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VIDEO ABSTRACT

Enhancing Self-Management Skills of Patients With Existing Diabetic Foot Ulcerations

A Quality Improvement Project

Janice Zima ◆ Nalini Jairath

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ABSTRACT

PURPOSE: The purpose of this quality improvement initiative was to determine the impact of a nurse-administered foot care intervention bundle (NA-FCIB) upon self-management knowledge, skills, and outcomes in patients with diabetic foot ulcerations.

PARTICIPANTS AND SETTING: The sample comprised 39 patients being treated for diabetic foot ulceration at a wound care clinic in a tertiary care hospital in Arlington, Virginia. The project was conducted from August 2017 to February 2018.

APPROACH: This quality improvement project used the Johns Hopkins Plan-Do-Study-Act Method supplemented by self-regulation theory for diabetic patient education and evidence in clinical literature. The 12-week-long intervention included one-on-one teaching in the prevention of ulcerations and optimal care of the diabetic foot, blood glucose level tracking logs, patient "teach-back" and skills demonstration, and free foot care tools.

OUTCOMES: From baseline to post-NA-FCIB, the number of participants knowing the reasons for temperature foot protection increased by 92%, those knowing major factors leading to diabetic foot ulceration by 85%, those knowing what to look for in the foot self-exam by 85%, and those able to demonstrate correct foot self-exam by 84%. The number of participants understanding proper footwear increased by 74%, and those identifying ways to avoid/decrease the likelihood of diabetic foot ulcers by 72%. Mean serum hemoglobin A_{1c} ($HgbA_{1c}$) levels decreased from baseline to postintervention (8.27%; SD 2.05% vs 7.46%; SD 1.58%; $P = .002$).

IMPLICATIONS FOR PRACTICE: The NA-FCIB intervention was successfully incorporated into routine clinic care as the standard of care. Our experience suggests that the NA-FCIB may be feasible and effective for use at comparable wound care clinics and may have secondary benefits for $HgbA_{1c}$ regulation.

KEY WORDS: Bundled interventions, Diabetic foot ulcerations, Patient education, Self-management.

INTRODUCTION

Approximately 34 million Americans are living with diabetes mellitus.[1,2] An estimated 15% to 25% of them develop diabetic foot ulcerations (DFUs), with recurrence rates of approximately 40%, 60%, and 65% at 1, 3, and 5 years, respectively.[1,3] Although DFUs typically start with superficial skin breakdown, between 50% and 60% become infected, triggering a cascade of events involving wound necrosis, systemic infection, and gangrene.[1,2,4,5] These events contribute to amputation rates of between 5% and 10%, and 5-year mortality rates as high as 50% in select subpopulations.[6,7] Research suggests that loss of a limb from ulceration exerts a larger effect on health-related quality of life than diabetes-related blindness, end-stage renal disease, and other major complications.[1,8-11]

The pathophysiology of DFU development and recurrence involves an interplay between local and systemic factors. Locally, ulcers arise from injury or repetitive stress that causes skin breakdown and ulcer formation; once healed, protective callus can be reinjured leading to subcutaneous injury and DFU recurrence. Systemic factors include poor glycemic control, motor, sensory, and autonomic neuropathies, and peripheral artery disease.[12-14] Diabetic motor neuropathies contribute to foot remodeling and biomechanical abnormalities increasing the risk of foot injury. Sensory neuropathies lead to sensory loss with lack of awareness of foot injury. Diabetic-related autonomic neuropathies contribute to drier, more friable skin on foot surfaces. Peripheral artery disease contributes to circulatory impairments, greater susceptibility to infection, and slower wound healing. While tighter glycemic control cannot reverse neuropathies or peripheral artery disease, it is associated with micro- and macrovascular improvements, new tissue formation, and a more favorable environment for DFU healing.[1,9]

