Challenges in Improving the Quality of Osteoporosis Care for Long-term Glucocorticoid Users

A Prospective Randomized Trial

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Background: In light of widespread undertreatment for glucocorticoid-induced osteoporosis (GIOP), we designed a group randomized controlled trial to increase bone mineral density (BMD) testing and osteoporosis medication prescribing among patients receiving long-term glucocorticoid therapy.

Methods: Using administrative databases of a large US health plan, we identified physicians who prescribed long-term glucocorticoid therapy to at least 3 patients. One hundred fifty-three participating physicians were randomized to receive a 3-module Web-based GIOP intervention or control course. Intervention modules focused on GIOP management and incorporated case-based continuing medical education and personalized audit and feedback of GIOP management compared with that of the top 10% of study physicians. In the year following the intervention, we compared rates of BMD testing and osteoporosis medication prescribing between intervention and control physicians.

Results: Following the intervention, intent-to-treat analyses showed that 78 intervention physicians (472 patients) vs 75 control physicians (477 patients) had similar rates of BMD testing (19% vs 21%, P=.48; rate difference, −2%; 95% confidence interval [CI], −8% to 4%) and osteoporosis medication prescribing (32% vs 29%, P=.34; rate difference, 3%; 95% CI, −3% to 9%). Among 45 physicians completing all modules (343 patients), intervention physicians had numerically but not significantly higher rates of BMD testing (26% vs 16%, P=.04; rate difference, 10%; 95% CI, 1%-20%) and bisphosphonate prescribing (24% vs 17%, P=.09; rate difference, 7%; 95% CI, −1% to 16%) or met a combined end point of BMD testing or osteoporosis medication prescribing (34% vs 44%, P=.07; rate difference, 10%; 95% CI, −1% to 21%) compared with control physicians.

Conclusions: In the main analysis, a Web-based intervention incorporating performance audit and feedback and case-based continuing medical education had no significant effect on the quality of osteoporosis care. However, dose-response trends showed that physicians with greater exposure to the intervention had higher rates of GIOP management. New cost-effective modalities are needed to improve the quality of osteoporosis care.
back would demonstrate higher rates of BMD testing and osteoporosis medication prescribing compared with control physicians.

**METHODS**

**PHYSICIAN IDENTIFICATION AND RECRUITMENT**

After obtaining local institutional review board approval, we used the linked claims and pharmacy databases from a large national managed care organization to identify patients who filled at least 60 days of prescriptions for oral glucocorticoids between July 1, 2001, and December 31, 2002. Their treating physicians were identified using the Drug Enforcement Administration numbers on the glucocorticoid prescriptions. The eligible physicians we identified were recruited to participate in an online continuing medical education program. Recruitment occurred between February 23, 2004, and September 7, 2004, and included printed materials mailed via a certified commercial carrier, broadcast faxes, and direct e-mails. The intensity of recruitment increased during the study. Modest incentives for participation were offered and included a subscription to an online medical journal, a medical textbook, or medical software for a personal digital assistant. The recruitment materials did not advertise that the program would be specific to osteoporosis but stated that it related to the care of medical patients with chronic illnesses and would be relevant for primary care physicians and subspecialists.

**INTERVENTION AND CONTROL MODULES**

A physician was considered a study participant and was randomized to the intervention group or the control group when he or she first logged on to the study Web site. Block randomization was used to balance the number of intervention vs control physicians randomized over time. The Web site verified the identity of the physician to ensure study eligibility. Physicians practicing in the same office as participants who had already logged on were randomized to the same study arm to avoid contamination. The intervention arm of the study consisted of (1) 3 case-based modules describing common clinical scenarios relevant to the management of patients with GIOP, (2) audit and feedback of physicians’ GIOP management within their practice compared with that of their peers, and (3) a GIOP-specific quality improvement “toolbox.” Each module was developed based on adult learning principles and included evidence-based content with direct hyperlinks to cited articles. The first few questions of the modules assessed a physician's familiarity with GIOP and then dynamically tailored the complexity of the content based on these responses. The audit and feedback component of the intervention compared the baseline rates of BMD testing and osteoporosis therapy prescribing within each physician’s practice (using his or her patients’ managed care organization claims and pharmacy data) with the mean rates of the top 10% of his or her physician peers, a benchmark known as the “achievable benchmark of care.” Finally, the intervention incorporated a toolbox with components that were physician and patient targeted. Physician-targeted components included GIOP-specific practice guidelines, research summaries, and management algorithms. Patient-targeted portions included printable patient education materials and self-assessment tools to gauge osteoporosis risk. In the control arm of the study, the 3 modules were text-based traditional continuing medical education modules focused on chronic illnesses other than osteoporosis (nonadherence in chronic disease, clinical prediction rules, and pain, opioids, and the law), and no audit or feedback was provided. The intervention and control modules were released during a 7-month period, spaced 2 to 3 months apart. Module completion was obtained by viewing the entire module’s content (and the audit and feedback component for the intervention modules), and physicians earned 1 continuing medical education credit for each completed module.

