An Internet-based Controlled Trial Aimed to Improve Osteoporosis Prevention among Chronic Glucocorticoid Users

Amy H. Warriner, Ryan C. Outman, Jeroan J. Allison, Jeffrey R. Curtis, Nathan J. Markward, David T. Redden, Monika M. Safford, Eric J. Stanek, Amy R. Steinkellner, and Kenneth G. Saag

ABSTRACT. ***Objective.*** To address the low prevention and treatment rates for those at risk of glucocorticoid-induced osteoporosis (GIOP), we evaluated the influence of a direct-to-patient, Internet-based educational video intervention using "storytelling" on rates of antiosteoporosis medication use among chronic glucocorticoid users who were members of an online pharmacy refill service.

Methods. We identified members who refilled ≥ 5 mg/day of prednisone (or equivalent) for 90 contiguous days and had no GIOP therapy for ≥ 12 months. Using patient stories, we developed an online video addressing risk factors and treatment options, and delivered it to members refilling a glucocorticoid prescription. The intervention consisted of two 45-day "Video ON" periods, during which the video automatically appeared at the time of refill, and two 45-day "Video OFF" periods, during which there was no video. Members could also "self-initiate" watching the video by going to the video link. We used an interrupted time series design to evaluate the effectiveness of this intervention on GIOP prescription therapies over 6 months.

Results. Among 3017 members (64.8%) exposed to the intervention, 59% had measurable video viewing time, of which 3% "self-initiated" the video. The GIOP prescription rate in the "Video ON" group was 2.9% versus 2.7% for the "Video OFF" group. There was a nonsignificant trend toward greater GIOP prescription in members who self-initiated the video versus automated viewing (5.7% vs 2.9%, p = 0.1).

Conclusion. Among adults at high risk of GIOP, prescription rates were not significantly affected by an online educational video presented at the time of glucocorticoid refill. ClinicalTrials.gov Identifier: NCT01378689. (J Rheumatol First Release July 1 2015; doi:10.3899/jrheum.141238)

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From the Division of Endocrinology, Diabetes and Metabolism, and Division of Clinical Immunology and Rheumatology, and Department of Biostatistics, and Division of Preventive Medicine, University of Alabama at Birmingham, Birmingham, Alabama; Department of Quantitative Health Sciences, University of Massachusetts Medical School, Worcester, Massachusetts; Express Scripts, St. Louis, Missouri; Novartis Pharmaceuticals Corporation, East Hanover, New Jersey; Real Endpoints LLC, Westport, Connecticut, USA.

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A.H. Warriner, MD, Division of Endocrinology, Diabetes and Metabolism; R.C. Outman, MS, Division of Clinical Immunology and Rheumatology, University of Alabama at Birmingham; J.J. Allison, MD, MS, Department of Quantitative Health Sciences, University of Massachusetts Medical School; J.R. Curtis, MD, MS, MPH, Division of Clinical Immunology and Rheumatology, University of Alabama at Birmingham; N.J. Markward, PhD, Express Scripts; D.T. Redden, PhD, Department of Biostatistics; M.M. Safford, MD, Division of Preventive Medicine, University of Alabama at Birmingham; E.J. Stanek, PharmD, Novartis Pharmaceuticals Corporation; A.R. Steinkellner, PharmD, Express Scripts, and Real Endpoints LLC; K.G. Saag, MD, MSc, Division of Clinical Immunology and Rheumatology, University of Alabama at Birmingham. * Affiliation at the time of study and manuscript preparation.*

Address correspondence to Dr. K.G. Saag, The University of Alabama at Birmingham, Division of Clinical Immunology and Rheumatology, 820 Faculty Office Tower, 510 20th St. South, Birmingham, Alabama 35294, USA. E-mail: ksaag@uab.edu, kenneth.saag@ccc.uab.edu

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Glucocorticoid-induced osteoporosis (GIOP) is a healthcare problem of major significance because of an estimated 1 million Americans alone taking longterm glucocorticoids (defined as ≥ 3 mos of therapy) at any given time to manage chronic disorders[1,2]. Glucocorticoid use is the most common cause of secondary osteoporosis and second only to menopause as the most common cause of osteoporosis overall.

