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The cost of a patient activation intervention for achieving successful outcomes: results from the PAADRN randomized controlled trial

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Abstract

Summary—In a large, pragmatic clinical trial, we calculated the costs of achieving four successful patient-centered outcomes using a tailored patient activation DXA result letter accompanied by a bone health brochure. The cost to achieve one successful outcome (e.g., a 0.5 standard deviation improvement in care satisfaction) ranged from \$127.41 to \$222.75.

Introduction—Pragmatic randomized controlled trials (RCTs) should focus on patient-centered outcomes and report the costs for achieving those outcomes. We calculated per person incremental intervention costs, the number-needed-to-treat (NNT), and incremental per patient costs (cost per NNT) for four patient-centered outcomes in a direct-to-patient bone healthcare intervention.

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Trial registration clinicaltrials.gov identifier NCT01507662

Compliance with ethical standards

Conflict of interest F. D. Wolinsky, Y. Lou, S. F. Hall, S. W. Edmonds, D. W. Roblin, M. P. Jones, and P. Cram, have no conflicts of interest. N. C. Wright has received unrestricted grant support from Amgen for work unrelated to this project. K. G. Saag has received grants from Amgen, Eli Lilly and Merck and has served as a paid consultant to Amgen, Eli Lilly, and Merck unrelated to this project.

Methods—The Patient Activation after DXA Result Notification (PAADRN) pragmatic RCT enrolled 7749 patients presenting for DXA at three health centers between February 2012 and August 2014. Interviews occurred at baseline and 52 weeks post-DXA. Intervention subjects received an individually tailored DXA result letter accompanied by an educational bone health brochure 4 weeks post-DXA, while the usual care subjects did not. Outcomes focused on patients (a) correctly identifying their results, (b) contacting their providers, (c) discussing their results with their providers, and (d) satisfaction with their bone healthcare. NNTs were determined using intention-to-treat linear probability models, per person incremental intervention costs were calculated, and costs per NNT were computed.

Results—Mean age was 66.6 years old, 83.8% were women, and 75.3% were non-Hispanic whites. The incremental per patient cost (costs per NNT) to increase the ability of a patient to (a) correctly identify their DXA result was \$171.07; (b) contact their provider about their DXA result was \$222.75; (c) discuss their DXA result with their provider was \$193.55; and (d) achieve a 0.5 SD improvement in satisfaction with their bone healthcare was \$127.41.

Conclusion—An individually tailored DXA result letter accompanied by an educational brochure can improve four patient-centered outcomes at a modest cost.

Keywords

Clinical trials; Costs; DXA; Osteoporosis; Patient activation

Introduction

Although the contrast between explanatory and pragmatic randomized controlled trials (RCTs) was made 50 years ago [1], the popularity of the latter is a recent development [2–5]. Indeed, the extension of the CONSORT guidelines to better accommodate pragmatic trials did not appear until 2008 [6]. There are important differences between explanatory and pragmatic trials [1–6]. Explanatory trials answer efficacy questions that focus on biological changes in ideal settings with homogenous participants and strictly enforced and labor intensive protocols that constrain patient and physician behaviors [1–6]. Pragmatic trials answer effectiveness questions about patient-centered outcomes and costs in everyday or “real world” practice settings with heterogeneous patients and flexible protocols that only minimally interfere with normal patient and physician behaviors [1–6]. In reality, however, most RCTs are an admixture lying somewhere along the continuum anchored by these two ideal trial types [7].

Osteoporosis is an important disease that for three reasons may be especially appropriate for pragmatic trials. First, it is fairly common with prevalence rates among those 50 years old in the USA of 10.3% for osteoporosis and 43.9% for osteopenia [8]. Second, osteoporosis sequelae are serious with three million osteoporotic fractures expected to occur in the USA in 2025 at a cost of \$25.3 billion [9]. Third, although the primary US strategy for reducing osteoporotic fractures involves screening for osteopenia and osteoporosis using dual-energy X-ray absorptiometry (DXA) [10] followed by appropriate pharmacotherapy when indicated [11], 7-year cumulative DXA screening incidence rates range from just 42.7 to 58.8%

among Medicare patients [5], and even after an osteoporosis diagnosis or fragility fracture pharmacotherapy rates range from just 23.3 to 28.5% [7, 8].

