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Assessment of a National Diabetes Education Program (NDEP) diabetes management booklet: the GRADE experience

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Abstract

Background and Purpose—The National Diabetes Education Program created the *4 Steps to Manage Your Diabetes for Life* booklet to help patients with diabetes learn the basics of self-management and care recommendations. The purpose of this study is to explore the impact of *4 Steps* on participants' diabetes management knowledge and self-efficacy in the Glycemia Reduction Approaches in Diabetes: A Comparative Effectiveness Study (GRADE).

Methods—A sample of 348 adults with type 2 diabetes enrolled in GRADE were included in this analysis. Participants took a pre-test, were sent home with *4 Steps*, then took a post-test at their next visit. The Wilcoxon signed rank test was used to detect differences in knowledge and self-efficacy between scale scores pre- and post-test.

Conclusions—Analyses revealed increases in participants' diabetes management knowledge ($p < 0.001$) and self-efficacy ($p < 0.001$) from pre- to post-test. Participants who reported no formal previous diabetes education showed a statistically significant increase in knowledge scores compared to those with previous diabetes education ($p < 0.05$).

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Statement of Contributions:

R.D. contributed to the design, writing, and critical review of the manuscript. C.N. contributed to the design, writing, and critical review of the manuscript. J.M.G. contributed to the design, writing, and critical review of the manuscript. H.K.-S. contributed to the design, writing, and critical review of the manuscript. M.L. contributed to the design, writing, and critical review of the manuscript. M.T. contributed to the design, writing, and critical review of the manuscript. D.M.T. contributed to the design, writing, and critical review of the manuscript. R.D. is the guarantor of this work and, as such, had full access to all the data in the study and takes responsibility for the integrity of the data and the accuracy of the data analysis.

Implications for Practice—Appropriate, relevant diabetes education materials may improve self-management knowledge and self-efficacy among adults with type 2 diabetes. Providers should feel confident using *4 Steps* as a resource for clinical practice.

Introduction

Type 2 diabetes is a serious disease that has reached epidemic proportions among Americans in the past decade (Centers for Disease Control and Prevention, 2014). Type 2 diabetes is primarily a chronic condition that relies on patient behavior and certain skills to reduce complications. Diabetes management knowledge and self-efficacy are important factors in patient behaviors; however, primary care providers are increasingly pressed for time during patient visits, and “supplementary” counseling around management of chronic diseases like diabetes may not be the priority during the time available (Ostbye et al., 2005). At the same time, current literature explores the impact of nurse practitioners and registered nurses on clinical and non-clinical outcomes for diabetes patients. For example, Richardson et al. (2014) found that integrating nurse practitioners into primary care teams had a significant impact on clinical measures, such as A1C and blood pressure, but also showed increases in patient self-efficacy. Further, one study found that primary care registered nurses can effectively expand their role beyond clinical assessment to include relevant education and self-management support as part of a collaborative care delivery system (Boyle, Saunders, & Drury, 2016).

Diabetes education requires a variety of interventions and tools, and diabetes education programs should continue to produce accessible, evidence-based information for patients, providers, and partners to help prevent and manage diabetes. An array of self-management tools and programs have been developed to help patients learn to manage their type 2 diabetes to maximize their health and help prevent and/or delay complications in the future. This includes tools to educate and empower patients to engage health care providers, cope with their disease, eat well, be active, and engage in every day behaviors such as medication adherence, foot care, and oral care.

There are a number of patient education resources available to support diabetes management counseling. The National Diabetes Education Program (NDEP) created the *4 Steps to Manage Your Diabetes for Life (4 Steps)* booklet (catalog no. NDEP-067) to provide key steps to help people with diabetes understand, monitor, and manage their disease. The NDEP is a federally-funded program sponsored by the National Institutes of Health and the Centers for Disease Control and Prevention and includes over 200 partners at the federal, state, and local levels, working together to improve the treatment and outcomes for people with diabetes, promote early diagnosis, and prevent or delay the onset of type 2 diabetes. While many of the NDEP’s resources are developed based on formative research and are pretested among members of the target audience, few efficacy studies have been conducted on how resources, including *4 Steps*, impact patient outcomes.