**STUDY END POINTS AND ELIGIBLE PATIENT POPULATION**

To identify patients eligible for the study end points after the intervention, we used a definition of long-term glucocorticoid use similar to that used to initially identify eligible physicians and required that each patient had filled prescriptions for at least 60 days of oral glucocorticoids during the study period or in the preceding 3 months. Patients were also required to have at least 3 months of follow-up during the 1-year study period after their qualifying glucocorticoid prescription. Our primary outcomes were the proportion of the long-term glucocorticoid users of each physician in the 1 year following the intervention who underwent BMD testing and received prescription osteoporosis medication (ie, bisphosphonates, estrogens, calcitonin, raloxifene hydrochloride, and teriparatide). We also examined a combined end point of BMD testing or osteoporosis medication prescribing (or both) during this period. The 1-year observation period was specific to each physician and began at the time he or she logged on to the study Web site for the first time.

**STATISTICAL ANALYSIS**

The χ² test of independence was used to examine nominal variables, and t tests were used to examine continuous variables to compare the characteristics of intervention vs control physicians and their patients. The primary analysis was an intent-to-treat approach that examined primary end points based on postintervention performance and grouped by randomized assignment. In a separate analysis (a completer, or per-protocol analysis), we compared the performance of intervention vs control physicians who completed all 3 modules to examine the effect of more intense exposure to the intervention. We used χ² tests to examine rates of BMD testing and osteoporosis medication prescribing after the intervention and used generalized estimating equations to account for nesting of patients within physician practices. However, because the intraclass correlation coefficients for our end points were low (range, 0.03-0.04) and the results from the generalized estimating equations were similar to those of the χ² tests, the χ² test results are shown for simplicity.

Based on a target goal of 150 physicians participating, the study had more than 80% power to detect a 10% difference between groups for the primary end points. In secondary analyses, we restricted eligible patients to those with a minimum of 90 days of glucocorticoid use and included up to 4 months of additional observation time (ie, a total of 16 months). In a separate secondary analysis, we examined the dates of the first BMD test and filled a prescription for an osteoporosis medication for each patient after his or her physician first logged on to the Web site and used time-to-event methods (Kaplan-Meier survival curves and log rank tests) for comparisons.

**RESULTS**

Seven hundred ninety-seven physicians were eligible for inclusion in the study, representing more than 4800 glu-
in the control course (median, 44 vs 17 minutes; P = .15). Physicians in the GIOP intervention course spent significantly more total time accessing the study Web site across all modules than participants in the control course (median, 44 vs 17 minutes; P < .001).

Results for the intent-to-treat population are given in Table 2. Following the intervention, there were no significant differences in the rates of BMD testing, bisphosphonate prescribing, or osteoporosis therapy prescribing between intervention and control physicians. Results were unchanged in secondary analyses comparing rheumatologists vs nonrheumatologists and examining patients with longer durations of glucocorticoid use (eg, ≥90 days of glucocorticoid therapy using a mean dose of ≥5 mg/d of prednisone) and with additional observation time (data not shown). The results of our secondary time-to-event analyses using Kaplan-Meier survival curves and log rank tests showed that there were no significant differences in the time to first BMD testing or GIOP treatment between patients of intervention vs control physicians.

Among physicians who completed all 3 modules, the results in Table 3 indicate that the intervention physicians were more likely to screen and treat for GIOP compared with control physicians, although most comparisons did not reach conventional levels of statistical significance. There were no significant differences in baseline characteristics (Table 1) between the physicians who completed all 3 modules and those who did not (data not shown).

### COMMENT

Although osteoporosis screening and treatment rates for long-term glucocorticoid users have increased in recent years, GIOP management remains generally suboptimal for these patients who are at substantial risk for fracture. In our intent-to-treat population, we found no significant differences in BMD testing and osteoporosis medication prescribing between control physicians and physicians randomized to a Web-based intervention incorporating case-based learning with personalized audit and feedback regarding GIOP management. In an analysis restricted to those who completed the 3 modules of the GIOP intervention or control Web-based course, trends suggested that intervention physicians who completed all 3 modules (34.6% of the intervention group) had higher rates of BMD screening and osteoporosis medication prescribing compared with control physicians who also completed all 3 (control) modules (24.0% of the control group). However, our study was underpowered to examine these subgroups, and these results were of borderline statistical significance.

