Evidence-Based Practice

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Evidence-Based Practice Protocol to Improve Glucose Control in Individuals with Type 2 Diabetes Mellitus

Type 2 diabetes mellitus is a major public health problem in the United States. In adult patients with type 2 DM, what is the effect of adding a follow-up telephone intervention by an APRN on blood glucose control as compared to standard treatment alone? Findings from one systematic review and five randomized control trials were used to support a protocol to elicit improvement in glycemic control.

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Diabetes mellitus (DM) is a group of diseases that includes type 1 DM, type 2 DM, gestational DM, medication-induced DM, and pre-DM; all are characterized by high levels of blood glucose (American Diabetes Association [ADA], 2008). Currently, 24 million children and adults in the United States (8% of the population) have diabetes; unfortunately, nearly one-third of those individuals are unaware they have the disease. In addition, 57 million Americans have pre-diabetes (ADA, 2007a). Type 2 DM accounts for 90%-95% of all cases of diabetes (Centers for Disease Control, 2003). In type 2 DM, the body does not use insulin properly due either to insulin resistance or relative insulin deficiency (ADA, 2007a).

In 2000, DM was the sixth leading cause of death in the United States, with heart disease leading the cause of diabetes-related deaths. About 65% of deaths occurring among people with DM are attributed to heart disease or stroke. DM is the leading cause of blindness among adults ages 20-74, and diabetic retinopathy is linked to 12,000-24,000 new cases of blindness each year. In 2000, nearly 130,000 people with DM underwent dialysis treatment or kidney transplantation. About 60%-70% of people with DM also have mild-to-severe forms of nervous system damage that impairs sensation in the feet or hands and slows digestion of food in the stomach. Also, more than 60% of non-traumatic lower-limb amputations in the United States occur among people with DM (ADA, 2007a).

To determine if a person has pre-diabetes or diabetes, health care providers conduct a fasting plasma glucose test (FPG) or an oral glucose tolerance test. Either test can be used to diagnose pre-diabetes or diabetes; however, the ADA (2007b) recommends the FPG because it is easier, faster, and less expensive to perform. A fasting blood glucose level of 100-125 mg/dl signals pre-diabetes, while FPG greater than 125 mg/dl signifies diabetes (ADA, 2007b). DM contributes to many complications which are very costly to patients and the U.S. health care system. Direct medical costs related to DM in 2007 were $116 billion, while indirect costs (e.g., disability, work loss, premature mortality) accounted for $58 billion. Total costs related to DM in the United States in 2007 were $174 billion (ADA, 2008). In Pennsylvania, where the APRN intervention occurred, direct medical costs related to DM in 2006 were estimated at nearly $5 billion and indirect costs at a little over $2 billion (ADA, 2006).

Research has shown that keeping blood glucose results as close to normal as possible can prevent or delay many of the complications and costs associated with DM. The classic randomized clinical trial conducted by The Diabetes Control and Complications Trial Research Group (1993) found maintenance of blood glucose as close to normal as possible slows the onset and progression of diabetes-related eye, kidney, and nerve dis-

eases. The findings showed a reduction in eye disease by 76%, kidney disease by 50%, and nerve disease by 60%. The study also demonstrated any sustained lowering of blood glucose has positive effects, even if the person has a history of poor glycemic control. The United Kingdom Prospective Diabetes Study (1998) also concluded intensive blood glucose control decreases the risk of microvascular complications and diabetes-related deaths.

To maintain tight glycemic control, the literature strongly supports use of the ADA Standards of Medical Care in Diabetes (2007b). Standards currently do not recommend a follow-up telephone intervention, but they do encourage use of a complex treatment regime for persons with type 2 diabetes in order to maintain tight glycemic control and delay or minimize diabetes-related complications. Because many persons diagnosed with type 2 diabetes are older adults, complex treatments may be difficult to implement. Involvement of an advanced practice nurse (APN) may empower patients to care for their chronic illness and maintain their optimal level of wellness. The purpose of this article is to explore the effectiveness of an APN-led follow-up telephone intervention on glycemic control in individuals with type 2 DM. The effectiveness of the intervention was measured by the interpretation of daily fasting blood glucose results.