According to evidence-based recommendations issued by the American College of Rheumatology and other international groups[3,4,5], patients receiving or anticipated to require chronic glucocorticoid therapy should use preventive measures, including calcium, vitamin D, and prescription antiosteoporosis therapy. Despite data on the efficacy of antiosteoporosis therapies in GIOP, only 5% to 62% of even the highest risk patients treated with longterm glucocorticoids in the United States and Europe receive therapies to prevent or treat GIOP[6,7,8,9]. Thus, despite increasing scientific evidence and international consensus guidelines, GIOP is still both underrecognized and undertreated.

There is a growing emphasis on "patient empowerment," with a goal of encouraging patients to be more involved in their medical care[10,11,12]. One method of doing this is through

patient "storytelling," which promotes health education and communication in a culturally appropriate context[13,14,15,16]. Use of storytelling has proven beneficial in reducing blood pressure in patients with hypertension (HTN)[17] and in studies of mammography screening[15]. The Internet is an ideal means of delivering patient storytelling because of its ability to reach large numbers of patients at a relatively low cost.

We tested the effectiveness of a direct-to-patient Internet-based intervention that was aimed to improve anti-osteoporosis treatment in patients at risk of GIOP. The intervention, an educational video with patient storytelling, was presented at the time of glucocorticoid prescription refill to members of an online pharmacy refill service affiliated with a large pharmacy benefits management organization located in the United States.

MATERIALS AND METHODS

Study population. The eligible population consisted of any member of the online pharmacy refill service that was administered by a national pharmacy benefits manager, 19 years or older, and identified as using chronic glucocorticoids. Chronic glucocorticoid use was defined as ≥ 5 mg/day of prednisone, or an equivalent, for ≥ 90 days with at least 1 additional refill in the year prior to study initiation. Members were excluded if they were currently or had previously been prescribed osteoporosis medication (including oral bisphosphonates, raloxifene, estrogen, and calcitonin) in the past 12 months. Because inherent fracture risks are associated with certain diseases and certain medications, we identified the risk factors using algorithms previously developed by the pharmacy benefits manager based on concurrent medication use. In addition, baseline characteristics thought more likely to be associated with initiation of osteoporosis prescription medications (female sex, lower comorbidity count[18], white race, and receipt of subspecialty medical care by physicians most experienced in osteoporosis management) were carefully characterized based on member medical claims, survey data previously obtained by the online pharmacy refill service, and pharmacy data. Subspecialty osteoporosis care was defined from pharmacy data by at least 1 visit with a physician typically caring for osteoporosis, specifically rheumatologists and endocrinologists. Participant waiver for informed consent was obtained from the University of Alabama at Birmingham Institutional Review Board.

Intervention material development. Four focus groups (n = 18 patients total) and 8 semistructured individual interviews were conducted with a convenience sample representative of the study population, but from a single academic medical institution. Focus group participants were queried regarding their experience with glucocorticoids and their knowledge of and experiences with osteoporosis. Additionally, they were asked questions about methods they used to communicate with their physicians. From the focus groups and from physician investigator referral (KS, JC, AW), individual interviews with patients with recognized histories of GIOP screening and treatment were completed to gain more detailed information about patient experiences with osteoporosis screening and treatments and stories of patient-physician communication. Based on this information, a series of video segments was developed in which a man and a woman, chosen from the individual interviews, told their personal stories about osteoporosis, fractures, osteoporosis screening, and osteoporosis treatment.

Using concepts from the Chronic Care Model[19] and the Practical Robust Implementation and Sustainability Model (PRISM)[20], and following an approach developed by Kreuter, *et al*[21], the patient video segments were selected and rated based on strength and clarity of content by the study team. The videos were tested among a second convenience sample (n = 25) of chronic glucocorticoid users, and structured telephone interviews (n = 7) were completed to obtain feedback. Requested feedback pertained to the format of the videos, video content, clarity of the message, and patient activation. The highest rated segments were then revised to address concerns raised during the pilot testing and compiled into two 4-min video segments, 1 with a man and 1 with a woman. Cognitive testing of the materials was completed to ensure participant comprehension. Following this process, additional video segments were also incorporated, consisting of an osteoporosis educator and a physician introducing the video segments and providing context to the patient stories and statements.