Given their magnitude and impact, early detection and treatment of incipient DFUs are essential. Sole reliance on clinician assessment and action is insufficient since the potential rapidity of ulcer formation may outpace the recommended 3- to 6-month intervals for hemoglobin A_{1c} ($HgbA_{1c}$) testing and routine patient visits.[15] Clinicians are less likely to manage patients in a timely fashion if the patient fails to detect injuries,[3,5,9,10,16] does not understand the need for prompt action, or experiences difficulty navigating the health care system.[3,17-21]

Janice Zima, DNP, FNP-C, *Wound Healing and Hyperbaric Center, Virginia Hospital Center, Arlington.*

Nalini Jairath, PhD, RN, *The Catholic University of America, Washington, District of Columbia.*

The authors declare no conflicts of interest.

Correspondence: *Janice Zima, DNP, FNP-C, 7912 Foxhound Rd, McLean, VA 22102 (jvolckerzima@gmail.com).*

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In addition, patients may postpone care due to concerns about the cost of treatment.[1,18] Optimizing patient self-assessment and management practices related to diabetic foot health and glycemic control is necessary, most notably in those with an existing history of DFUs.

Literature Review

This evidence-based and theoretical literature review addresses (*a*) effective and feasible patient self-assessment and self-management practices; and (*b*) strategies for clinicians and diabetes educators to support development and maintenance of these practices.

Patient Self-Assessment and Self-Management Practices

Self-assessment and management practices advocated in the literature include periodic and frequent foot examination, implementation of basic foot hygiene procedures, the use of measures to protect feet from injury and infection, and the prompt seeking of clinical care in the event of injury. The effectiveness of these best practices is found in multiple clinical guidelines and best practice documents.[22-26] Supporting research is limited, perhaps because of the simplicity, minimal risk, and inherent plausibility of these interventions, or the challenges created when attempting to measure self-care accomplished in a community-dwelling setting.

Evidence regarding the influence of diabetic foot health through glycemic control is more robust. Systematic reviews, meta-analyses, and multiple randomized clinical trials indicate a positive relationship between frequent glucose monitoring, dietary management, and glycemic control as measured by $HgbA_{1c}$ levels. Poorer glycemic control is associated with greater risk of DFUs.[22-25]

Strategies to Promote Self-Management

Education is the principal strategy to promote glycemic control and patient self-assessment and management.[25,26] Several randomized, control studies indicate that educational interventions promoting patient self-management of diabetes are associated with improved glycemic control.[27-29] Educating patients about diabetic self-management is associated with risk reduction; evidence suggests that ameliorating even a single risk factor may help to prevent ulcerations.[7,26,28,30-32] Randomized controlled trials indicate that the greatest improvement in self-management skills and patient outcomes is associated with one-on-one patient education, addressing both low literacy issues and barriers to self-management.[10,25,28,29,32,33] Further benefits may be derived when an intensive diabetes management team is involved, and an evidence-based treatment algorithm is used. While research suggests benefits of one-on-one education to all patients, some evidence suggests that those with lower literacy benefit to a greater degree than patients with higher literacy.[34] Several quasi-experimental studies have indicated positive relationships between patient empowerment and foot care behaviors following foot care interventions.[35-37]

Patients with a history of DFUs are at a substantially higher risk for recurrence. Their ulcer care is often provided through multiple visits at wound care clinics, including that used in this quality improvement (QI) project. Because our clinic had no standardized educational approach, the purpose of this QI project was to develop, implement, and evaluate a systematic approach to promote self-assessment and management practices for foot health in clinic patients being treated for DFUs. In the absence of existing clinical guidelines or care protocols, an additional purpose was to obtain "proof of concept" such that the intervention approach could be adapted for use with related patient populations.

This QI project addressed the following question: For patients with type 2 diabetes attending a wound care clinic for treatment of at least 1 DFU, what is the effect of implementation of a nurse-administered foot care intervention bundle (NA-FCIB) upon demonstrated foot care self-assessment and self-management skills, reported foot care self-management behavior, ulcer healing characteristics, and HbA_{1c} levels from baseline to intervention midpoint (6 weeks) to postintervention (ie, 12 weeks post-baseline)?

