Motivational Brochures Increase the Number of Medicare-Eligible Persons With Diabetes Making Therapeutic Footwear Claims

JONATHAN R. SUGARMAN, MD2,3
JOSEPH W. LEMASTER, MD1,3
GAYLE E. REIBER, PHD3,4,5
GREG BAUMGARDNER, MS2

OBJECTIVE — This study tests the hypothesis that Medicare beneficiaries at high risk of foot complications who are mailed a motivational brochure describing the Medicare diabetes-related therapeutic footwear benefit will increase their therapeutic footwear-related Medicare claims.

RESEARCH DESIGN AND METHODS — In this quasi-experimental study, a motivational brochure was mailed in the summer of 1997 to 5,872 Medicare beneficiaries in Washington, Alaska, and Idaho who were identified as being at high risk for foot-related claims on the basis of their prior Medicare claims history. Beneficiaries were identified through footwear claims made in these states—and also in three comparison states (Oregon, Montana, and Wyoming)—during the 18 months before and after the mailing. Linear regression was used to compare the number of persons making claims in the intervention states with the comparison states before, at the time of, and after the mailing.

RESULTS — Before the intervention, the number of persons making claims was increasing in the nonintervention states and decreasing in the intervention states. During the first month after the intervention mailing, the number of persons making claims remained nearly the same in nonintervention states, but increased 13 persons per month in intervention states (95% CI 3.5–11 persons/month). After the intervention, the number of persons making claims continued to increase similarly in both intervention and nonintervention states.

CONCLUSIONS — Mailed motivational brochures were associated with an increase in the number of persons making therapeutic footwear claims. Randomized trials should confirm these findings.

Motivational brochures have been used in a number of settings to increase compliance among targeted patients for health interventions. Randomized trials have shown that mailed brochures or postcards are effective in increasing utilization of mammography (1) and influenza vaccination (2). A recent Cochrane Collaboration meta-analysis found that patient reminders, including postcards, improve overall childhood vaccination rates (odds ratio [OR] 2.02; 95% CI 1.49–2.72), as well as rates for childhood influenza vaccination (OR 4.25; 95% CI 2.10–8.60), adult pneumococcus or tetanus vaccination (OR 5.14; 95% CI 1.21–21.78), and adult influenza vaccination (OR 2.29; 95% CI 1.69–3.10) (3). New uses for such brochures seem worthy of exploration.

Foot ulcers are an important cause of morbidity and high medical costs in people with diabetes. Among 17 million people with diabetes in the U.S., up to 15% will develop a foot ulcer in their lifetime and 15% of these will require amputation (4). Treatment costs for a single episode of foot ulcer in the U.S. have been estimated at $25,000 (5). By eliminating lower-extremity amputation, an estimated 2–3 million dollars in direct health care costs could be saved every 3 years for every 10,000 individuals with diabetes (6). If inexpensive “reminder” brochures could increase utilization of foot care services and decrease amputation in this population, the human and financial benefits would be substantial.

Programs that provide therapeutic footwear for people with diabetes have reported marked decreases in foot ulcers and amputations. In one specialized foot clinic, the foot ulcer relapse rate for those who wore custom shoes was 26% versus 83% in those who did not (7). However, evidence from randomized trials that therapeutic footwear reduces the risk of foot ulcers is mixed: in one Italian trial of footwear among 69 participants with diabetes, ulcers occurred in 27.7% of persons wearing therapeutic footwear vs. 58.3% wearing their own footwear (8). Another recent clinical trial in Seattle by Reiber et al. (9) showed no reduction in the risk of foot ulcers among persons with diabetes and prior foot ulceration (but without severe foot deformities) who were randomized to therapeutic footwear and insoles, compared with those who wore their usual footwear. Persons with severe foot deformities (who were ex-
The Cost and Who Pays It

Good news! Medicare typically pays up to 80% of the cost of the allowed charge for therapeutic footwear. The customer is responsible for coinsurance and deductibles. Payment is subject to coverage and medical necessity review by the Medicare carrier.

Some footwear suppliers accept direct payment from Medicare. If a supplier does not, the customer pays the initial cost to the supplier. Then Medicare reimburses each qualified customer for the covered amount. In either case, the amount Medicare does not cover is the responsibility of the customer if the supplier accepts direct payment from Medicare. The amount they charge the customer cannot be more than the coinsurance and deductible.