Video intervention delivery. The intervention was delivered to members at the time of completion of their online glucocorticoid refill, drawing on a previously established alternating time series design[22,23]. Therefore, intervention exposure was determined by time-period allocation, i.e., when during the ongoing study each member used the online pharmacy refill service. The first video began automatically streaming in a new browser window when eligible members completed their refill requests for their oral glucocorticoid medication. The first video was presented to members for a 45-day period, the "Video ON" period. After the initial 45 days, a second 45-day period, the "Video OFF" period, was initiated during which no video was presented to subsequent members who satisfied the eligibility criteria, refilled their online glucocorticoid prescriptions, and were not included in the first "Video ON" period. This "ON"/"OFF" period was repeated twice in sequence and included only members who had not been included in prior "Video ON" or "Video OFF" periods. A video with a male patient was used during the first cycle, and a video with a female patient was used during the second cycle (Figure 1). Members could stop the video at any point after its initiation. In addition, members had the opportunity to "self-initiate" video segment viewing and were offered supplemental video segments, including a video specific to calcium and vitamin D supplementation that had been previously developed by the pharmacy benefit manager for patient education. Measurable viewing time registered for a member when he or she watched any portion of the video that started automatically at the time of glucocorticoid refill. If members viewed the same video again or viewed any of the other offered videos, an additional action was required to self-initiate that viewing. Members who were eligible for viewing the video during the first "Video ON/OFF" period were not eligible for video viewing during the second period, thus preventing possible contamination using the alternating time series approach for randomization. Therefore, the first period of the study included more members than the other study periods (Figure 1).

Based on the pharmacy benefits manager's protocol for online interaction with clients, an external vendor was responsible for monitoring and communicating information on the intervention and was unable to provide the duration of video viewing time.

Outcomes. The primary outcome of interest was the new filling of prescription antiosteoporosis medications following each of the "Video ON" or "Video OFF" periods. Through the pharmacy transaction database, all prescription use of bisphosphonates, raloxifene, teriparatide, calcitonin, estrogen, and testosterone was accessible for data review. Members were identified as starting a prescription osteoporosis medication if one of the above medications was filled through the online prescription refill service within the 6 months following the intervention period for that member. We were unable to reliably identify members treated with zoledronic acid or denosumab because these medications are commonly administered in a physician's office and not obtained through the online prescription refill service.

Statistical analysis. We used descriptive statistics to compare baseline characteristics of the online pharmacy refill service participants. A design factor D was used to calculate power needed to test the differences between the control and intervention groups[24]. The adjusted sample size was derived from the magnitude of within-physician correlation (ICC) and average number of patients for each physician. *A priori* power calculations indicated that an adjusted sample size of 813 participants (using an ICC of 0.11 and assuming 10 patients per physician) would provide 80% power with a 2-sided α of 0.05 to detect an absolute detectable difference of 3.6% and 4.7% with the control group treatment rates of 5% and 10%, respectively.