APPROACH

We used the Johns Hopkins P.E.T. Nursing Evidence-Based Practice Model for QI projects.[38] After identifying the problem to be addressed, we reviewed and synthesized pertinent evidence, and used the Plan-Do-Study-Act methodology to implement the P.E.T. model's translational component. The project implementation team included the first author (J.Z.) as the team leader and institutional champion; remaining institutional team members included the clinic medical director, clinic nursing, podiatric and physiotherapy staff, and the diabetes educator. External-based team members included 2 PhD-prepared nurses with expertise in diabetes management, foot care, patient education, and implementation of evidence-based practice interventions. Patient perspective was represented by the inclusion of team members with diabetes.

The project setting was a wound care center affiliated with a 450-bed private, nonprofit, community hospital serving adult patients in the greater Washington, District of Columbia, area. The wound care center has a daily patient caseload of 30 to 40 general wound care patients, and offers multiple treatment options including on-site hyperbaric oxygen treatment. Clinical personnel included 2 physicians, 2 nurse practitioners, several nursing staff, and associated podiatric and physiotherapy staff. The QI project duration was 5 months, with 2 months allotted for patient accrual and 12 weeks for each patient to receive the NA-FCIB. Additional time was allotted for data analysis and report preparation. The project was conducted from August 2017 to February 2018.

Project participants (n = 39;100%) included all clinic patients (except 1 lost to clinical follow-up) with type 2 diabetes being treated in the first author's caseload for existing Wagner grade 1 or 2 DFUs, able to speak, read, and understand the English language, and had telephone access necessary for ancillary teaching and follow-up. Complete data were obtained for all participants (n = 39; 100%). Tables 1 and 2 summarize demographic characteristics and diabetic history. Median age was 67 years (range = 53 years, SD 12.356). Age was bi-modally distributed with most patients either younger than 57 or older than 79 years. The sample was relatively well educated with some high school education at a minimum but lacking recent access to diabetic education (Table 1). The mean body mass index (BMI) of participants was 30.9; SD 6.7 kg/m^2 (obese range), though 21% (n = 8) had a BMI of less than 25%. At project intake, $HgbA_{1c}$ values were positively skewed (median = 7.6%; mean = 8.3%; SD 2.1%; range 8.3%) suggesting varying degrees of glycemic control (Tables 1 and 2).

TABLE 1.
Patient Characteristics at Baseline (n = 39)

Characteristics	n (%)
Gender	
Male	20 (51.3)
Female	19 (48.7)
General education level	
≤8th grade	0 (0.0)
Some HS	4 (10.3)
HS graduate	17 (43.6)
College/technical school	18 (46.2)
Current medication regimen	
Oral medications and GLP-1s	11 (28.2)
Insulin	10 (25.6)
Mixed oral medications and insulin	17 (43.6)
Diet control only	1 (2.6)
Prior attendance at diabetic classes	
Yes	15 (38.5)
No	24 (61.5)
No prior attendance	25 (65.8)
0-4	2 (5.2)
5-9	4 (7.9)
≥10	8 (21.1)

Abbreviation: HS, high school.

This project was completed as part of the team leader's (J.Z.) Doctor of Nursing Practice (DNP) degree requirements. Both the Hospital's Nursing Research Council and the University's Vice Provost for Sponsored Research, Research Compliance, and Technology Transfer designated the project as QI falling outside of the jurisdiction of the respective institutional review boards. Project oversight was provided by the Hospital's Nursing Research Council and J.Z.'s DNP project committee, respectively.

The intervention, the NA-FCIB was developed by the team lead (J.Z.) based on literature review and in consultation with QI team members. Independent review of the NA-FCIB's content, scope, and feasibility was conducted by the Clinic Medical Director and the 2 external PhD-prepared team members. All concerns were addressed resulting in complete agreement regarding suitability for practice. Intervention fidelity was promoted through use of a clear, written intervention protocol for NA-FCIB intervention, use of a single nurse (J.Z.) to administer the intervention, and periodic review with team member(s) to ensure adherence to the intervention protocol.