Maximum Medicare payment varies slightly by state. As of April 1997, approximate maximum payment amounts are:
- One pair of custom-molded shoes and inserts: $350
- One pair of depths: $125
- One pair of depth shoe inserts: $60

Some health plans, such as health maintenance organizations (HMOs) or supplemental insurance, may cover the patient’s portion of the costs.

A Pair Every Year

Medicare’s therapeutic shoe program will cover the purchase of one of the following options every year, for those who qualify for coverage:
- One pair of depth shoes and three pairs of inserts OR
- One pair of custom-molded shoes with an insert and two additional pairs of inserts

Qualifying for Therapeutic Shoes

Most people with diabetes enjoy healthy feet while wearing regular shoes. However, a patient and his/her doctor may determine that therapeutic footwear is needed. In that case, certain conditions must be met in order for Medicare to pay their portion of the cost.

The patient must:
- Be on Medicare Part B (medical)
- Have diabetes
- Currently be under a doctor’s comprehensive plan of care for diabetes
- Meet one or more of the following physical conditions:
  - History of foot ulcers
  - History of preulcerative ulcers
  - Foot deformity
  - Peripheral neuropathy with calluses
  - Poor circulation
  - Previous amputation of foot or part of foot

Figure 1—Fold-out educational brochure describing the footwear benefit to Medicare beneficiaries.
Table 1—CMS common procedure codes for therapeutic footwear

<table>
<thead>
<tr>
<th>Procedure code</th>
<th>Procedure</th>
</tr>
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<tbody>
<tr>
<td>A5500</td>
<td>For diabetic patients only, fitting (including follow-up), custom preparation, and supply of off-the-shelf depth-inlay shoe manufactured to accommodate multi-density insert(s), per shoe</td>
</tr>
<tr>
<td>A5501</td>
<td>For diabetic patients only, fitting (including follow-up), custom preparation, and supply of shoe molded from cast(s) of patient’s foot (custom molded shoe), per shoe</td>
</tr>
<tr>
<td>A5502</td>
<td>For diabetic patients only, multiple density insert(s), per shoe</td>
</tr>
<tr>
<td>A5503</td>
<td>For diabetic patients only, modification (including fitting) of off-the-shelf depth-inlay shoe or custom-molded shoe with roller or rigid rocker bottom, per shoe</td>
</tr>
<tr>
<td>A5504</td>
<td>For diabetic patients only, modification (including fitting) of off-the-shelf depth-inlay shoe or custom-molded shoe with wedge(s), per shoe</td>
</tr>
<tr>
<td>A5505</td>
<td>For diabetic patients only, modification (including fitting) of off-the-shelf depth-inlay shoe or custom-molded shoe with metatarsal bar, per shoe</td>
</tr>
<tr>
<td>A5506</td>
<td>For diabetic patients only, modification (including fitting) of off-the-shelf depth-inlay shoe or custom-molded shoe with offset heel(s), per shoe</td>
</tr>
<tr>
<td>A5507</td>
<td>For diabetic patients only, not otherwise specified modification (including fitting) of off-the-shelf depth-inlay shoe or custom-molded shoe, per shoe</td>
</tr>
</tbody>
</table>

Enccluded from Reiber et al.’s clinical trial may still benefit from optimal footwear.

In May 1993, the U.S. Congress passed legislation to add coverage of therapeutic shoes for diabetic Medicare beneficiaries at risk of foot disease as a Part B Medicare benefit. Although the demonstration project preceding this legislation showed that the number of beneficiaries who applied for this benefit was lower than expected (10), research seems indicated to determine if an increase in patient awareness of the benefit might increase utilization. The current quasi-experimental study compares the number of high-risk beneficiaries making Medicare therapeutic footwear claims before those in targeted intervention states were mailed a motivational brochure describing the benefit versus after the motivational mailing. The study also tests the hypothesis that the brochure increased utilization of the Medicare footwear benefit.

**Intervention**

In 1997, Qualis Health designed an educational brochure describing the footwear benefit to Medicare beneficiaries. (Qualis Health, formerly known as PRO-West, is a Seattle-based not-for-profit quality improvement organization.) The fold-out brochure (Fig. 1) included photographs of therapeutic shoes illustrating different footwear styles and components; a description of footwear types and the importance of such footwear in preventing foot complications; an explanation of the Medicare benefit and how it could be obtained; and who was eligible. The brochure also included a tear-out prescrip-
tion to be given to health care providers. We randomly assigned each intervention subject to be mailed a brochure on either 16 June or 8 August 1997. The brochure was sent to 5,872 high-risk beneficiaries in total (4,852 beneficiaries in Washington, 834 in Idaho, and 186 in Alaska).