To improve bone healthcare, we conducted a pragmatic RCT [12–16]. In the patient activation after DXA result notification (PAADRN; NCT-01507662) trial, we enrolled 7749 patients presenting for DXA testing at three US healthcare centers. The intervention involved patient-tailored letters that explained their DXA results and fracture risks and included an educational bone-health brochure. In this short communication, we report on the number needed-to-treat (NNT) and the incremental cost to generate one improved outcome (i.e., cost per NNT) for four patient-centered study outcomes: patients correctly identifying their results, patients contacting their healthcare providers, patients discussing their DXA results with their healthcare providers, and patient satisfaction with their bone healthcare.

Methods

Design and sample

PAADRN was a pragmatic RCT that enrolled 7749 patients presenting for DXA between February 2012 and August 2014 at the University of Iowa (UI), the University of Alabama at Birmingham (UAB), and Kaiser Permanente of Georgia (KPGA) which all have rather different settings and practice orientations [12–16]. We excluded patients less than 50 years old; prisoners or patients with overt cognitive disability; and patients who did not speak or read English, were deaf, or lacked access to a telephone. Baseline telephone or face-to-face interviews were conducted by trained research assistants from 28 days before up to 3 days after their baseline DXA, with other trained staff conducting follow-up telephone interviews at 52 weeks post-DXA. All interviewers were blinded to group assignment when conducting these interviews, as were all investigators until all phases of data collection had been completed. The study protocol was approved by the Institutional Review Boards at UI, UAB, and KPGA. The full PAADRN protocol is available online at <https://clinicaltrials.gov/ct2/show/NCT01507662>.

Intervention

Intervention patients were notified of their DXA results via an individually tailored letter accompanied by an educational bone health brochure [12–16]. The letter included the clinical impression of each patient's DXA result (normal, osteopenia, or osteoporosis), their 10-year fracture risk based on FRAX, and the suggestion that the patient bring the letter to their next physician visit and discuss it with their healthcare provider [15]. The brochure explained osteoporosis and reviewed the benefits of proper calcium and vitamin D intake, exercise, fall prevention, and cessation of smoking and excessive alcohol intake [16]. Intervention materials were mailed to patients from the UI coordinating center 4 weeks post-DXA [12–14]. Usual care patients received their DXA results based on the existing practices of their physicians and healthcare systems.

Patient-centered outcomes

The four patient-centered outcomes were patients correctly identifying their DXA results, contacting their healthcare providers, discussing their DXA results with their healthcare

providers, and patients who are satisfied with their bone healthcare. At the 52 week post-DXA follow-up telephone interviews, we asked patients four questions to ascertain these patient-centered outcomes. The first was “Do you know the results of your DXA scan from (insert scan date)?” Then, among those who reported knowing their results, we asked “What were the results of this DXA from (insert scan date; normal, osteopenia, or osteoporosis)?” and “Have you had contact with your health care provider since your DXA scan that was done on (insert scan date)?” Finally, among those who reported contacting their providers, we asked “During any of these contacts with a health care provider did you discuss your DXA scan or bone health?” If the patient’s answer to the question about knowing what their results matched the clinical interpretation, the correct identification of DXA result outcome was coded as “1,” and if not it was coded as “0.” Patients who reported not knowing their results were also coded as “0”. For the provider contact question, “yes” responses were coded as “1,” and “no” responses were coded as “0.” Answers to the provider discussion question were coded “1” for “yes” and “0” for “no”, with patients not having had contact with their providers coded “0” because such discussions did not occur.

Among patients who had had one or more prior DXAs, satisfaction with their bone healthcare was measured at the baseline and 52 weeks follow-up interviews using a five-item scale which assessed patient satisfaction with notification and understanding DXA results, understanding osteoporosis treatments, receiving adequate information to make an informed decision, and overall satisfaction with bone healthcare ($\alpha = 0.77$) [17]. Response options ranged from strongly agree to strongly disagree, and summary scores ranged from 5 (least satisfied) to 25 (most satisfied). The patient satisfaction outcome was coded as a “1” if the improvement in scale scores from baseline to 52 weeks post-DXA was ≥ 0.5 SD and as “0” otherwise.

Covariates

The covariates were measured at baseline and included clinical site, patient age, sex, race, education, self-rated health, history of COPD, history of depression, smoking status, alcohol use, weight-bearing exercise, history of fractures after age 40, parental hip fractures after age 50, prior DXA testing, index FRAX risk (<https://www.shef.ac.uk/FRAX/tool.jsp>), prior diagnoses for osteopenia or osteoporosis, and current or former osteoporosis medication use.