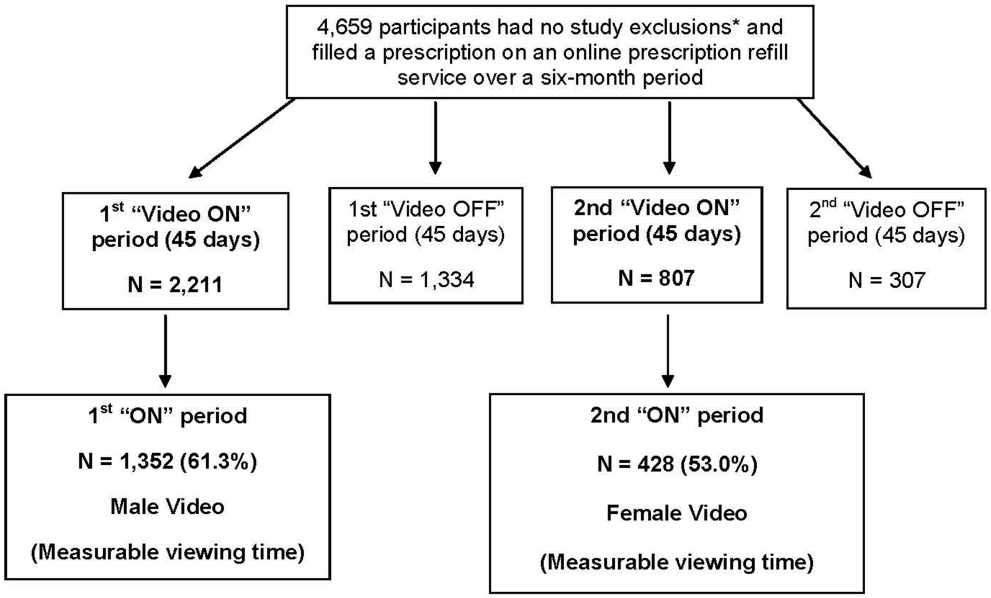

Figure 1. Flow chart of study design and study participant distribution. * Age 19 and older, ≥ 5 mg of prednisone or glucocorticoid dose equivalent for ≥ 90 days within the last year. Video ON: Video was presented to participants who initiated a refill of their glucocorticoid prescription through the online prescription refill service. Video OFF: Video was not presented to participants who initiated a refill of their glucocorticoid prescription through the online prescription refill service.

"Video ON" and "Video OFF" periods were determined by the dates the videos became available on the online pharmacy refill service. Members were grouped into 3 categories: (1) members with no video exposure, (2) members with automatic video exposure only, and (3) members who self-initiated video exposure. All members who accessed the online pharmacy refill service to refill their glucocorticoid during a "Video ON" period were included in the intent-to-treat group, whereas those who had measurable viewing time were included in the per-protocol group. We used multivariable logistic regression to examine the influence of the video on GIOP prescription fill rates.

We completed additional posthoc analyses to stratify members based on age because of a concern that the older participants (≥ 70 yrs) may be less efficient with the video technology of the intervention. Multivariable logistic regression also examined the influence of sex, age, postal code (as a proxy of socioeconomic status), and other demographic and clinical factors/comorbidities (inferred from concomitant prescription therapies) as covariates that could alter the likelihood of receiving appropriate osteoporosis care. Interaction terms between intervention status and member characteristics were included to determine whether the effect of the intervention varied by any of these covariates. All analyses were performed using SAS 9.2 (SAS Institute).

Table 1. Study participant characteristics. Values are n (%).

Characteristic	All Participants, n = 4659	"Video ON"*, n = 3017	"Video OFF"**, n = 1642
Men	2646 (56.8)	1720 (57.0)	929 (56.6)
Age, yrs			
< 50	1127 (24.2)	730 (24.2)	401 (24.4)
50–70	2497 (53.6)	1605 (53.2)	895 (54.5)
> 70	1030 (22.1)	685 (22.7)	348 (21.2)
Gastrointestinal disease	1752 (37.6)	1143 (37.9)	608 (37.0)
Rheumatoid arthritis	815 (17.5)	528 (17.5)	291 (17.7)
Organ transplant	1393 (29.9)	896 (29.7)	501 (30.5)
Gout	429 (9.2)	278 (9.2)	149 (9.1)
Anxiety or depression	499 (10.7)	326 (10.8)	171 (10.4)

* "Video ON": Video was presented to the members who initiated a refill of their glucocorticoid prescription through the online prescription refill service. ** "Video OFF": Video was not presented to the members who initiated a refill of their glucocorticoid prescription through the online prescription refill service.

RESULTS

Member characteristics. The study members consisted of chronic glucocorticoid users (n = 4659) who logged on to the online pharmacy refill service Website over a 6-month period to refill his or her glucocorticoid medication. Members exposed to the video during the "Video ON" periods were similar in age, sex, and underlying glucocorticoid-associated conditions to those in the "Video OFF" period (Table 1). An evaluation of the glucocorticoid users in the online pharmacy refill service in the year prior to study initiation revealed a baseline rate of 19.1% osteoporosis medication use, with 98% of those using a bisphosphonate (data not shown).

Educational video viewing. The interventional video was presented to members in 2 time periods. During these "Video ON" periods, 2211 members logged on during the first period (video of a man) and 807 members logged on during the second period (video of a woman) to refill their glucocorticoid medications. Of these, 1352 (61.3%) in the first period and 428 (53.0%) in the second period had measurable inter-

vention video viewing time (Figure 1). A total of 87 video viewers (2.9%) in the 2 periods self-initiated intervention video viewing in addition to the automated video exposure.

Osteoporosis prescription medication use. Of the 4659 total study population, 131 (2.8%) initiated an osteoporosis-specific prescription medication in the 6 months following the intervention. The rates of osteoporosis-specific prescription use were similar among those who had the potential to view the video (intent-to-treat), those who had detectable viewing time (per protocol), and those who were not exposed to the video (2.8% vs 2.9% vs 2.7%, respectively; Table 2). Five of the 87 members (5.7%) who self-initiated video viewing also initiated an osteoporosis-specific medication (OR when compared with no video exposure 2.2, 95% CI 0.9–5.5; Table 3). These findings were minimally affected by further adjustment for age and sex (self-initiated video viewing vs no video exposure, OR 2.0, 95% CI 0.8–5.1; Table 3).

