Advancing Patient Safety and Access to Concentrated Insulin (U-500 Regular Insulin) in the Veterans Health Administration: A Clinician Education Program in the Primary Care Setting

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IN BRIEF The national epidemic of diabetes and the exposure of Vietnam veterans to Agent Orange has led to insulin resistance requiring concentrated insulin (U-500 regular [U-500R] insulin) for glycemic control. Initiation of U-500R insulin is limited to endocrinology expertise housed at "hub" Veterans Health Administration locations hours away from smaller "spoke" facilities. To overcome potential health care disparities and improve patient safety, a program was developed ensuring that all clinicians could co-manage U-500R insulin. This program evaluation was undertaken to improve patient safety and access to U-500R insulin by improving spoke clinicians' knowledge of safe delivery and management of U-500R insulin.

Problem and Available Knowledge

Limited access to endocrinology specialists leads patients to rely on primary care clinicians for their diabetes care. Primary care clinicians often do not have knowledge about using concentrated insulin (U-500 regular [U-500R] insulin), leading to suboptimal control for insulin-resistant patients.

As patients age and insulin resistance increases, there is a growing need for concentrated insulin regimens. Individuals can often control their diabetes effectively with diet, weight loss, and exercise. When these efforts fail, individuals may need to rely on medications, including oral medications, glucagon-like peptide-1 receptor agonists, and insulin. These standard treatments are effective most of the time. However, a subset of diabetes patients have severe insulin resistance, which presents a challenge to health care providers (1).

Obesity is common, affecting >36.5% of adults in the United States. Obesity is the leading cause of preventable deaths, including heart disease, stroke, type 2 diabetes, and some cancers (2). Medical costs of obese patients are an estimated $1,429 higher annually than costs of nonobese patients. The Veterans Health Administration (VHA) estimated that 78% of veterans are overweight or obese and >165,000 veterans who receive their health care from the VHA have a BMI >40 mg/m^2, indicating morbid obesity (3).

At the VHA, nearly one in four veterans has diabetes (4) due to their older age and significant comorbidities compared to the average American population. More than 70% of patients in VHA facilities are overweight or obese. According to Linda Kissinger, MD, MPH, chief consultant for preventive medicine at the VHA (5), veterans tend to be older, with lower incomes, limited access to quality food, and social disparities; Vietnam veterans have also been exposed to Agent Orange. More than 1 million Vietnam veterans were exposed to the herbicide and defoliant chemical Agent Orange (phenoxyl herbicides: 2,4-dichloro-

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phenoxyacetic acid), which increases their risk of developing diabetes (6).

U-500R insulin is reserved for severely insulin-resistant patients. Primary care providers and other clinicians are relatively unfamiliar with this concentrated insulin formulation (7). Education plays a key role in the use of U-500R insulin for both clinicians and patients to ensure patient safety. A key to improving patient safety with U-500R insulin includes the use of the correct syringe for this insulin. At the time of this program, no U-500R insulin syringe existed, and often U-100R insulin syringes were used, resulting in errors. To avoid potential errors, tuberculin syringes should have been used, and the dose should have been written in units with the corresponding volume written in milliliters (8). Health care professionals should be well educated and vigilant about patient safety issues related to U-500R insulin prescription, dosing, and administration (7). Collaboration between primary care providers and specialists is essential for meeting diabetes goals and protecting patient safety. Disease management should include goals for patient centeredness, safety, and clear communication (9).

When patients need >200 units/day of insulin, they are considered to be severely insulin resistant. According to Reutrakul et al. (1), "U-500 regular insulin (U-500R) is fivefold concentrated, such that each 1 mL contains 500 units of insulin. Therefore, the volume of insulin injected is reduced by 80%, resulting in fewer injections and less discomfort, as well as potentially improved insulin absorption." Concentrated insulins have a significant impact on lowering A1C levels without hypoglycemia (10). The study by Granata et al. (10) is important because it links the epidemic of obesity and diabetes with severe insulin resistance. Severe insulin resistance cannot be overcome with standard insulin regimens.