Focused Problem

In adults with type 2 DM, what is the effect of adding a follow-up telephone intervention by an APN on blood glucose control as compared to ADA-recommended standard treatment alone? Target population for the intervention was adults diagnosed with type 2 DM who could read, write, and understand English; were able to perform self-blood glucose monitoring every day before eating; and were willing to call or fax the results to the collaborating physician's office on a weekly basis. Excluded from the evidence-based practice protocol (EBPP) were persons with a diagnosed psychotic disorder or

disabling sensory or cognitive impairment; who had a new diagnosis of type 2 DM and had not attended standard outpatient DM education classes; were receiving drugs that can cause medication-induced hyperglycemia or hypoglycemia (steroids, antibiotics) at the time of APN intervention implementation; and patients with an acute illness that may cause hyperglycemia. Individuals who were pregnant or planning to become pregnant, those without access to a telephone, those without a blood glucose monitor or without access to one, persons with hypoglycemia unawareness, and those with a life expectancy of less than 1 year were excluded from the EBPP.

Intended users of the EBPP included adult health clinical nurse specialists, family and adult nurse practitioners, and internal medicine and family physicians with whom an APN could collaborate to initiate the stated intervention. Other potential beneficiaries of the EBPP were all health care professionals who have direct contact with individuals with type 2 DM and can facilitate their appropriate referrals and education.

The objective of the EBPP protocol was to improve glucose control in individuals with type 2 DM, as demonstrated through the trending of FBG results. The ADA (2007b) recommends self-monitoring of blood glucose (SMBG) as a component of effective therapy that allows patients to evaluate their individual responses to therapy and assess whether glycemic targets are being reached. SMBG can be useful in preventing hypoglycemia, adjusting medications, and identifying effects of physical activity. The optimal frequency and timing of SMBG for patients with type 2 DM is not known but should be sufficient to facilitate attainment of glucose goals. Use of hemoglobin A_{1c} testing in combination with SMBG allows better evaluation of blood glucose management as well as verification of accuracy of self-reported blood glucose results. However, inclusion of this measure was not possible in the current study.
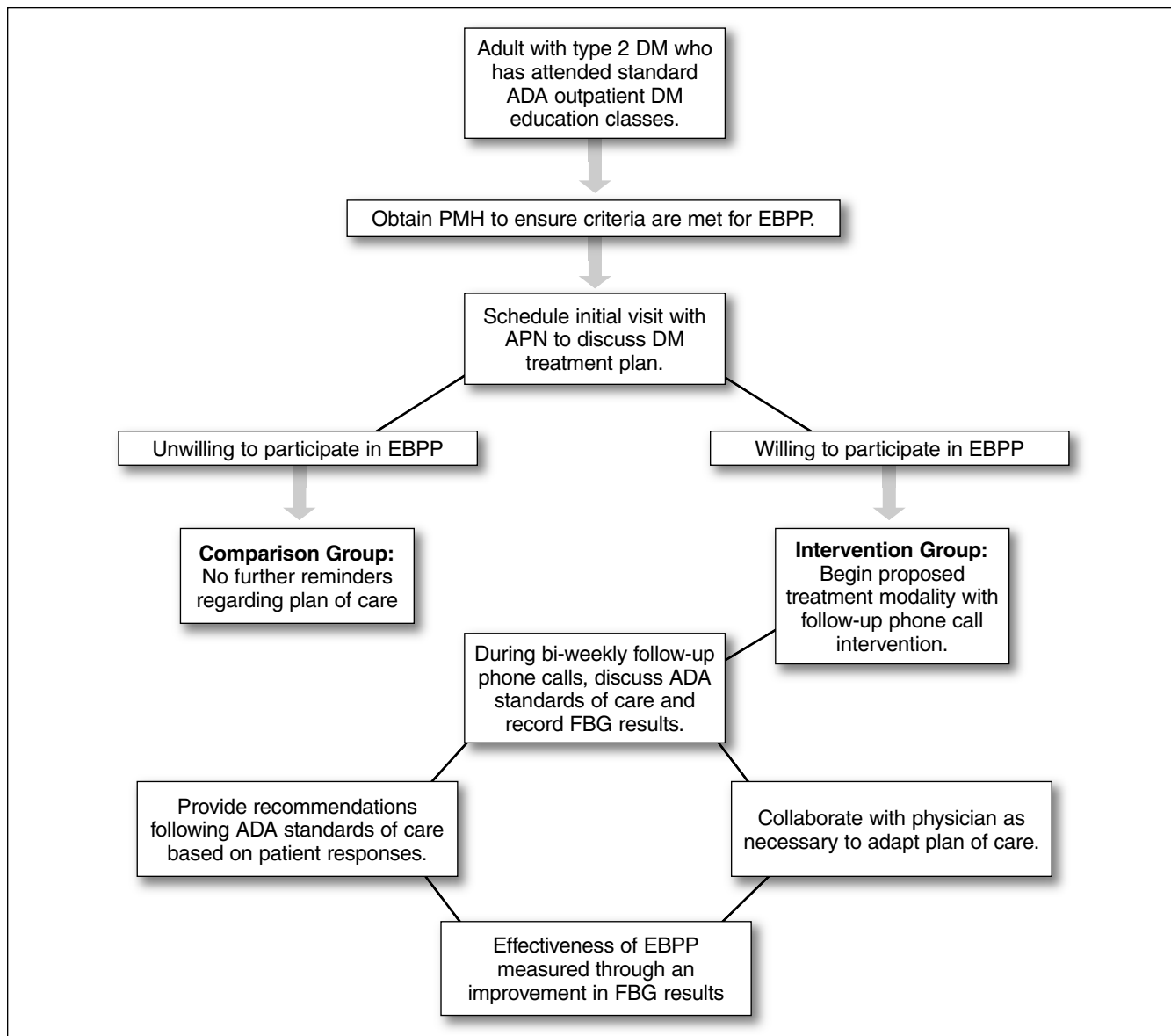
Literature Review