When members were stratified by age, we identified further differences in the rates of osteoporosis-specific medication (50–70 yrs old: OR 2.1, 95% CI 1.3–3.5; > 70 yrs old: OR 1.8, 95% CI 1.0–3.2). These differences persisted when further adjusted for additional potential confounding factors, such as rheumatoid arthritis, gout, gastrointestinal disease, organ transplant, anxiety, or depression, as defined by medication claims (data not shown). When members were also stratified by sex, men were less likely to start osteoporosis treatment (OR 0.2, 95% CI 0.2–0.3). This sex variation persisted with the addition of the above additional covariates (OR 0.2, 95% CI 0.2–0.4).

DISCUSSION

Educational materials provided through a brief patient storytelling video presented online to pharmacy benefits members at high risk of GIOP resulted in no significant improvement of osteoporosis-specific medication use. Rates of treatment initiation following the intervention were low overall, and no significant differences were seen in an intent-to-treat analysis.

Table 2. Osteoporosis prescription medication initiation following the Internet intervention based on Internet video viewing time.

Variables	Total, n = 4659, n	Osteoporosis Prescription Started within 180 Days Since Intervention, n (%)
"Video ON"*, intent-to-treat	3018	86 (2.8)
"Video ON"*, per protocol	1780	52 (2.9)
Self-initiated[#]	87	5 (5.7)
"Video OFF"[§]	1642	45 (2.7)

* Glucocorticoid refilled during "Video ON" period. [#] Viewing of Internet video self-initiated. [§] Glucocorticoid refilled during "Video OFF" period. Intent-to-treat: all study participants who refilled a glucocorticoid prescription during a "Video ON" period. Per protocol: all study participants who refilled a glucocorticoid prescription during a "Video ON" period with measurable viewing time; measurable viewing of the "Automatic" video.

Table 3. OR for osteoporosis prescription initiation among patients for which video viewing was documented for the automatic video and the self-initiated video.

Variables	Automatic*, OR (95% CI)	Self-initiated[#], OR (95% CI)	No Exposure
Unadjusted	1.0 (0.7–1.5)	2.2 (0.9–5.5)	Referent
Partially adjusted[§]	1.1 (0.8–1.6)	2.0 (0.8–5.1)	Referent
Fully adjusted[**]	1.1 (0.8–1.6)	2.1 (0.8–5.4)	Referent

* Viewing of automatic Internet video detected. [#] Viewing of Internet video self-initiated. [§] Age and sex. ** Age, sex, and covariates.

Greater treatment initiation appeared to occur in groups of members who self-initiated video viewing and were thus more likely to view video content.

To our knowledge, our study is the first to evaluate a low cost Internet-based intervention designed to promote patient activation to prevent or treat GIOP. There have been a limited number of prior studies aimed at identifying methods to improve GIOP prevention and treatment, and most of these studies have focused on educating physicians. In a randomized controlled study targeting rheumatologists, physicians were randomized to either a 3-part educational intervention (lecture/discussion, doctor-specific audit, and reminder mailing) or no education[25]. Despite this effort-intensive intervention, no significant increase was seen for either screening or treatment of their patients at risk of GIOP in the subsequent 6 months. Another randomized study consisted of an Internet-based continuing medical education module with audit and feedback and peer comparisons provided to physicians known to prescribe chronic glucocorticoids[26]. This educational intervention had no significant effect on osteoporosis screening in the intent-to-treat analysis (rate difference –2%, 95% CI –8%–4%) and osteoporosis prescription medication use overall (rate difference 3%, 95% CI –3%–9%). However, among physicians who completed all the educational modules, greater improvement in osteoporosis screening was seen.