A study by Eby et al. (11) on the efficacy of U-500R insulin confirmed the expectations that U-500R insulin decreases A1C values, decreases diabetes complications, and has minimal hypoglycemia associated with its use. Researchers at the New Mexico VHA in Albuquerque conducted single-center chart reviews to determine the glycemic effect of converting U-100R insulin to U-500R insulin in veterans from April 2009 to February 2013. A1C values were reviewed before conversion and at least 2 months after conversion, and a significant decrease in values was noted—namely, from 9.4 to 8.7% (10).

Valentine (12) discussed the importance of considering the use of U-500R insulin when U-100R insulin exceeds 200 units/day. Valentine suggested that education is the most crucial aspect of initiating U-500R insulin with patients, but providers are hesitant to use it because of the potential for dosing errors and adverse outcomes. This article also discussed savings of nearly half the cost of U-100R insulin when using U-500R insulin.

The VHA currently relies on an integrated service delivery network to provide care for veterans. This network has been described as a hub and spoke system of care that "is an integrated service delivery network. Tertiary care centers (hub) provide primary and specialty care for veterans. All VHA medical centers without special care (spoke) have responsibility for the provision of basic medical care by designated and trained providers" (13).

In 2009, the VHA initiated electronic consults (e-consults) in the form of chart reviews and recommendations by specialists at the hub medical centers for the spoke medical centers. Researchers at the VHA in Pittsburgh, Pa., conducted a quality improvement project evaluation to assess satisfaction with the e-consult process and perceived facilitators and barriers to the process (14). Telephone interviews were conducted with patients, primary care providers, and specialty clinic providers from December 2009 to August 2010. Results were favorable and veterans and VHA health care providers were satisfied with the e-consult process. The e-consult program through the hub VHA has continued its expansion into many specialty areas, is well accepted, improves access to specialty care, and provides alternative options for rural veterans (Figure 1). The endocrine service is a major participant in e-consult care. The endocrinology providers have not been able to prescribe U-500R insulin to all spoke patients because of the lack of adequate local patient education and clinicians' ability to safely co-manage this therapy.

Computer templates are used throughout the VHA and the private sector to document health care encounters and education provided. According to Swinglehurst et al. (15), such templates can positively contribute to chronic disease management and care delivery. The use of templates can help providers not as familiar with their use to adequately educate patients and co-manage care by eliminating missed assessment and plan elements for patient care.

Primary care providers rely on home telehealth to care for their patients and co-manage them with specialty providers. The VHA initiated home telehealth in 2003 with the purpose of coordinating veterans care related to chronic conditions at home with the goal of avoiding unnecessary admission to long-term care facilities (16). Home telehealth monitors patients' vital signs, blood glucose readings, and chronic conditions at home and electronically sends them for review by the primary care and specialty providers. Primary care providers and specialists use these data to monitor and manage medical conditions. Patients receive home monitoring equipment, and a nurse care manager monitors their readings. These specialty-trained nurses make decisions about when to call the patient to discuss changes or inter-