The NA-FCIB was designed as an educational strategy to promote and empower patients to adopt a set or "bundle" of self-assessment and management behaviors, which support long-term diabetic foot health and glycemic control. Content and strategies were based on existing evidence and validated by the project team members who served as content matter experts. The bundled approach was consistent with recent recommendations that evidence-based practices be organized so that multiple best practices are coordinated and uniformly presented to patients in a consistent manner.[39,40]

The NA-FCIB's approach to empowerment was based on the application of self-regulation theory to diabetic patient education[38] and involved 5 structural elements (identity, cause, timeline, consequences, and treatment effectiveness). These elements related to the patient's individual beliefs, understanding, and expectations regarding their self-management role (ie, illness representation). For this QI project, identity focused on the patient's understanding of what diabetic foot care was and what it entailed. Cause focused on the patient's knowledge of the causes of diabetic foot care problems. Timeline focused on the patient's understanding that self-assessment and management of foot health were permanently required. Consequences and treatment effectiveness focused on the patient's understanding that self-care practices had short- and long-term effects on diabetic foot health and were effective in controlling or minimizing DFU recurrence.[37,41]

Patient education and interventions began at the first visit and were reinforced at each visit (Table 3). Teaching strategies included (1) one-on-one teaching with patients and available partners, (2) hands-on, interactive demonstrations to model desired foot care management (including risks and specific preventative measures), (3) use of the teach-back technique to address health literacy concerns, build patient confidence and competence,[42-44] (4) periodic review and reinforcement of content, and (5) targeted feedback to patients at each time point based on responses to a checklist addressing knowledge and skills. In addition, all patients received a resource package or "goody bag" containing general tools, which support foot care (ie, hand-held mirror, nail clippers, and foot cream); evidence-based written materials addressing diabetes, nutritional management, and diabetic foot health; and a log for tracking blood glucose levels. The Figure summarizes both the NA-FCIB intervention protocol and the outcome measures at specific time points.

These structural elements were then addressed at a minimum of 3 intervention points timed to coincide with routine clinic visits. Each participant communicated with the project director at least 5 times over the course of the project, most with a physical presence. If routine clinical visits were scheduled more than 1 month apart, the intervention was administered via telephone with patient "hands-on" demonstration of their foot care skills performed at the next clinic visit. No

TABLE 2.
Clinical Data (n = 39)

Patient Characteristics	Median	Mean	SD	Range
Age, y	67	67.90	12.356	53
Body mass index, kg/m^2	30.90	30.91	6.715	26.8
Years since diagnosis of diabetes mellitus	14	15.74	8.867	47
Hemoglobin A_{1c}, %	7.6	8.274	2.05	8.3
Michigan Neuropathic Screening Instrument scores	6	6.3	2.3	9

TABLE 3.
Percentage of Patients Scoring Adequate at Baseline and Post-Nurse-Administered Foot Care Intervention Bundle