The *4 Steps* resource is one of the NDEP’s most popular diabetes management publications. The 16-page booklet incorporates plain language principles, is available for free in print and digital, and designates clear calls to action for patients with check marks throughout the

booklet. *4 Steps* helps patients learn (1) about diabetes, (2) the diabetes ABCs (A1C test, blood pressure, cholesterol, and smoking cessation), (3) how to live well with diabetes, and (4) routine care needed to stay healthy. The resource, which includes colorful images and graphics to enhance appeal and comprehension, also includes a summary of important points from the booklet, a diabetes care record to keep track of important test results, and links to additional resources.

The NDEP revised the *4 Steps* publication in 2012, incorporating health literacy and plain language principles. Having low health literacy skills is a serious problem for individuals with chronic diseases, such as diabetes. These individuals may struggle to understand diabetes concepts and the changes they need to make to manage their diabetes (Schillinger et al., 2002). According to Fransen et al. (2015), health care providers report not having the insights or tools available to systematically support diabetes management education among low health literacy patients. The NDEP aims to support patients across health literacy levels with its resources.

There are few studies exploring the effectiveness of diabetes management resources in “real-life” settings. One New Zealand study explored the impact of a *Diabetes Passport* booklet, containing a medication list, tailored action plans, and self-assessments (Simmons, Gamble, Foote, Cole, & Coster, 2004). Although the passport booklet was not associated with an increase in diabetes knowledge or self-empowerment, it was associated with a relative reduction in A1C, and investigators suggested it could be more useful in combination with another intervention. However, this study was done only with a New Zealand population and is not generalizable to the U.S. population. Furthermore, Wallace et al (2008) found that in combination with counseling, the *Living with Diabetes* guide was associated with an increase in participant self-efficacy, self-reported behaviors, and knowledge. However, this study and others have not examined the impact of printed resources in isolation of a larger intervention or program, which is a gap in the literature.

This study was designed to assess how *4 Steps to Manage Your Diabetes for Life*, an evidence-based diabetes education resource, performs in a clinical trial setting. Objectives of this study were to:

- Determine if knowledge of diabetes management increased after exposure to the booklet; and
- Determine if diabetes management self-efficacy—one’s belief that one can perform an action in a variety of settings—increased after exposure to the booklet.

To conduct the study, the NDEP partnered with the GRADE study (Glycemic Reduction Approaches in Diabetes: A Comparative Effectiveness Study, [ClinicalTrials.gov](https://clinicaltrials.gov/ct2/show/study/NCT01794143) Identifier NCT01794143), which used the *4 Steps* patient booklet as a standardized educational tool during the run-in phase of the study. The GRADE study sought to enroll 5,000 patients with relatively recent onset (less than 10 years’ duration) type 2 diabetes across 36 centers in the U.S. to compare the metabolic effects of four common anti-diabetic drugs when combined with metformin (Nathan et al., 2013). Using *4 Steps* in this setting provided a cost-effective

opportunity for the NDEP to obtain data on the effectiveness of its resource, as a component of a broader diabetes education effort, for adults with type 2 diabetes of short duration.

Methods

All participating sites obtained Institutional Review Board approval to administer the *4 Steps* assessment. Patients were eligible to participate if they met the following inclusion criteria: enrolled in GRADE; provided informed consent; had not completed the initial run-in visit; and able to read and understand English. All GRADE participants who met this criteria during the study period were enrolled in this ancillary study. Once participants enrolled in the GRADE study, they engaged in a run-in period designed to adjust metformin dosing for the clinical intervention. Diabetes education was included during this phase via the *4 Steps* booklet, as needed. Other elements of education, such as interim contacts, were also provided in the clinics, which were not controlled across centers but allowed for local practice and style tailored to each participant. However, study coordinators were trained in the consistent administration of the *4 Steps* questionnaires, and investigators ensured consistent intervention and data collection across study sites.