Analysis

Baseline characteristics of the intervention and usual care patients were compared using bivariable methods and have been previously reported [13, 14]. We re-estimated those previous results using intention-to-treat analyses with multiple imputation for missing data and multivariable linear probability models (LPMs; i.e., ordinary least squares linear regression) with random effects to adjust for the clustering of patients within physicians and for all covariates to derive the intervention effect at 52 weeks post-DXA. LPMs have an intuitive advantage over logistic regression models because the regression coefficients estimated from LPMs are directly interpretable as marginal effects rather than as odds ratios. Furthermore, the LPM regression coefficients on the four patient-centered outcomes in this case reflect the absolute proportional increase in successful outcomes in the intervention vs.

control group, which is in fact the absolute risk reduction (ARR). NNTs can then be calculated as $1/ARR$.

We took the perspective of a healthcare system or DXA center choosing to implement our system of mailing results to patients for our costing approach. Costs in our analysis were drawn from the actual costs and resources consumed in our research study to generate and mail the individually tailored DXA result letter accompanied by the educational bone health brochure. Personnel costs were determined by time and motion studies of the number of minutes it took for the radiologic technician to obtain the minimal additional information to calculate the FRAX scores (<https://www.shef.ac.uk/FRAX/tool.jsp>) and for the medical secretary to generate and mail the letter and brochure. Material costs (paper, mailing envelope, address label, and postage) were determined using national averages. The incremental cost to achieve one improved outcome (i.e., cost per NNT) for the four patient-centered study outcomes was determined by summing the personnel and material costs for sending the intervention letter and brochure and then multiplying by the NNT. We also estimated the total number of improved outcomes across all four patient-centered measures under the assumption that the cost to pay for improving the highest cost outcome was paid. This was done by dividing the cost per NNT for the outcome with the highest cost to achieve success by the costs per NNTs for each of the three other outcomes, and summing those dividends. All statistical analyses were performed using *SAS 9.4* (SAS Inc., Cary, NC).

Results

Because the PAADRN CONSORT patient flow chart and descriptive baseline data for the covariates have previously been published [18], only a brief review is presented here. Approximately 54% (7749) of the 14,280 patients known to be eligible for the study consented to participate and were enrolled. Follow-up interviews were completed by 6021 participants (77.7%) at 52 weeks post-DXA, although with multiple imputation for missing data. All 7749 participants were included in the intention-to-treat analyses for the first three patient-centered outcomes. Of these, 5200 (67.1%) participants had had previous DXAs and were included in the intention-to-treat analysis for the patient satisfaction with their bone healthcare outcome. In general, there were no meaningful differences between patients assigned to the intervention and usual care groups on the baseline covariates [18]. Mean age was 66.6 years old, 83.8% were women, and 75.3% were non-Hispanic whites. The prevalence of osteoporosis (19.5%) and osteopenia (53.1%) were higher than the recent national estimates (10.3 and 43.9%) because PAADRN patients were recruited from patients presenting for DXA testing rather than from the general population (e.g., the National Health and Nutrition Examination Survey) [8].

Table 1 contains the component costs of generating and mailing the tailored patient activation letter and the educational bone health brochure to patients. We did not include the developmental research costs for both the study-derived patient activation letter and educational bone health brochure because both are now in the public domain [15, 16]. The educational brochure can be downloaded directly from the National Osteoporosis Foundation web site (go to <https://www.nof.org/patients/diagnosis-information/>, click on the resources bar, and open “What Can I Do for My Bone Health”). Overall, the largest cost was

\$4.55 for printing the bone health brochure. The remaining material costs amounted to \$0.64. The cost for the 5 min needed by the radiologic technician to obtain the information to calculate the FRAX scores (<https://www.shef.ac.uk/FRAX/tool.jsp>) was \$2.34. The cost for the 5 min for the medical secretary to generate and mail the letter and brochure was \$1.38. The total cost of mailing the intervention materials to each patient was \$8.91.

Table 2 contains the crude and adjusted absolute improvements (ARRs) attributable to the direct-to-patient intervention on the four patient-centered outcomes obtained from the LPMs. For the patient to correctly identify the results of their DXA, the ARR was 5.2%, the NNT was 19.2, and the cost per NNT was \$171.07 (i.e., if 19.2 patients were mailed our DXA result intervention materials, we would expect one additional patient to correctly recall their DXA result at a cost of \$171.07). For the patient to contact their healthcare provider, the ARR was 4.0%, the NNT was 25.0, and the cost per NNT was \$222.75. For the patient to discuss their results with their healthcare provider, the ARR was 4.6%, the NNT was 21.7, and the cost per NNT was \$193.35. For the patient's satisfaction with their bone healthcare to improve by 0.5 SD, the ARR was 7.0%, the NNT was 14.3, and the cost per NNT was \$127.41. The least effective cost per NNT was for patients contacting their healthcare provider. If that cost was paid, the total number of improved outcomes would be 5.2 across the four patient-centered outcomes.