Outcomes
Medicare therapeutic footwear claims for the period 1 January 1996 to 31 December 1998 were identified that were filed in intervention states where the brochure had been sent to beneficiaries (Washington, Alaska, and Idaho) and in comparison states (Oregon, Montana, and Wyoming) where the mailing did not occur. Claims were included that used a series of CMS Common Procedure Coding system codes that exclusively denote diabetic footwear claims (Table 1). The number of persons making footwear-related claims during this interval was the outcome of interest. We monitored the number of persons making claims before and after the first mailing of the brochure (June 1997). Persons were excluded who had died before 15 October 1997, and thus may have had insufficient time before their deaths to make a claim in response to the mailing.

Analysis
Stata version 7.0 (12) and SAS version 6.12 (13) were used for analysis. Statistical tests were two-sided, with \( P < 0.05 \) considered statistically significant.

An ordinary least-squares regression model was used to compare 1) changes in the number of persons making footwear claims before the intervention versus the number making claims after the intervention and 2) changes in the number of persons making claims in the intervention states versus the number in the comparison states. The estimated number of persons making footwear claims was adjusted for sex and age at the time of the claim. For each claimant, the observation was weighted analytically by the total number of diabetic persons in the claimant’s state. We used linear splines to model a change in the slope of the regression line (showing the rate of change in the number of persons making footwear claims per month) at a specified point in time, i.e., the date of the first mailing (Fig. 2). This allowed the number of persons making claims per month to differ between those in the intervention versus comparison states, and between the time periods before and after the intervention mailings. We used interaction tests to detect statistical differences in the number of persons per month making footwear claims. This was done by 1) comparing the 18-month period after the intervention to a similar period of time before the intervention, and 2) comparing concurrent periods between the intervention and nonintervention states.

Residual plots were examined to assess the normality of error distributions from the linear regression models, and models that fit well were accepted.

RESULTS — Observed and estimated numbers of persons making footwear claims for the study period are shown in Fig. 2. We found that 4,363 persons had made at least one claim during the study period. Of these, 1,761 (40%) made one or more claims in the comparison states and 2,602 (60%) made one or more claims in the intervention states.

In comparison states, an average of 44 persons made a claim each month at the beginning of the study. The number of persons making claims in these states increased by 1 person/month every 5 months (95% CI 0.02–1.9) from the beginning of the study until the date of the first mailing. In intervention states, more were making claims at the start of the study (65 persons/month), but this number was on the decline (decreasing 1 person/month every 5 months, 95% CI 0.25–1.7) between the start of the study and the date of the first mailing. A test of interaction comparing the rate of change in the number of persons making claims in the intervention versus the comparison states during this period was highly significant (\( P < 0.001 \)).

In the month after the first intervention mailing, the number of persons/month making claims in comparison states stayed about the same (i.e., it decreased 0.5 person/month, 95% CI 3.5 decrease to 1.1 persons/month increase). In contrast, in intervention states in that first month, there was a significant increase of 13 persons/month making claims (95% CI 11–15 persons/month). A test of interaction comparing the effect of the intervention on the change in the number of persons making claims per month in the intervention states versus the comparison states was highly significant (\( P < 0.001 \)).

In later months after the intervention, the number of persons/month making footwear claims in both the intervention and comparison states continued to increase significantly. In comparison states, \(~1\) additional person/month made a footwear claim each month after the intervention (95% CI 0.89–1.11), whereas in the intervention states, only 0.68 additional persons made a claim each month (95% CI 0.55–0.80). In both intervention and comparison states, the rate of change in the number of persons/month making claims increased significantly, comparing the time period before the intervention to that afterward (\( P < 0.001 \)). However, a test of interaction showed that there was no significant difference in the rate of change in the number of persons/month making claims during the entire 18 months after the mailing, comparing the intervention to the comparison states (\( P = 0.397 \)).

CONCLUSIONS — This study shows that the number of beneficiaries making footwear-related claims increased significantly in the intervention states shortly after an educational brochure describing the Medicare therapeutic footwear benefit was mailed to high-risk beneficiaries. Further, in the intervention states after the brochure was mailed, a downward trend in the rate of persons/month making claims was reversed, a finding that was highly significant.