Investigators developed a short paper questionnaire that was used for this pre- and post-test design study. The questionnaire used existing, validated items to the extent possible, such as those from the Michigan Diabetes Research and Training Center's Diabetes Knowledge Test and the Stanford Patient Education Research Center's Diabetes Self-Efficacy Scale (Michigan Diabetes Research and Training Center, 1998; Stanford Patient Education Research Center, n.d.). To minimize study complexity, only English-language materials were assessed. The questionnaire contained 16 questions, was administered on paper, and all items were closed-ended.

- The composite knowledge score was determined by seven multiple-choice items related to diabetes management, calculated as one point for each correct answer. Knowledge items assessed key diabetes self-management information contained in *4 Steps*, such as the A1C test, general food choices, routine physical activity, foot care, and taking medications as prescribed.
- The composite self-efficacy score was determined by six Likert scale items associated with confidence and belief in ability to succeed in diabetes management efforts, with more points assigned to answers conveying more confidence or certainty in diabetes management. Self-efficacy items assessed beliefs that one can engage in lifestyle behaviors such as medication adherence and routine health care to successfully manage diabetes.

In addition to collecting baseline data on knowledge and self-efficacy, the questionnaire included questions regarding prior formal diabetes education and English proficiency:

- Have you ever received diabetes education? (For example, attended one or more individual or group classes or meetings with a diabetes educator, nurse or dietitian?)
 - a. No

- b. Yes
 - c. Not sure
- Which of the following best describes you?
 - a. English is the only language I know
 - b. I am more comfortable communicating in English than another language
 - c. I am equally comfortable communicating in English and another language
 - d. I am more comfortable communicating in another language, not English

Additionally, the investigators obtained demographic data (age, race/ethnicity, gender, educational level) from the GRADE study data.

GRADE study coordinators asked participants to complete the pre-test questionnaire at the first run-in visit prior to providing them with *4 Steps* materials. The pre-test established baseline diabetes management knowledge and self-efficacy. Participants were given the *4 Steps* booklet to take home. Coordinators encouraged participants to review *4 Steps* but did not mention the follow-up questionnaire. When they returned at a later date for their interim or final run-in visit, study coordinators asked participants to complete the post-test before any additional diabetes education was delivered. The post-test was administered even if the participant stated they did not review the booklet. Prior to administering each questionnaire, study coordinators informed participants that their participation was voluntary. Completed questionnaires were sent by sites to the investigators for data entry. The questionnaire data were provided to the GRADE coordinating center which provided a final de-identified dataset for analysis. The collaborating investigators conducted the analysis on de-identified data. Data collection was conducted from October 2013 to June 2014.

Data Analysis

Data were analyzed in MS Excel Data Analysis Tools Add-In, within Office 365 ProPlus suite. The Wilcoxon signed rank test was conducted to detect significant differences between individuals' composite knowledge and self-efficacy scores at pre- and post-test. This non-parametric test converts scores to ranks and compares pre- and post-test ranks for participants. Effect sizes were calculated as the z value divided by the square root of the number of observations and categorized using Cohen (1988) criteria of 0.1 = small effect, 0.3 = medium effect, and 0.5 = large effect. Cohen's effect size can be interpreted approximately as the standardized mean difference.

To further explore differences by demographic characteristics, investigators used a two-sample t-test to investigate whether change in knowledge or self-efficacy from pre- to post-test varied by gender, ethnicity, or participation in previous diabetes education. One-way analysis of variance (ANOVA) was conducted to assess differences in pre- and post-test knowledge and self-efficacy scores by race and education level. Finally, linear regression

was used to examine any linear relationships between change in knowledge and age or interval days between pre- and post-test.

Results

The sample included 348 participants recruited from 36 centers in the U.S. A description of sites can be found in the GRADE design paper by Nathan et al. (2013). A total of 168 participants completed a pre-test but not a post-test and were not included in the final dataset. The average number of days between pre-test and post-test was 45, ranging from 18 to 84 days. Participants were majority male (62%), non-Hispanic (89%), White (62%) or African American (22%), and fairly educated (67% reporting at least some college). See Table 1 for a description of the sample. [Table 1]

Knowledge

Out of a range of possible scores from 1 to 7, participants' pre-test knowledge scores ranged from 1 to 7, and post-test knowledge scores ranged from 3 to 7. [Figure 1]