The results from the intent-to-treat analysis vs the per-protocol analysis answer complementary but different research questions. In clinical trial situations, randomization to the control arm is not usually associated with lower adherence to the (placebo) treatment. In contrast, our findings suggest that randomization to the control arm resulted in lower participation (adherence) in the 3-module course (34.6% vs 24.0%, P = .15). Although our study was underpowered to make strong inferences, we can postulate not only that the GIOP modules increased active participation in the full course but also that the intervention had a potential beneficial effect...
among the 3-module participants in the intervention vs the control group. We recognize that physicians who are more fully engaged in an intervention are likely different from those who participate only minimally, but our comparison of physicians who fully participated in the intervention arm vs the control arm (summarized in Table 3) should account for this behavioral factor. Therefore, our intent-to-treat results suggest that implementation of the type of intervention we developed is unlikely to have a discernible effect across a broad population of physicians, including those with limited interest or motivation to participate. However, the results of the per-protocol analysis suggest that there is an important subgroup of physicians (approximately one third of those we studied) who are amenable to prescribing behavior change, achievable through our intervention.

To maximize the likelihood of success, significant resources should be allocated to increase the exposure that physicians have to interventions aimed at changing behavior. The net effect of greater exposure among fewer physicians may exceed the net effect of less exposure among more physicians. Moreover, future quality improvement interventions that have no need for a control group may have greater success than we found because the topic can be identified in advance and the physicians who are most likely to benefit from the intervention will self-select to participate. From a research perspective, the recognition that only a subgroup of physicians may be amenable to behavior change using the approach we used may have important implications for making power calculations and for estimating the magnitude of the detectable effect size when planning future studies of this type.

Few interventions have attempted to improve the quality of care for patients with or who are at risk for GIOP. In an intervention in Tasmania, Australia, educational materials and management guidelines were sent to all general practitioners and community pharmacies within a defined geographic region. This information was followed by academic detailing visits and by patient and provider reminders. Although a significant improvement in the use of osteoporosis preventive therapies was observed following the intervention, limitations of this study included a lack of randomization at the provider level and outcome assessment only in patients treated with glucocorticoids who were hospitalized. Another study randomized 21 rheumatologists treating 373 patients with rheumatoid arthritis at an academic medical center to an intervention consisting of a continuing medical education conference with a practice audit of GIOP management, followed by reminders. In the 6 months following the intervention, there was no difference between intervention physicians in the rates of BMD testing or osteoporosis medication prescribing compared with control physicians.

Previous work has shown that traditional continuing medical education activities typically fail to result in measurable changes in physician practice. There is limited literature testing approaches to improve screening and treatment for postmenopausal patients with osteoporosis who are at high risk for fracture. The interventions specific to osteoporosis have included electronic reminders to physicians within health systems that use computerized medical records, academic detailing with nurses or pharmacists engaging physicians in 1-on-1 encounters, patient-targeted pamphlets and mail-

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<th>Variable</th>
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<th>Control Group</th>
<th>Rate Difference (95% Confidence Interval)</th>
<th>P Value</th>
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<td>.72</td>
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Abbreviation: BMD, bone mineral density.

*Data are given as percentages unless otherwise indicated.
†Includes bisphosphonates, estrogens, calcitonin, raloxifene hydrochloride, and teriparatide.

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<td>BMD testing</td>
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<td>BMD testing or osteoporosis medication prescribing</td>
<td>54</td>
<td>44</td>
<td>10 (−1 to 21)</td>
<td>.07</td>
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Abbreviation: BMD, bone mineral density.

*Data are given as percentages unless otherwise indicated. The analysis included 27 intervention physicians (196 patients) and 18 control physicians (147 patients) who completed all 3 Web modules.
†Includes bisphosphonates, estrogens, calcitonin, raloxifene hydrochloride, and teriparatide.
ings,21,22 direct-to-patient computerized telephone calls prompting them to schedule BMD testing,23 pharmacist-led direct-to-patient educational interventions,24 and combination modalities using more than 1 approach.25,26 Academic detailing, interventions using electronic medical record systems, and combination strategies have achieved the greatest success in promoting physician behavior change for patients who have experienced a fracture. Each of these interventions addressed particular physician, patient, or health system factors and barriers that may be important in improving quality of care, although some interventions capitalize on the possibility that a new fracture may represent a “teachable moment.” Except perhaps for intervening at the time a glucocorticoid prescription is filled, whether there is a similar teachable moment for patients receiving long-term glucocorticoid therapy is unclear. Based on experiences in other disciplines and in osteoporosis, our focus was on a more innovative and multimodal approach to changing physician behavior. Our intervention recruited physicians from a national health plan, did not require specific resources unique to particular health systems (such as an electronic medical record), and had the advantage of being generalizable across diverse practice settings. Compared with interventions such as academic detailing, it required only a modest investment of resources to develop and sustain.