Checklist Item	Baseline n (%)	Post-NA-FCIB n (%)	Absolute Percentage Improvement	Repeated-Measures ANOVA
Importance of temperature protection/guidelines	0 (0)	36 (92)	92	$F_{(2,37)} = 222$, $P < .001$ Wilks' $\lambda = 0.077$ Partial $\eta^2 = 0.923$
5 factors that may lead to diabetic ulcerations	0 (0)	33 (85)	85	$F_{(2,37)} = 138.0$, $P < .001$ Wilks' $\lambda = 0.118$ Partial $\eta^2 = 0.882$
What to look for during foot self-exam	2 (5)	35 (90)	85	$F_{(2,37)} = 53.6$, $P < .001$ Wilks' $\lambda = 0.256$ Partial $\eta^2 = 0.398$
Demonstration of foot self-exam	1 (3)	34 (87)	84	$F_{(2,37)} = 101.7$, $P < .001$ Wilks' $\lambda = 0.154$ Partial $\eta^2 = 0.846$
Understanding of what is proper footwear	10 (26)	39 (100)	74	$F_{(2,37)} = 53.7$, $P < .001$ Wilks' $\lambda = 0.256$ Partial $\eta^2 = 0.744$
Identification of 5 ways for improved chances/avoidance of diabetic foot ulcerations	2 (5)	30 (77)	72	$F_{(2,37)} = 61.3$, $P < .001$ Wilks' $\lambda = 0.232$ partial $\eta^2 = 0.768$
Issues that may be difficult for diabetics, and how this impacts foot care/healing	2 (5)	28 (72)	67	$F_{(2,37)} = 53.7$, $P < .001$ Wilks' $\lambda = 0.256$ Partial $\eta^2 = 0.744$
Troubleshooting techniques	16 (41)	36 (92)	51	$F_{(2,37)} = 19.5$, $P < .001$ Wilks' $\lambda = 0.487$ Partial $\eta^2 = 0.513$
Identification of 2 ways for diabetics to control blood sugar	23 (59)	37 (95)	36	$F_{(2,37)} = 10.4$, $P < .001$ Wilks' $\lambda = 0.641$ Partial $\eta^2 = 0.359$
Problem-solving, identification of correct true/false questions regarding self-management skills in the prevention of DFU	32 (82)	39 (100)	18	$F_{(1,38)} = 8.31$, $P < .006$ Wilks' $\lambda = 0.821$ Partial $\eta^2 = 0.179$

Abbreviations: ANOVA, analysis of variance; DFU, diabetic foot ulcer; NA-FCIB, nurse-administered foot care intervention bundle.

other adjustments to the intervention approach were made. This approach ensured that patients received the same time and attention as those able to attend all clinic visits within constraints of routine patient care. All participants completed 3 phases of the intervention, at pretest/baseline and at 6 and 12 weeks postintervention, and no missing data points were identified when testing was completed.

In all interactions, emphasis was placed on shared clinician and patient collaboration in disease management. To address the structural elements more concretely (ie, identity, cause, timeline, consequences, and treatment effectiveness), the NA-FCIB used specific patient self-assessment and management content and teaching strategies. Content areas were (1) self-assessment procedures for foot health, (2) ideal foot care behaviors, (3) management of diabetic foot care issues, and (4) prevention and healing of DFUs. Patients were also counseled about prescribed medications such as traditional oral hypoglycemic agents, GLP-1 agonists, and DPP-4 agonists/SGLT2 inhibitors. Finally, we educated patients about administration and adjustment of insulin based on blood glucose testing, diet, exercise, along with strategies to address diabetes management challenges, solve problems, and troubleshoot.

Instruments

Descriptive measures used to characterize the sample were determined at baseline; these measures included patient demographic data and results from the routinely administered Michigan Neuropathy Screening Instrument, which measured the absence or presence of reflexes, vibratory perception, and monofilament testing results. Scores of more than 7 are associated with significant neuropathic symptomatology, with scores of 4 or more indicating confirmed clinical neuropathy[45] (see Table 4).

Outcome measures related to knowledge were evaluated using a checklist as noted in Table 3. These were determined at baseline (ie, pre-NA-FCIB intervention), intervention midpoint (approximately 6 weeks), and post-NA-FCIB (approximately 12 weeks post-baseline) (see the Figure). Outcomes related to patient knowledge and skill were evaluated using a 12-item checklist (inadequate/adequate, with ≥2 correct answers indicating adequacy in understanding/interpretation). The 12 items on the checklist were based on literature review and validation from consultation with expert committee members who supported the implementation of an intensive integrated approach, combining more than one preventative