A literature review was performed for the most current and relevant information related to the research question. Six computerized research data bases were accessed: Cumulative Index to Nursing and Allied Health Literature (CINAHL), Health Source: Nursing/Academic Edition, MEDLINE, Educational Resource Information Center (ERIC), the Cochrane Library, and DiabetesPro (professional resources online). The keywords used to retrieve documents were *diabetes mellitus, type 2 diabetes mellitus, diabetes mellitus and follow-up interventions, diabetes mellitus and follow-up interventions and advanced practice nursing, diabetes mellitus and follow-up interventions and clinical nurse specialists, diabetes mellitus and follow-up interventions and meta analysis, diabetes mellitus and follow-up interventions and systematic reviews, diabetes mellitus and follow-up phone call interventions, diabetes mellitus and nursing education, diabetes mellitus and glucose control, diabetes mellitus and glucose control and advanced practice nursing, diabetes mellitus and glucose control and clinical nurse specialists*. After completion of the literature review, 22 studies were reviewed for the EBPP; however, only six studies (1999-2007) met the selection criteria based for the proposed APN intervention. One study was a systematic review, and five studies were randomized control trials.

The selected studies suggested follow-up phone call interventions can help improve glycemic control in individuals with DM.

Conceptual Model

The conceptual model used to direct the EBPP was Dorthea Orem's Self-Care Deficit Theory of Nursing. Within Orem's conceptual model, three theories are expressed: theory of nursing systems, theory of self-care deficit, and theory of self-care. The current study was based on Orem's Mid-Range Theory of Self-Care, which identified self-care as "a human regulatory function that individuals must, with deliberation, perform themselves or have

Figure 1.
Type 2 DM Follow-Up Phone Call Treatment Algorithm:
A Coaching/Collaboration Protocol

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                    ┌─────────────────────────┐
                    │ Adult with type 2 DM who│
                    │ has attended standard   │
                    │ ADA outpatient DM       │
                    │ education classes.      │
                    └─────────────────────────┘
                                │
                    ┌─────────────────────────────────────┐
                    │ Obtain PMH to ensure criteria are    │
                    │ met for EBPP.                        │
                    └─────────────────────────────────────┘
                                │
                    ┌─────────────────────────┐
                    │ Schedule initial visit  │
                    │ with APN to discuss DM  │
                    │ treatment plan.         │
                    └─────────────────────────┘
                    /                         \
    ┌─────────────────────────────┐    ┌─────────────────────────────┐
    │ Unwilling to participate     │    │ Willing to participate in    │
    │ in EBPP                      │    │ EBPP                         │
    └─────────────────────────────┘    └─────────────────────────────┘
              │                                      │
    ┌─────────────────────┐              ┌─────────────────────────┐
    │ Comparison Group:   │              │ Intervention Group:     │
    │ No further reminders│              │ Begin proposed          │
    │ regarding plan of   │              │ treatment modality with │
    │ care                │              │ follow-up phone call    │
    └─────────────────────┘              │ intervention.           │
                                         └─────────────────────────┘
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Adult with type 2 DM who has attended standard ADA outpatient DM education classes.