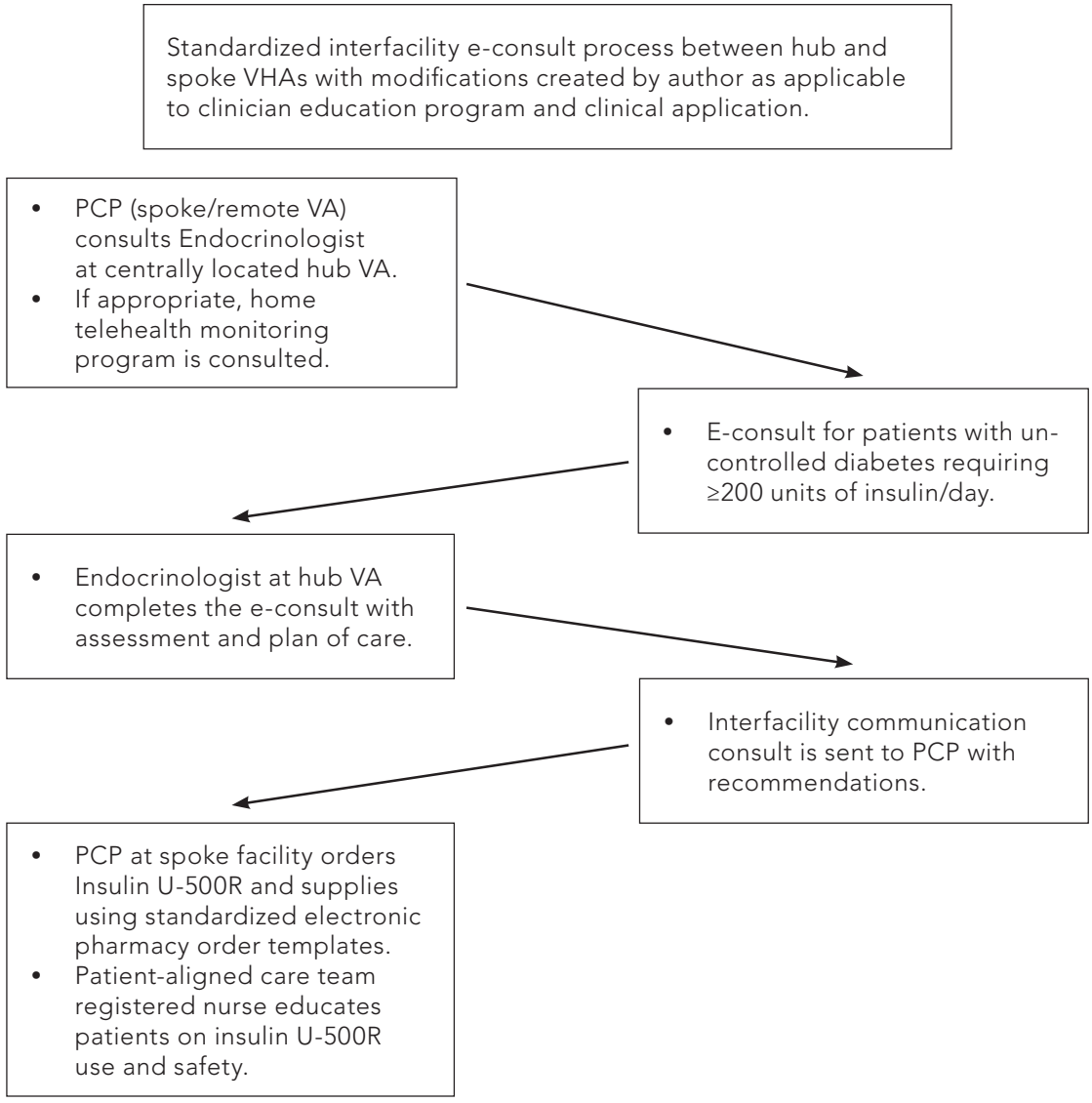

FIGURE 1. Interfacility e-consult flow chart between spoke and hub VHA. PCP, primary care provider.

vene when a problem occurs. In 2009, Darkins et al. (16) analyzed data from >17,000 home telehealth patients between July 2003 and October 2007 and found a 25% reduction in the number of bed-days of care, a 19% reduction in hospital admissions, a satisfaction score of 86% for enrollees, and an average savings of $1,600 per patient. These findings indicated that the home telehealth program is an appropriate and cost-effective way of managing patient care.

Rationale

At the VHA, specialty care is in high demand, but it is housed only at tertiary care medical centers (hubs), leading to veterans' decreased access to specialty care. Smaller medical centers (spokes) and rural community-based outpatient clinics (CBOCs) are often located several hours away from the tertiary care medical centers. Consequently, obtaining endocrine care often involves traveling more than 2 hours. Decreased access to endocrinologists in the VHA can lead to increased diabetes complications and suboptimal diabetes care. An estimated 20% of enrolled veterans at the VHA have diabetes, compared to 8.3% of the general population (17). The VHA has adopted telemedicine to combat this problem, and specialty care can be delivered with video telehealth without patients leaving their home clinic.