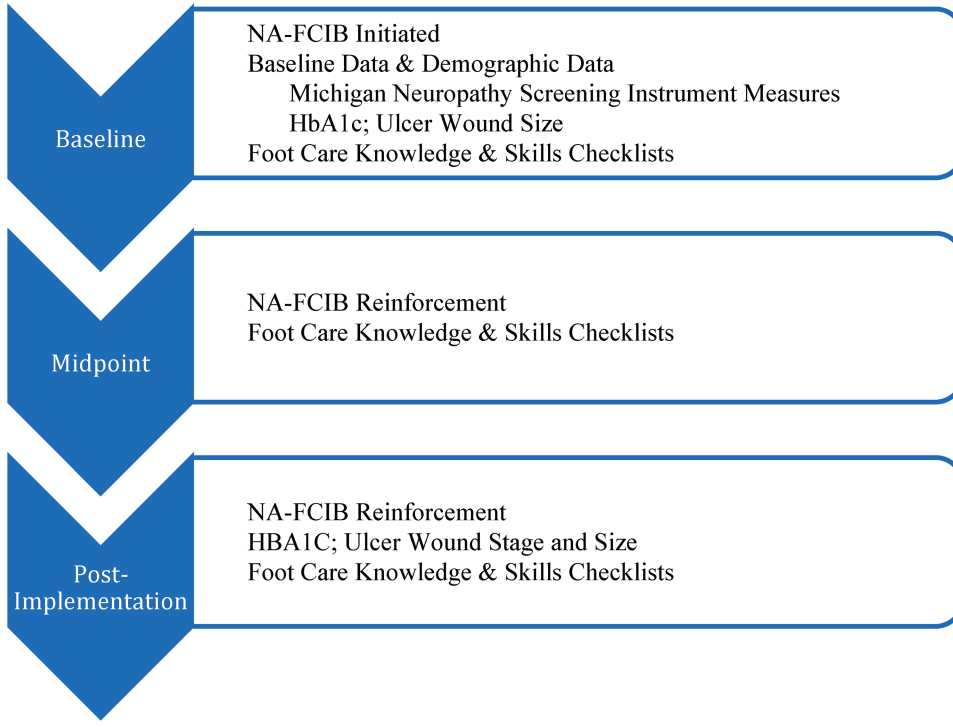

Figure. Timeline for project implementation and data collection.

strategy. This format allowed evaluation of each patient's knowledge about factors affecting glycemic control and development of DFUs, and problem-solving/troubleshooting in response as well as demonstrated ability to perform a foot examination.

Physiological-based outcome measures included $HgbA_{1c}$ and total ulceration area. Consistent with clinical protocols, these were determined at baseline and 3 months (ie, post-NA-FCIB). Serum $HgbA_{1c}$ was directly abstracted from the electronic health record, while total ulceration area was calculated based on recorded information about the size, number of foot ulcerations, and Wagner grade scores.

The process elements associated with introducing the NA-FCIB as a practice change in the wound clinic were documented by the team lead (J.Z.). She also met periodically with members of the team and additional clinic personnel to identify emerging issues with the project, provide progress updates, and seek and address any emerging questions or concerns.

TABLE 4.
Physical Exam Neurological Indicators of Neuropathy

Neuropathic Symptoms	n (%)
1	1 (2.6)
2	0 (0.0)
3	3 (7.9)
4	5 (13.2)
5	7 (18.4)
6	5 (13.2)
7	6 (15.8)
8	6 (15.8)
9	1 (2.6)
10	5 (13.2)

Data Analysis

The null hypotheses (there will be no significant changes in $HgbA_{1c}$ and total ulceration scores from baseline to post-NA-FCIB intervention) were analyzed using paired *t* tests. Changes in checklist item scores were addressed in 2 ways. First, the hypotheses that there would be no significant differences in the interval level raw scores for each checklist category across the 3 time points were analyzed using a 1-way repeated-measures analysis of variance. Second, to facilitate clinical interpretation, the scores for each checklist category were reduced to the ordinal level, with a score for the lowest level denoting an inadequate response, and that for the highest level an adequate response. The proportion of participants achieving an "adequate" on checklist items at baseline and post-intervention was then determined (see Table 3).