Obtain PMH to ensure criteria are met for EBPP.

Schedule initial visit with APN to discuss DM treatment plan.

Unwilling to participate in EBPP

Willing to participate in EBPP

Comparison Group: No further reminders regarding plan of care

Intervention Group: Begin proposed treatment modality with follow-up phone call intervention.

During bi-weekly follow-up phone calls, discuss ADA standards of care and record FBG results.

Provide recommendations following ADA standards of care based on patient responses.

Collaborate with physician as necessary to adapt plan of care.

Effectiveness of EBPP measured through an improvement in FBG results

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performed for them to maintain life, health, development, and well being" (Orem, 1995, p. 103). The theory of self-care was related to the EBPP because individuals with type 2 DM must adhere to treatment guidelines (self-care) in order to maintain life, health, development, and well-being, as evidenced by improved glycemic control and blood sugar stability. The APN intervention served as one method to facilitate self-care.

Major Recommendations

Two guidelines were reviewed using the Appraisal of Guidelines for Research and Evaluation (AGREE) Instrument (2001) to formulate the APN algorithm (see Figure 1) and questions (see Figure 2) in the follow-up phone call intervention. The *Standards of Medical Care in Diabetes* (ADA, 2007b) guided the formulation of questions and recommendations involving diabetes management. The intervention included questions and recommendations about appropriate medical evaluations, management plans, SMBG, diagnostic testing, physical activity,

psychosocial assessment, immunizations, hypoglycemia/hyperglycemia problems, sick day guidelines, hypertension control, lipid management, aspirin therapy, smoking cessation, foot care, and nephropathy/retinopathy screening, and treatment.

Based on the guidelines (ADA, 2007b), patient recommendations were made during the APN intervention, including SMBG for achievement of glycemic goals and hemoglobin A_{1c} testing at appropriate intervals. Meal planning (carbohydrate counting and limiting

Figure 2.
Content of Follow-Up Telephone Intervention

The following will be covered in the 15-20 minute bi-weekly phone call:
1. Do you have a follow-up appointment with your primary care provider?
2. Are you self-monitoring your blood glucose levels at home?
3. If yes, how often?
4. Are you satisfied with your blood glucose monitor?
5. What were your blood glucose values over the last 48 hours?
6. Are you going to have a HgbA$_{1c}$ drawn within next 3-4 months?
7. If previously done, what was the value?
8. Are you taking medication for your DM?
9. If yes, what medications?
10. If yes, are you having any problems with it?
11. Any hyperglycemia or hypoglycemia problems?
12. What was your blood pressure at your last screening?
13. If it was greater than130/80, are you being treated with lifestyle and behavioral changes (exercise, diet modifications)?
14. If it was greater than 140/90, are you being treated with medication as well as lifestyle and behavioral changes? (preferably ACE inhibitors or ARBs as they have been shown to delay the progression of macroalbuminuria and nephropathy)
15. What was your last cholesterol level?
16. Are you taking a statin (shown to delay onset of CVD)?
17. Do you take an aspirin daily (75-162 mg/day)?
18. Have you been tested for the presence of microalbuminuria?
19. If present, are you currently taking an ACE inhibitor or an ARB?
20. Have you had a dilated and comprehensive eye examination by an ophthalmologist or optometrist since diagnosis?
21. Have you had a foot examination since diagnosis?
22. Provide smoking cessation counseling.
23. Have you had the flu shot this year?
24. Is your pneumonia vaccine up to date?
25. Discuss sick day guidelines.
26. Are you getting exercise of moderate intensity at least three times a week for 30 minutes at a time?
27. Discuss meal planning.
28. How are you feeling emotionally?
29. Is there anything that we have not discussed that you would like to discuss concerning your treatment plan?

fat intake) and physical activity of at least 150 minutes/week were discussed with all patients, and a brief psychosocial assessment was performed on all patients in the EBPP as a screening for any emotional problems. Also discussed was treatment of hypoglycemia with 15-20 grams of a rapid-acting carbohydrate. The importance of obtaining the pneumococcal vaccine and the annual influenza vaccine also was identified.

