic impairment.

Renal Impairment—In 5 patients with severe renal impairment (CrCl $<$ 30 mL/min), the AUC and T_{1/2} of teriparatide were increased by 73% and 77%, respectively. Maximum serum concentration of teriparatide was not increased.

OVERDOSAGE: Incidents of overdose in humans have not been reported in clinical trials. Teriparatide has been administered in single doses of up to 100 mcg and in repeated doses of up to 60 mcg/day for 6 weeks. The effects of overdose that might be expected include a delayed hypercalcemic effect and risk of orthostatic hypotension. Nausea, vomiting, dizziness, and headache might also occur.

FORTEO® (teriparatide [rDNA origin] injection)

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In postmarketing spontaneous reports, there have been cases of medication errors in which the entire contents (up to 800 mcg) of the FORTEO delivery device (pen) have been administered as a single dose. Transient events reported have included nausea, weakness/lethargy and hypotension. In some cases, no adverse events occurred as a result of the overdose. No fatalities associated with overdose have been reported.

Overdose Management—There is no specific antidote for teriparatide. Treatment of suspected overdose should include discontinuation of FORTEO, monitoring of serum calcium and phosphorus, and implementation of appropriate supportive measures, such as hydration.

DOSAGE FORMS AND STRENGTHS: Multi-dose prefilled delivery device (pen) for subcutaneous injection containing 28 daily doses of 20 mcg.

PATIENT COUNSELING INFORMATION: Patients should read the FDA-approved *Medication Guide* and delivery device (pen) *User Manual* before starting therapy with FORTEO and re-read them each time the prescription is renewed. Patients need to understand and follow the instructions in the FORTEO delivery device *User Manual*. Failure to do so may result in inaccurate dosing.

PLEASE SEE FULL PRESCRIBING INFORMATION FOR ADDITIONAL INFORMATION.

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