Postcards, printed informational brochures, and telephone counseling have recently been used to increase utilization of mammography and immunization services. In two randomized controlled trials, one consisting of 1,127 women (14) and another of 1,099 women (15), telephone counseling either alone or combined with printed brochures was superior to the use of postcards alone in increasing mammography. A 1994 randomized trial in Montana and Wyoming found that reminder postcards increased influenza vaccination 8.4%, compared with a 4.4% increase among those who did not receive a letter (16). However, results have not always been consistent. Maglione et al. (17) have reported that several similar, unpublished educational mailing projects conducted by peer review organizations showed no substantial effect on influenza immunization rates. Another Montana Medicare study using a similar approach found that direct mail
interventions increased the frequency of eye examinations among persons with diabetes immediately after the mailing was received, although this increase did not persist 6 months after the mailing (18). Motivational brochures such as the one used in this study may not work as effectively as reminders sent by a patient’s own physician, and may be less effective if not sent to a targeted population. However, even modest increases in the use of therapeutic footwear could lead to substantial reductions in morbidity and cost of diabetic foot ulcers in patients who are at highest risk (19). Effectiveness in this setting may depend largely on the practical difficulty of obtaining the benefit, which for therapeutic footwear can be substantial due to the multiple steps required to obtain the shoes once a beneficiary begins the attempt (see Fig. 1).

Although this study found that using an educational brochure was associated with an increase in the number of persons making Medicare therapeutic footwear claims, several study limitations exist:

1. Baseline information on Medicare beneficiaries was unavailable for persons in the comparison states who did not make a claim during the study period. Therefore, survival analysis was not possible. The analysis relied on the number of persons making footwear-related claims during the study period, assuming that those in the comparison states who made footwear claims would have received the intervention had they lived in the intervention states. Thus, we cannot conclude that there was an increased probability that high-risk beneficiaries who received the mailing were more likely to make a therapeutic footwear claim, compared with those who did not receive the mailing.

2. Because the intervention in this study was not applied randomly, systematic confounding differences may also have existed between the intervention and comparison states that were not accounted for in the analysis, e.g., ethnic diversity and educational or socioeconomic status of beneficiaries. The intervention was also applied at a multi-state level, rather than an individual level. Factors that affect acceptance of therapeutic footwear may thus have differed between the intervention and comparison states.

3. Contamination of the intervention may have occurred between states, contributing to the similarity in the overall increase in the number of persons making footwear claims over the 36-month study period. With the exception of Alaska, each comparison state shared at least one border with an intervention state. It is not impossible that patients in intervention states shared the brochures with high-risk patients in comparison states. Our study method did not assess the degree to which this possible situation actually occurred. However, to our knowledge no other systematic, substantive campaigns that were intended to boost footwear use took place in either the intervention or comparison states during the period covered by this study.

4. Differences in the number of high-risk Medicare beneficiaries in each state were not completely accounted for in the regression. Although a weighting scheme was used to take into account the total number of diabetic patients in each state, an ideal weight would have been the number of high-risk persons in each state with diabetes who would be likely to make a footwear claim. However, this was not possible, again due to unavailability of baseline data in the comparison states.

In summary, although this project was not conducted as a randomized controlled trial, and its results cannot be used to infer cause and effect, these results are consistent with the suggestion that mailed educational brochures increase Medicare therapeutic footwear claims. This type of intervention may be worthy of further investigation among Medicare beneficiaries with diabetes who would most benefit from therapeutic footwear, such as those with significant foot deformities. A randomized controlled trial should be conducted to confirm the efficacy of using mailed motivational techniques to increase the use of therapeutic footwear among those for whom footwear is indicated.

**CMS DISCLAIMER**

The analyses on which this publication is based were performed under contract no. 500-99-WA02, entitled “Utilization and Quality Control Quality Improvement Organization for the State of Washington,” sponsored by CMS, Department of Health and Human Services. The content of this publication does not necessarily reflect the views or policies of the Department of Health and Human Services, nor does mention of trade names, commercial products, or organizations imply endorsement by the U.S. government.

The authors assume full responsibility for the accuracy and completeness of the ideas presented. This article is a direct result of the Health Care Quality Improvement Program initiated by CMS, which has encouraged identification of quality improvement projects derived from analysis of patterns of care, and therefore required no special funding on the part of this contractor. Ideas and contributions to the authors concerning experience in engaging with issues presented are welcomed.

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