Other patient recommendations included blood pressure screening to identify individuals with hypertension and further treatment involving medications, lifestyle, and behavioral therapy. Dyslipidemia screening was recommended annually, or more frequently based on lipid values, in order to achieve goals and treatment with a HMG-CoA reductase inhibitor medication (statin) for all patients trying to achieve a reduction in low-density lipoprotein (LDL) of 30%-40% regardless of baseline LDL levels. Also, aspirin therapy was recommended as a primary prevention strategy for individuals with an increased risk of cardiovascular disease and as a secondary prevention strategy in persons with a history of cardiovascular disease. All patients in the EBPP were advised not to smoke.

Patients also were advised to perform an annual test for the presence of microalbuminuria and receive appropriate pharmacotherapy if indicated. Yearly dilation and comprehensive eye examinations by an ophthalmologist or optometrist were recommended to reduce the risk and progression of diabetic retinopathy. Finally, a comprehensive foot exam was recommended annually to patients in the EBPP to identify risk factors predictive of ulcers or amputations, or identify any areas of skin breakdown.

Risks and Benefits of the Guideline

Risks of following the guidelines included events such as severe hypoglycemia and weight gain, which is attributed to the improved glycemic control. Other risks involved liver dysfunction from statin therapy and fluid retention for patients receiving oral thiazolidinediones for hyperglycemia. Benefits of following the guidelines included the opportunity for optimal management of diabetes involving improved glycemic control as well as appropriate prevention and management of diabetes complications (ADA, 2007b).

Implementation of the Guideline

Implementation of the EBPP occurred with oversight of a collaborating preceptor, Dr. Karen Paczkowski, a practitioner with Physician Health Alliance. The process evolved over an 8-week period and began with an initial face-to-face meeting in which the patient was asked to join the EBPP and participate in follow-up telephone calls at mutually determined times. The proposed algorithm allowed patient coaching for improved blood glucose control. In addition, collaboration with a physician permitted necessary medication adjustments and changes, diagnostic tests, and additional referrals when necessary to assist the patient to improve blood glucose control and self-care by eliminating the knowledge deficit. Initial face-to-face office visits with the APN followed by bi-weekly telephone contact also helped to guide patients in assumption of self-care and improved adherence to the treatment regime. The intervention environment supported personal development by allowing patients to discuss areas of concern or interest and by APN coaching.

Fasting blood glucose (FBG) results were used as the outcome

Figure 3.
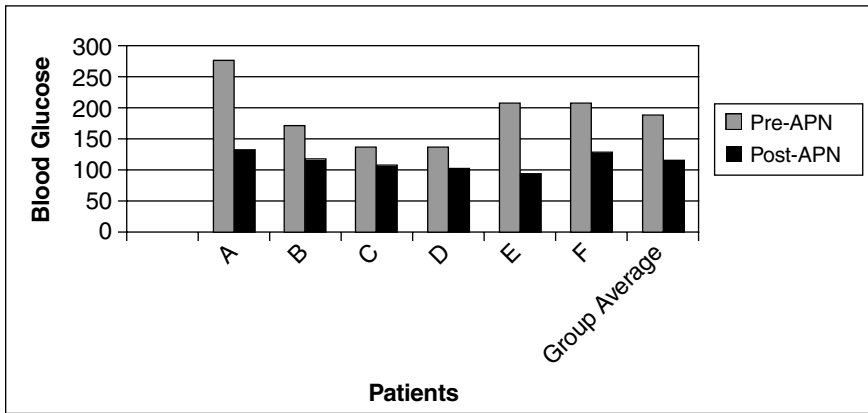## Comparison of Intervention Group Before and After APN Intervention