Analyses showed a statistically significant increase in individual composite knowledge scores at post-test with a large effect size ($r = 0.56$), based on Cohen (1988) criteria. The median knowledge score increased from pre-test (median = 85.7%) to post-test (median = 100%), and the mean knowledge score also increased from pre-test (mean = 87.1%) to post-test (mean = 91.4%). [Figure 2]

Participants generally had high knowledge scores at pre-test (78% scoring 6 out of a possible 7) and post-test (89% scoring 6 out of a possible 7). The knowledge questions revealing the largest shifts from pre- to post-test were those related to:

- A1C frequency (14% increase in correct responses);
- Personal role in diabetes management (6% increase in correct responses); and
- First step to daily physical activity (6% increase in correct responses).

In exploring differences across previous diabetes education status, analyses showed that pre-test knowledge scores were significantly higher among participants who reported previous diabetes education versus those who did not ($p = 0.03$). While both segments with and without previous diabetes education showed significant increases in knowledge scores from pre-test to post-test, participants who reported no previous diabetes education had a statistically significantly higher increase in knowledge scores compared to those with previous diabetes education ($p = 0.03$). [Figure 3]

Change in knowledge from pre- to post-test did not vary by gender, race, ethnicity, education level, age, or interval days (days between pre- and post-test).

Self-Efficacy

Out of a range of possible scores from 0 to 30, participants' pre-test self-efficacy scores had a range of 11 to 30, and post-test self-efficacy scores ranged from 6 to 30. The change in

minimum self-efficacy score was limited to four participants who scored below the pre-test minimum of 11. [Figure 4]

Analyses revealed a statistically significant increase in individual composite self-efficacy scores at post-test with a small effect size ($r = 0.29$), based on Cohen (1988) criteria. The median self-efficacy score remained the same from pre-test to post-test (median = 83.3%), while the mean self-efficacy score increased slightly from pre-test (mean = 80.7%) to post-test (mean = 82.7%). [Figure 2]

Participants generally had high self-efficacy scores at pre-test (87% scoring 20/30) and post-test (90% scoring 20/30). The self-efficacy questions with the largest shifts in scores from pre- to post-test were those related to:

- Choosing the right foods when hungry (21% increase in those feeling extremely sure);
- Exercising most days of the week (13% decrease in those feeling extremely sure);
- Coping with diabetes-related stress (31% increase in those strongly agreeing); and
- Knowing enough about diabetes to make the right choices (22% increase in those strongly agreeing).

Change in self-efficacy from pre- to post-test did not vary by previous diabetes education. However, pre-test self-efficacy scores were higher among participants who reported having previous diabetes education compared to those who did not ($p < 0.001$).

Change in self-efficacy from pre- to post-test did not vary by gender, race, ethnicity, or education level. However, regression analyses revealed a statistically significant, though weak ($r^2 = 0.01$), decrease in positive self-efficacy change from pre- to post-test as participant age increased ($\beta = -0.04$, $p = 0.04$). [Figure 5]

Investigators did not find a significant relationship between interval days (days between pre-test and post-test) and change in self-efficacy.

Discussion

This study evaluated the utility of an informational booklet to improve self-management knowledge and self-efficacy among persons with type 2 diabetes. The results above highlight several important findings. While participants had generally high knowledge and self-efficacy scores at both pre- and post-test, participants experienced an increase in diabetes management knowledge from pre- to post-test. Pre-test scores may have skewed high due to patients already being engaged and enrolled in a high-touch diabetes clinical trial, and further studies may explore limiting participation to those with only low pre-test scores. The knowledge topic areas showing the most gain were: A1C frequency, personal role in diabetes management, and first step to daily physical activity. Those with no previous diabetes

education showed a higher increase in knowledge scores than those with previous diabetes education, and the effect size of this difference suggests a minimally important difference.

Participants also experienced an increase in diabetes management self-efficacy from pre- to post-test. The self-efficacy topic areas showing the most gain were: choosing the right foods, coping with diabetes-related stress, and knowing enough about diabetes to make the right choices. However, participants experienced a decrease in confidence related to exercising most days of the week, which may reflect a gain in knowledge about what the recommended level of exercise is and the participants' views of how achievable that recommendation is for them. Baseline self-efficacy scores were higher among participants with previous diabetes education versus those with no previous diabetes education. There was a slightly negative relationship between gain in self-efficacy and increasing age of participants.