Endocrinology is one of the specialties delivered via video telehealth. A need exists for U-500R insulin to combat severe insulin resistance in veterans. Concentrated insulin is only initiated by endocrinologists at the VHA through a live clinic appointment to ensure that expert clinical staff members provide education to the veterans. An educational program to improve knowledge would enable

physicians and nurse practitioners at smaller medical centers and CBOCs to order U-500R insulin and all clinicians (physicians, nurse practitioners, nurses, and pharmacists) to co-manage U-500R insulin with endocrinology.

Intended Improvement

We intended to improve and increase clinicians' competence and knowledge of concentrated insulin, which led to the expanded availability of U-500R insulin to more veterans with diabetes and improved patient safety when using the concentrated insulin. Clinicians need to have expertise in the use of U-500R insulin to educate their patients and answer questions. After implementation of the education program, improved diabetes outcomes were expected, along with enhanced patient safety.

Study Question

Did the educational program provided to clinicians at VHA spokes increase their perceived competence and knowledge of U-500R insulin initiation and co-management with endocrinology specialists?

Methods

Context

The purpose of this program evaluation was to improve patient safety and access to concentrated insulin (U-500R insulin) in the VHA. The goal of the program evaluation was to improve clinicians' perceived competence and knowledge of the safe prescribing and co-management of U-500R insulin. Before this program evaluation, only endocrinologists at the VHA hub initiated concentrated insulin during face-to-face encounters. An educational program to improve perceived competence and knowledge allowed physicians and nurse practitioners at spokes to order U-500R insulin effectively and all clinicians (physicians, nurse practitioners, nurses, and pharmacists) to co-manage U-500R insulin with endocrinology.

A spoke VHA in northwestern Pennsylvania and its CBOCs served as the setting for this study. A convenience sample of clinicians (physicians, nurses, nurse practitioners, and pharmacists) who provided care to veterans with diabetes was used for the study. The physicians and nurse practitioners provided primary care at the spoke VHA or CBOCs. The nurses included were primary care nurses who were part of patient-aligned care teams, home-based primary care nurses, and/or home telehealth nurses. The pharmacists included all members of the pharmacy team at the spoke VHA.

Interventions

We presented an educational program for clinicians (i.e., primary care, home-based primary care, CBOC, pharmacy, and home telehealth) at the spoke VHA and CBOCs. We used a PowerPoint presentation to educate clinicians about the program and about concentrated insulin. The PowerPoint presentation included education about diabetes, U-500R insulin, patient safety alerts, the use of a new order template for U-500R insulin, a patient education template, and the pharmacy process. In addition, we distributed the VHA national patient education handout on U-500R insulin. These resources are available on the VHA Intranet as a reference for enduring educational needs. Clinicians can use the educational program's information as a reference when initiating U-500R insulin.

Measures and Analysis

The research design was a quasi-experimental matched-pairs pre- and posttest design. Participating clinicians completed an anonymous survey that included the Perceived Competence Scale (PCS) (18), a 10-item author-created knowledge quiz based on expert opinion related to the safe use of U-500R insulin, and a demographic information questionnaire. The pre-survey also included informed consent information explaining that completion of the survey was voluntary. The post-survey was identical to the pre-survey, with the deletion of the informed consent document and demographic questions. The PCS included four items to determine clinicians' perceptions of competence when carrying out a treatment regimen or training program. The items were worded slightly differently for targeted behaviors (18). The reliability for the perceived competence items in a combined analysis across four studies was $\alpha = 0.90$ (19). The demographic section and 10-item quiz were developed and pilot-tested for face and content validity with the help of an endocrinologist, two nurse practitioners, one primary care physician, a registered nurse, and a pharmacist.

The participants were given the anonymous pre-survey, including the informed consent, and post-survey, each in one manila envelope, before the educational program. Surveys were assigned arbitrary matching numbers. Participants were asked to complete the pre-survey before the educational program. The pre-surveys were collected before the program by having the participants place them back in the envelope. Any clinician who did not want to complete the survey could turn the survey in blank or not turn it in at all. Once the educational program was completed, participants were asked to complete the post-survey, which was collected in the same manner. Participants' consent to participate in the study was indicated by their completion of the surveys. Exclusionary criteria were blank, unmatched, or incomplete surveys.