Figure 4.
Differences of Comparison Group Before and After APN Intervention
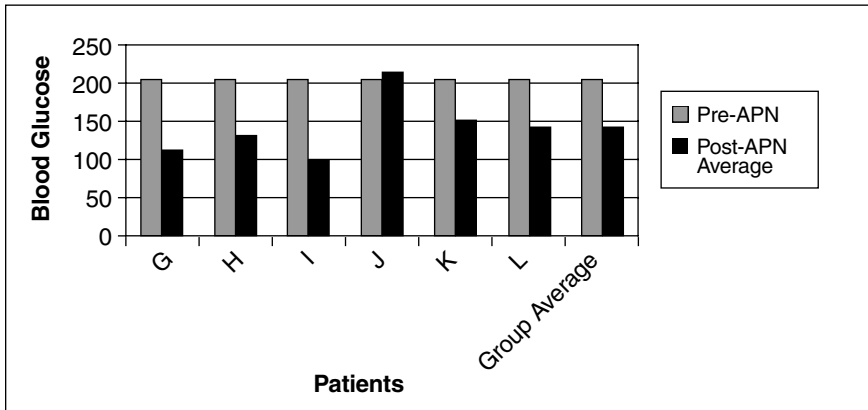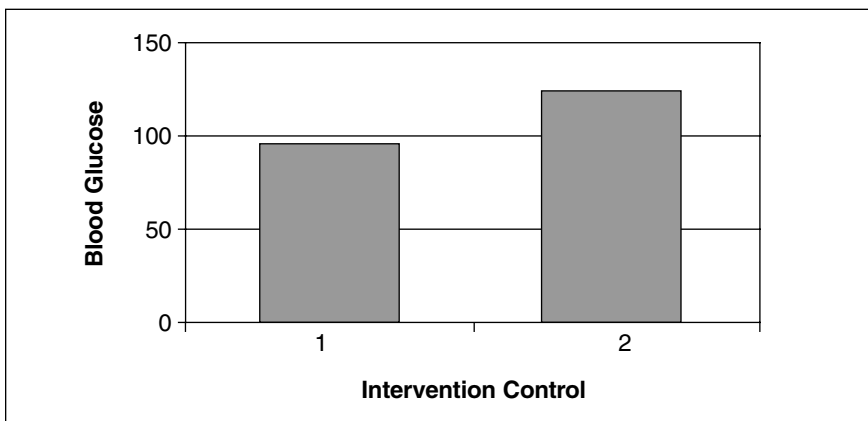

Figure 5.
Differences Between Intervention and Comparison Groups

measure and recorded with each telephone intervention so trends could be tracked and medication changes or adjustments, diagnostic testing, and appropriate referrals made by the collaborating physician when necessary. As shown in Figure 3, a downward trend of FBG occurred in the intervention group. Also, participants in the intervention group received advanced coaching on the latest ADA standards of care by an APN. The comparison group received the ADA standards of care and called or faxed in their FBG results bi-weekly to the collaborating physician's office but received no APN intervention.

Discussion

As displayed in Figure 3, the EBPP showed a significant reduction in FBG results of 72 mg/dL, correlating to 2% decrease in hemoglobin A_{1c} (ADA, 2007b). However, bias might have influenced the results in a nonhomogeneous sample because of convenience sampling and time constraints. The sample of the intervention group was all female, ages 69-79, whereas the comparison group had male and female participants ages 39-87. Baseline hemoglobin A_{1c} was 5.9%-9.5% for the intervention group and 6.9%-8.2% for the comparison group. Also, participant contamination may have occurred during the APN intervention. As shown in Figure 4, participants in the comparison group benefitted from the collaborative efforts of the APN and physician regarding elevated FBG results. They did not receive the bi-weekly follow-up telephone intervention but may have received a medication adjustment or change in treatment regime in order to improve glycemic control. However, the intervention group maintained better glycemic control as compared to the comparison group (see Figure 5).

Limitations

Limitations of the EBPP included time constraints, which did not allow for hemoglobin A_{1c} testing, self-reported FBG data, failure to limit extraneous variables (includ-

ing glucometer malfunction), and a small sample size (six participants in each groups). In addition, one individual in the intervention group required surgery and another required corticosteroid treatment during the EBPP, interventions that may have altered FBS results.