Discussion

In this short communication, we calculated the incremental costs of a direct-to-patient activation intervention, the NNT, and the incremental cost per NNT for four patient-centered outcomes that were significantly improved by the PAADRN pragmatic RCT at one-year post-DXA. We found that a healthcare system or clinic could produce tangible improvements in proximal bone health outcomes that are in the causal pathway towards improving osteoporosis care. More specifically, for \$222.75, a system could insure that one additional patient could correctly identify his/her DXA result, contact and meet with their provider to discuss their results, and increase satisfaction with their bone healthcare by a clinically significant amount.

Our intervention included individual, patient-tailored letters that explained their DXA results and fracture risks, and an educational bone health brochure. The four patient-centered outcomes were patients correctly identifying their results, contacting their healthcare providers, discussing their results with their healthcare providers, and patients who are satisfied with their bone healthcare. LPMs identified the ARRs associated with the intervention effect on each outcome after adjusting for the clustering of patients within providers and all of the covariates. The ARRs were used to calculate NNTs, and the per person incremental costs per NNT of sending the intervention materials were calculated using national averages for material and personnel. Costs per NNT ranged from a low of \$127.41 for improved satisfaction (a >0.5 SD gain from baseline) to a high of \$222.75 for having a patient contact their healthcare provider. Thus, an investment sufficient to lead to one additional patient contacting their provider yielded 5.2 improved outcomes overall across the four patient-centered outcomes.

It is important to consider our results in the context of the recently revised recommendations for cost-effectiveness analysis [19]. Through an extremely rigorous process, an accomplished panel updated and strengthened the existing guidelines that were nearly 20 years old [20]. Importantly, the updated recommendations do not consider any of our study's patient-centered outcomes, most notably patient satisfaction with their bone healthcare, as appropriate outcomes for purposes of cost-effectiveness analysis. That is, improving patient satisfaction is not currently considered a legitimate outcome from a cost-effectiveness standpoint. That position is in contrast to the fact that payers including the Centers for Medicare and Medicaid Services (CMS) and National Health Service (England) as well as most hospitals and physician practices carefully measure and track patient satisfaction. Moreover, a robust body of literature suggests that satisfaction is important to patients [21]. Thus, we might argue that our study points to an important shortcoming in the existing cost-effectiveness framework: the failure to include patient satisfaction as a recognized outcome.

Although the direct-to-patient activation intervention significantly improved all four of these patient-centered outcomes, decisions about the prudence of implementing this approach will have to be made by individual providers, practices, and healthcare systems. Only they can determine whether at the local level the costs are acceptable given the return on their investment. Among the many factors that will affect those decisions are how closely patient-centered outcomes align with the mission, vision, and values of the healthcare providers and managers involved, as well as the available operating margin for them to make such investments.

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Table 1

Incremental component costs to generate and mail the tailored patient activation letter and educational brochure.

Cost category	Incremental cost estimate (USD)
Materials	
Bone health brochure	\$4.55
Paper	0.01
Printed envelope	0.13
Address label	0.01
Postage stamp	0.49
Personnel	
Medical secretary	\$1.38
Radiologic technologist	2.34
Total	\$8.91

Personnel costs based on national averages for 5 min of a radiologic technologist to collect the information necessary for FRAX calculations and input the data, and for 5 min of a medical secretary to generate and mail the letter

Table 2

Absolute increase in successful outcomes due to the PAADRN intervention, number needed to treat, and incremental cost of achieving a successful outcome per patient

Study outcome	Adjusted absolute increase due to the intervention (ARRs)		NNT	Cost per NNT
	Crude	Adjusted		
Patient correctly identifies their DXA test result	5.2% **	5.2% **	19.2	\$171.07
Patient has contact with their healthcare provider	4.1% *	4.0% *	25.0	\$222.75
Patient discusses their DXA test results with their healthcare provider	4.3% **	4.6% **	21.7	\$193.35
Patient satisfaction with their osteoporosis care improves by 0.5 standard deviation	7.6% ***	7.0% ***	14.3	\$127.41

Absolute increases (absolute risk reductions [ARR]) derived from linear probability models in which the absolute increase is adjusted for the clustering of patients within providers and all covariates. Number of participants is 7749 with the exception of satisfaction with their osteoporosis care which is limited to the 5200 participants with one or more prior DXAs. NNT is the number needed to treat. Cost per NNT is the PAADRN incremental cost for achieving a successful outcome

*
 $p < 0.05$;

**
 $p < 0.01$;

 $p < 0.001$