

Pharmacist in Practice Improved Glucose Control

BY M. ALEXANDER OTTO

FROM A CONFERENCE ON PRACTICE IMPROVEMENT

SAN ANTONIO – When pharmacists enter the exam room to educate patients about diabetes, physicians save time and diabetes control improves.

At least that's what happened at the Cabarrus Family Medicine clinic in Concord, N.C., according to Sandy Robert-

son, a Cabarrus Pharm.D.

At a time when clinics across the country are adding pharmacists to patient-centered medical home teams, the Concord experience indicates what works, and what does not.

The story there began in July 2009, when Dr. Robertson volunteered to counsel patients on 2 half-days per week, taking time off from her usual teaching duties in Cabarrus's residency program.

She and managers at the 11-clinic family medicine chain wanted to see if pharmacist counseling would improve care. Dr. Robertson worked primarily with diabetes patients, she said in an interview.

To prepare for the visits, she scanned the clinic's electronic health records to identify diabetic patients who needed extra help – those with hemoglobin A_{1c} values above 9%. Dr. Robertson then asked doctors to schedule her with struggling

patients during upcoming visits. Patients, she found, were happy to talk so long as she was first introduced by a doctor. The initial visits almost always took a half hour or longer. Meanwhile, doctors would see other patients, popping back into the exam room in about 30 minutes.

"I did a lot of listening. My job was to find out why they were having problems. I certainly didn't have a canned diabetes talk," Dr. Robertson said. "Some patients didn't even understand how to take their insulin, and asked me the most elementary questions. Some were well educated about their diabetes, but were choosing not to follow [recommendations] because they're too hard," she said.

In the latter cases, Dr. Robertson would say something like, " 'Okay, let's make a deal. Instead of eating a whole bowl of ice cream every night, will you shake my hand and promise me that you'll only eat half a bowl? I am going to try to negotiate with you.' They would respond to that," she said.

Much of the time, Dr. Robertson was a cheerleader, telling patients, for instance, " 'You're going to have to come back in 3 months and your numbers are going to be great, and your doctor is going to be so pleased with you,' " she said.

Dr. Robertson also called patients between visits to remind them of upcoming appointments, and to encourage them to take better care of themselves; physicians in Concord simply didn't have time for such hand holding, she said.

Her methods worked.

At the conference, sponsored by the Society of Teachers of Family Medicine, Dr. Robertson presented data from her 9 toughest patients out of the 130-plus she counseled. Each dropped their HbA_{1c} levels within the first 3 months. One patient's HbA_{1c} fell from 14% to 5.8%, another's from 11% to 7%, and a third's from 10.8% to 6.8%.

"We don't have enough data yet to do any kind of statistical analysis, [but] I feel really good about" the outcomes, she said. Physicians did, too. After a while, they were simply pulling Dr. Robertson into exam rooms to talk with newly diagnosed patients.

When Dr. Robertson's pilot project ended, Cabarrus hired another pharmacist to do similar work full time, and then another several months later.

Polled about the new pharmacist, 9 of the 12 doctors at the clinic strongly agreed that patients appreciated her attention and that she improved patients' medication knowledge, overall chronic disease management, and physicians' satisfaction in managing challenging patients.

During her pilot project, Dr. Robertson was paid out of the residency program. The two new pharmacists are also on salary. Only about half of third-party payers are reimbursing their efforts – billed mostly as medication management – at about \$35-\$75 per half hour. "We are billing what we can," Dr. Robertson said.

The conference was also sponsored by the American Academy of Family Physicians.

important adverse renal effects were observed in clinical studies. Assessments included creatinine clearance; measurements of blood urea nitrogen (BUN), creatinine, and electrolytes in serum; urine specific gravity and pH; and examination of urine sediment. *Studies in Men and Women with Glucocorticoid-Induced Osteoporosis* The safety of FORTEO in the treatment of men and women with glucocorticoid-induced osteoporosis was assessed in a randomized, double-blind, active-controlled trial of 428 patients (19% men, 81% women) aged 22 to 89 years (mean 57 years) treated with ≥ 5 mg per day prednisone or equivalent for a minimum of 3 months. The duration of the trial was 18 months with 214 patients exposed to FORTEO and 214 patients exposed to oral daily bisphosphonate (active control). All patients received 1000 mg of calcium plus 800 IU of vitamin D supplementation per day. The incidence of all cause mortality was 4% in the FORTEO group and 6% in the active control group. The incidence of serious adverse events was 21% in FORTEO patients and 18% in active control patients, and included pneumonia (3% FORTEO, 1% active control). Early discontinuation because of adverse events occurred in 15% of FORTEO patients and 12% of active control patients, and included dizziness (2% FORTEO, 0% active control). Adverse events reported at a higher incidence in the FORTEO group and with at least a 2% difference in FORTEO-treated patients compared with active control-treated patients were: nausea (14%, 7%), gastritis (7%, 3%), pneumonia (6%, 3%), dyspnea (6%, 3%), insomnia (5%, 1%), anxiety (4%, 1%), and herpes zoster (3%, 1%), respectively. **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 ≥ 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 ≥ 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. 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.

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PLEASE SEE FULL PRESCRIBING INFORMATION FOR ADDITIONAL INFORMATION.

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