The ideal time to intervene and the ideal mechanisms to modify patient behavior and increase patient-physician communication are unknown. Outpatient medical office visits with healthcare providers are frequently brief and focused on acute medical issues other than bone health. A main obstacle is finding a "teachable" moment and determining a method to improve patient uptake of these interventions. Pharmacy-based interventions have been beneficial in improving osteoporosis screening and treatment[27], but require considerable effort and costs among the involved pharmacies. In 1 study completed in Canadian pharmacies, patients at risk of osteoporosis (including those receiving chronic glucocorticoid therapy) were randomized to receive either a 30-min face-to-face osteoporosis intervention with a pharmacist or "usual care"[28]. Through this effort-intensive intervention, osteoporosis-specific medication initiation alone was insig-

nificant (RR 2.1, p = 0.298). We similarly used the moment of glucocorticoid medication refill to educate patients about GIOP and available treatment options, but using a relatively low-cost, and potentially more generalizable, method. However, unlike a face-to-face intervention, the uptake of our intervention aimed at patient activation could not be ensured, and most patients did not have a meaningful viewing time of our videos.

Unlike many prior Internet-based interventions, our study used patient storytelling to educate patients on GIOP. Patient storytelling has been shown to be an effective means to relay messages to patients regarding medical care[13,14,15,16]. In a study using patient storytelling though a DVD provided to inner-city African American patients with HTN, patients with uncontrolled HTN at baseline had significant reductions in systolic (11.21 mmHg reduction, 95% CI 2.51–19.9 mmHg) and diastolic blood pressures (6.43 mmHg reduction, 95% CI 1.49–11.45 mmHg)[17]. Through patient storytelling, patients can become "transported" or absorbed into the story being told rather than concentrating on the underlying message[29,30]. The women with breast cancer who viewed the storytelling video were more engaged and felt a connection to the content, leading to a greater cognitive and emotional response[16]. We used similar storytelling methods for intervention development and were able to expand the exposed population by using the Internet. Most of the cost for creating patient storytelling videos is during the video development, with minimal additional cost for distribution.

We recognize that there are other important causes of bone loss and increased fracture risk, but we focused our study on GIOP because of the underdiagnosis and undertreatment of this condition, despite available treatment guidelines. One of the limitations of our study was the inability to preidentify the potential participants who would be exposed to the intervention videos during the quality improvement activity. Having the ability to know the participants' characteristics prior to an intervention may allow for greater tailoring of the content, which is known to improve effectiveness of behavior change interventions[31]. Moreover, studies that have used Internet-based interventions that have included a component of tailoring have been more successful than those without tailoring[32,33,34]. In contrast to the above studies[15,17], the majority of our patients were older men. Another limitation of our study was the inability to determine length of exposure to the intervention on the Internet. Because of the Health Insurance Portability and Accountability Act restrictions, the computer software vendor could not report the length of video views at the individual member level. It has been shown that patients who completed Internet-based interventions (per protocol) typically have a greater benefit from the intervention than those who may not have completed the intervention (intent-to-treat)[26,35,36]. It is possible that a number of participants included in the per-protocol analysis who were assumed to have viewed the intervention materials closed the video quickly, viewing little if any of it. Without this information, we are unable to determine whether there is an amount of exposure (dose effect) that might have increased our measured outcome.

We can see through the group of participants who self-initiated the video viewing that there was a trend toward more initiation of osteoporosis-specific medication use, and it is possible that a similar trend would be seen in those who viewed the video longer compared with those with minimal exposure. Lastly, because a physician is required to prescribe the desired therapy, it is possible that a combined patient and physician intervention could work better in this circumstance than either intervention alone. Although the deidentified nature of the participants in this real-world quality improvement project limits our ability to speculate about reasons for the lack of an increase in osteoporosis medication use in the intervention group, we believe that this was likely multifactorial. From prior osteoporosis implementation science investigations, we suspect that participant factors, technical factors, and other factors most likely further decreased the participation rate, including the unwillingness of participants' physicians to prescribe osteoporosis treatments, patient contraindications to osteoporosis medication use, and use of osteoporosis medications not detected through the online pharmacy refill database. Future qualitative studies that involve access to patients' clinical information to allow for further tailoring of the intervention materials and also taking steps to monitor the intervention use by patients will aid in clarifying these limitations.

Our storytelling intervention aimed to educate chronic glucocorticoid users about the risk of osteoporosis and the available treatment options through a video presented during online refill of glucocorticoid medications. Overall, there was not a significantly increased rate of osteoporosis-specific medication receipt in the exposed groups, but there was increased receipt noted in those patients who self-initiated video viewing. Internet-based interventions hold hope for reaching large numbers of patients at a relatively low cost, but further studies are needed to assess methods to improve the effectiveness of these interventions more broadly.

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