Even with these limitations, the author still finds the results clinically significant. The APN intervention may have been more successful than interventions in reviewed literature (Aubert et al., 1998; Maljanian, Grey, Staff, & Conroy, 2005; Oh, Kim, Yoon, & Choi, 2003; Piette et al., 2000; Wong, Mok, Chan, & Tsang, 2005) due to the educational knowledge and training of APNs.

Conclusion

According to Bourbonniere and Evans (2002), "An APRN demonstrates a high level of expertise in assessing, diagnosing, and treating complex health responses of individuals, groups, and communities. Through the lens of their expert skills, interventions are based on greater depth and breadth of knowledge and a finely honed ability to synthesize physiological, psychological, social, and environmental data" (p. 2062). The EBPP's impact may have been due in part to the APN's holistic view of the patient, who received care consistent with ADA (2007b) recommendations with the addition of the APRN intervention. ∎

References

American Diabetes Association (ADA). (2006). *The estimated prevalence and cost of diabetes in Pennsylvania.* Retrieved from http://www.diabetes archive.net/advocacy-and-legal resources/cost-of-diabetes-results. jsp?state=Pennsylvania&district= 0&DistName=Pennsylvania+%28Entire +State%29

American Diabetes Association (ADA). (2007a). *Diabetes statistics.* Retrieved from http://www.diabetes.org/diabetes-basics/diabetes-statistics/

American Diabetes Association (ADA). (2007b). *Standards of medical care in diabetes-2007.* Retrieved from http://care.diabetesjournals.org/content/30/suppl_1/S4.full

American Diabetes Association (ADA). (2008). *Economic costs of diabetes in the U.S in 2007.* Retrieved from http://care.diabetesjournals.org/content/31/3/596.full.pdf+html

Aubert, R.E., Herman, W.H., Waters, J., Morre, W., Sutton, D., Peterson, B.L., ... Koplan, J.P. (1998). Nurse case management to improve glycemic control in diabetic patients in a health maintenance organization. *Annals of Internal Medicine, 129*(8), 605-612.

Bourbonniere, M., & Evans, L. (2002). Advanced practice nursing in the care of frail older adults. *Journal of American Geriatric Society, 50*(12), 2062-2076.

Centers for Disease Control. (2003). *2003 National diabetes fact sheet.* Retrieved from http://www.cdc.gov/diabetes/pubs/general.htm#what

Maljanian, R., Grey, N., Staff, I., & Conroy, L. (2005). Intensive telephone follow-up to a hospital-based disease management model for patients with diabetes mellitus. *Disease Management, 8*(1), 15-25.

Oh, J.A., Kim, H.S., Yoon, K.H., & Choi, E.S (2003). A telephone-delivered intervention to improve glycemic control in type 2 diabetic patients. *Yonsei Medical Journal, 44*(1), 1-8

Orem, D.E. (1995). *Nursing: Concepts of practice* (5th ed.). St. Louis: Mosby.

Piette, J.D., Weinberger, M., McPhee, S.J., Mah, C.A., Kraemer, F.B., & Crapo, L.M. (2000). Do automated calls with nurse follow-up improve self-care and glycemic control among vulnerable patients with diabetes. *The American Journal of Medicine, 108*(1), 20-27.

The AGREE Collaboration. (2001). *The appraisal of guidelines for research and evaluation (AGREE) instrument.* Retrieved from http://www.agreecollaboration.org/pdf/agreeinstrumentfinal.pdf

The Diabetes Control and Complications Trial Research Group. (1993). The effect of intensive treatment of diabetes on the development and progression of long-term complication in insulin-dependent diabetes mellitus. *The New England Journal of Medicine, 329*(14), 977-986.

UK Prospective Diabetes Study (UKPDS) Group. (1998). Intensive blood-glucose control with sulphonylureas or insulin compared with conventional treatment and risk of complications in patients with type 2 diabetes. *The Lancet, 352*(9131), 837-851.

Wong, F.K., Mok, M.P., Chan, T., & Tsang, M.W. (2005). Nurse follow-up of patients with diabetes: Randomized controlled trial. *Journal of Advanced Nursing, 50*(4), 391-402.

Additional Reading

Sparacino, P. (2005). The clinical nurse specialist. In A.B. Hamric, J.A. Spross, & C.M. Hanson (Eds.), *Advanced practice nursing: An integrative approach* (3rd ed.) (pp. 416-435). St. Louis: Elsevier Saunders.