Incorporating the *4 Steps* assessment into the existing GRADE study provided a cost-effective and efficient platform to evaluate the usefulness of an important patient education resource.

The limitations of this study included factors outside of the *4 Steps* booklet that may have impacted pre- and post-test scores, as well as repeated measurement effects in which the participants' exposure to the pre-test affected post-test results. For example, investigators could not control for diabetes information provided to participants from sources other than *4 Steps* during the pre- and post-test period, including the clinic-tailored interim contacts and other diabetes education provided by clinic and study staff. Without a control group—individuals not receiving the *4 Steps* booklet—it was not possible to control for these confounding variables. The variability in length of time from pre-test to post-test may have also had unintended effects on the results, though this was controlled for in the analysis. Finally, non-English speakers and those with limited reading literacy were excluded, and the participants represented a highly educated cohort, where 67 percent had at least some college education, which may have resulted in outcomes that are less representative of the larger population.

Due to constraints in time and funding, investigators were not able to expand the study to follow participants longer-term to assess whether changes in knowledge or self-efficacy early in the trial impacted long-term knowledge and self-efficacy or clinical outcomes. The NDEP will consider this expansion and more robust evaluation approach in the future.

Implications for Practice

The NDEP's *4 Steps* was an effective, easy-to-deliver standardized educational tool for the GRADE study. The results noted in this study imply that *4 Steps* could be used successfully in other settings. Nurse practitioners, whose practice model puts an emphasis on health promotion and education, have an increasing role in the management of patients with chronic diseases such as diabetes. However, time constraints in a busy primary care practice can pose a challenge to the provision of comprehensive diabetes education. Findings from this study indicate that the *4 Steps* booklet can assist primary care providers to educate and support patients with type 2 diabetes and increase diabetes management knowledge and self-efficacy. Furthermore, plain language materials like *4 Steps* are written in simple, easy-to-

understand language and set a strong foundation for providers to use those materials in consultation with patients.

Question-specific data indicated that self-efficacy for exercising most days of the week was a specific area for improvement, with a number of respondents reporting decreased confidence from pre-test to post-test. These results highlight the need to consider a patient's understanding or perceptions related to physical activity recommendations that may seem daunting or difficult to achieve. Health care professionals can support their patients by helping them break down goals into manageable steps that can fit into a patient's lifestyle.

Both knowledge and self-efficacy are important factors in patients' readiness to adopt healthy behaviors to manage diabetes and prevent complications. Diabetes education requires a variety of interventions and tools, and diabetes education programs should continue to produce accessible, evidence-based information for patients, providers, and partners to help prevent and manage diabetes.

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Figure 1.

Figure 2.

Figure 3.

Figure 4.

Figure 5.

Table 1

Participant Demographic Characteristics

Variable	N	Range	Mean
<i>Age (years)</i>	348	32–85	55.4
Variable	N	(%)	
<i>Gender</i>			
Female	132	38%	
Male	216	62%	
<i>Ethnicity</i>			
Not Hispanic	308	89%	
Hispanic	39	11%	
Unknown	1	0%	
<i>Primary Race (self-reported)</i>			
White	215	62%	
Black or African American	78	22%	
Other	20	6%	
Asian	18	5%	
American Indian or Alaska Native	12	3%	
Unknown or not reported	4	1%	
Native Hawaiian or Other Pacific Islander	1	0%	
<i>Education Level</i>			
Less than high school	9	3%	
High school or GED	53	15%	
Some college	92	26%	
College	86	25%	
Graduate school	57	16%	
Unknown or not reported	51	15%	
<i>English Proficiency</i>			
Only communicates in English	256	74%	
More comfortable with English than another language	58	17%	
Equally comfortable with English and another language	32	9%	
More comfortable with another language other than English	2	1%	
<i>Previously Received Diabetes Education</i>			
No	127	36%	
Yes	206	59%	
Not sure	15	4%	