Concordant with data suggesting that the practice patterns of individual physicians are the most important determinant of osteoporosis management,27 we targeted physicians who prescribed long-term glucocorticoid therapy to at least 3 patients and provided them with case-based learning and audit and feedback of their GIOP management compared with that of the top 10% of their peers. This audit and feedback benchmark has been successfully used to improve management of other diseases.28

We were able to recruit our targeted number of more than 150 physicians necessary to detect a 10% difference between groups based on our initial power calculations. Rather than randomizing all eligible physicians before recruiting them, we randomized them at the time they first logged on to the Web to ensure balance between groups, and we randomized all physicians within the same office to the same group to avoid contamination. Other strengths of our intervention included case-based learning modules that were extensively pilot tested. These were formatted to convey information visually without long narratives and were evidence based with hyperlinks to associated journal article abstracts. Supporting an interest in our GIOP content, there were significant differences in the amount of time that intervention vs control physicians spent on the study Web site. Three modules were released during 6 months to avoid a decay effect, and we examined a dichotomous end point and performed a time-to-event analysis using survival methods to assess the possibility that the effect of the intervention was time dependent. Although our overall study results were negative using the dichotomous end point and the time-to-event analysis, rates of screening and treatment for GIOP were higher for intervention vs control physicians who were exposed to all 3 modules, suggesting a dose-response effect.

Despite these strengths, some limitations of our work may inform future efforts in this area. Although the health plan database contains a substantial amount of information such as various medical diagnoses, burden of comorbidity, and prescription drug use, it lacks information that physicians may use to make treatment decisions such as fall risk and, for those who had dual-energy x-ray absorptiometry scans, T-scores. However, we would not expect these factors to significantly differ between patients of intervention vs control physicians because of randomization. We did not explicitly advertise in our recruitment materials that the intervention would contain GIOP-specific content. This may have affected the number and specialty of the physicians who were recruited, although it increased the generalizability of our study and was necessary because we had a control group that did not receive osteoporosis-related materials. In addition, we intentionally partitioned the module content and audit and feedback across the 3 Web modules to induce participating physicians to return and ideally to demonstrate sustainability of our intervention. For the 34.6% of intervention physicians who completed all 3 modules, trends suggested that GIOP management was better, but the remaining 65.4% were exposed only to part of the intervention. Because we required that physicians treat at least 3 long-term glucocorticoid users to be eligible for the GIOP intervention, a high proportion of our physicians were rheumatologists. Quality improvement interventions may have a different effect on primary care physicians compared with specialists, and the timing of the intervention relative to a sentinel patient health event such as a fracture may affect differential participation and action. Our study found no differences in results between physician specialties, although it was underpowered to examine these subgroups. Engaging physicians in the type of intervention we conducted while in training or earlier in practice may be more effective than once they are already established.29 Our audit and feedback materials did not specifically identify long-term glucocorticoid users by name, and this may have limited a physician’s ability to take actionable steps for individual patients. In future quality improvement interventions, assisting physicians to identify at-risk individuals proximate to or at the point of care may be useful. Last, while we chose the Web to take advantage of state-of-the-art technology in dynamic randomization and Web-based course design, we do not know if our intervention might have produced different effects and been of interest to other physicians if we had delivered it using a more traditional paper copy.

In conclusion, physicians randomized to a multimodal Web-based intervention did not perform GIOP management better compared with control physicians, although dose-response trends suggested greater effect among those exposed to the entire 3-module intervention. Because patients receiving long-term glucocorticoid therapy are at substantial risk for fracture, effective strategies that promote appropriate management for these patients continue to be needed to improve quality of care and to reduce GIOP-related morbidity. Combination strategies targeting providers and patients may result in incremental benefit and are being tested.
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Statistical analysis: Curtis, Westfall, and Ockershausen. Obtained funding: Kiefe and Saag. Administrative, technical, and material support: Curtis, Becker, Melton, Freeman, MacArthur, Ockershausen, and Stewart. Study supervision: Curtis and Saag.

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REFERENCES