Outcomes

Serum $HgbA_{1c}$ levels were significantly lower (8.27%; SD 2.05% vs 7.46%; SD 1.58%; $P = .002$) following NA-FCIB; the average decrease was 0.818% (95% confidence interval [CI] of 0.327-1.31). Total ulceration area scores were significantly lower following the NA-FCIB (6.03; SD 7.68 vs 1.04; SD 2.17; $P = .000$); the average decrease was 4.98 (95% CI of 2.71-7.25). All item checklist scores (except problem-solving scores where the maximum scores were achieved at midpoint) significantly improved ($P = .001$) over the 3 time points (Table 3).

DISCUSSION

This QI project focused upon evaluation of the NA-FCIB's use in patients being treated for DFUs in a wound clinic and the feasibility of the practice change. Our findings and experience with the implementation process support use of the NA-FCIB when treating patients with DFUs in similar clinic settings.

The percentage of patients demonstrating adequate scores for all content areas increased over all categories (Table 3). Though the magnitude of changes varied, they were sufficiently large to suggest clinically meaningful improvements. The greatest improvements pertained to patient knowledge of temperature protection guidelines, how to conduct a foot assessment, ability to accurately perform a foot self-assessment, and articulate contributory factors for DFUs. Project findings regarding the NA-FCIB's effectiveness are congruent with existing evidence that supports simple, habitual, early teaching and reinforcement of proactive, preventative measures that patients can take to address further progression the disease.[16,25,29-33,35,46-48] Project findings also provide support for educational interventions that address patient empowerment and nurse-patient collaboration as important components of care.[49]

Our experience suggests that the use of the NA-FCIB as part of standard nursing care in the wound clinic is feasible, cost-effective for our practice. The intervention and evaluation time frame aligns with the reality of clinical practice, and the intervention can be integrated into the routine work and teaching responsibilities of clinic wound care nurses. We assert that standardization and repetition of teaching content and approaches fostered knowledge retention and skills development. Additionally, the intervention supports the provision of a systematic, comprehensive approach to promoting foot health in a cost-effective manner. As a translational QI project, the experiences and project outcomes provide preliminary "proof of concept" for use in other wound care settings or contexts.

The biggest challenge to project implementation was variable "buy-in" among some team members. This resistance may be attributable to nursing workload and a perception that because the practice change was also part of a DNP project, implementation was primarily the responsibility of the team lead. To counteract these perceptions, interim results were presented with reinforcement of the value of the project and the progress to date during monthly staff meetings.

Staff collaboration on some of the more creative aspects of the project was also emphasized. Messaging to staff emphasized that simple measures and small incremental improvements in the care provided can be effective and clinically relevant. Challenges associated with introduction of the NA-FCIB were successfully overcome and the NA-FCIB is now part of standard care at the wound clinic.

CONCLUSION

The NA-FCIB we implemented, with its emphasis on patient empowerment, nurse-patient collaboration and repeated education, and skills demonstration, proved effective in our clinic. It provides an opportunity to facilitate and reinforce self-care behaviors during required periodic evaluation of patients with diabetes mellitus during primary care or diabetic clinic visits. The NA-FCIB also provided our nurses with a feasible, low-risk intervention approach to help their patients with diabetes to understand their risk for, and the consequences of, foot ulcerations.

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KEY POINTS

- The development of self-assessment and management skills necessary to prevent DFU recurrence and attain/maintain the recommended glycemic control can be integrated into routine clinical nursing care in wound centers.
- The NA-FCIB is a simple and feasible means to implement intervention to improve self-assessment and management skills within a patient empowerment educational framework.
- This evidence-based project provides proof of concept for implementation of the NA-FCIB in wound care clinics and other settings given suitable tailoring to the setting and learner characteristics.

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