Ethical Considerations

Ethical considerations included the anonymity of participants and full disclosure of the program evaluation. Participation was voluntary without coercion, and no patients were included in the study. There were no foreseen risks to the study partici-

TABLE 1. Descriptive Statistics: Concentrated Insulin PCSs and Knowledge Scales (Pretest and Posttest) (n = 55)

	M	SD	Minimum	Maximum	$Z_{skewness}$	α
PCS (Pretest)	4.06	1.49	1.00	7.00	–0.38	0.91
PCS (Posttest)	6.11	0.59	4.75	7.00	–1.83	0.91
Knowledge Scale (Pretest)	67.27	16.15	20.00	100.00	–2.62	NA
Knowledge Scale (Posttest)	94.00	7.35	70.00	100.00	–3.39	NA

NA, not applicable.

pants. This program helped overcome health care disparities caused by decreased access to specialty care.

The institutional review board at Edinboro University of Pennsylvania evaluated this study and approved it as exempt before implementation. The chief of staff at the spoke VHA in northwestern Pennsylvania approved the proposed educational program, and no institutional review board approval was required.

Results

Study Participants

The study participants were 55 predominantly female (n = 42, 76.4%) clinicians. The mean age of participants was 48.98 years (SD 10.20, range 24–72). Almost one-third (n = 18, 32.7%) of participants had bachelor's degrees, while one-fifth of participants had doctorate degrees. Ten (18.2%) participants each had associate's and master's degrees, while six (10.9%) were diploma nurses. The majority of study participants (n = 35, 63.6%) were registered nurses; nine (16.4%) were pharmacists, six (10.9%) were physicians, and five (9.1%) were nurse practitioners. More than one-third (n = 19, 34.5%) of participants had 26 or more years of experience, while one-fifth (n = 11, 20.0%) of participants had between 21 and 25 years of experience.

Variables

The study scales measured pre- to postintervention differences in concentrated insulin, perceived competence, and knowledge among clinicians. Descriptive statistics for these scales are presented in Table 1. The four-item Likert-type scaled PCS was used to measure perceived competence before and after the concentrated insulin education training. The PCS pretest and posttest scale were analyzed for inter-item reliability through the computation of Cronbach's α using the respective PCS items. Cronbach's α values for the PCS at both pretest and posttest were excellent (e.g., α = 0.91).

The PCS items were summed to create the composite PCS. To determine if the pretest and posttest PCS displayed normality, the Z score for skewness ($Z_{skewness}$) values were computed by dividing the scale skewness value by its standard error; a scale that has a $Z_{skewness}$ value that is less than ±1.96 is considered to have a normal distribution of scores (20). Kolmogorov-Smirnov (K-S) χ^2 tests were then conducted; a nonsignificant K-S χ^2 indicates that the scale displays normality (20). The PCSs at pretest and posttest had $Z_{skewness}$ values of –0.38 and –1.83, respectively, indicating a lack of skewness. These findings were supported by nonsignificant K-S χ^2 for the PCS pretest (K-S χ^2 = 0.119, P = 0.060) and the PCS posttest (K-S χ^2 = 0.118, P = 0.068). The mean PCS pretest score was 4.06 (SD 1.49), and scores ranged from 1.00 to 7.00. The mean posttest PCS score was 6.11 (SD 0.59); the range of scores was truncated at posttest, ranging from 4.75 to 7.00.

An educational evaluation tool, the 10-item knowledge scale, was used to assess knowledge of topics regarding concentrated insulin. The knowledge scale used a true/false scoring scale. Composite pretest and posttest knowledge scales were computed by assigning "true" a value of 1 and "false" a value of 0 and summing the 10 items; as such, the scale scoring could range from 0 to 100%. Because of the true/false coding of the knowledge scale, Cronbach's α values were not applicable to this scale (20). The knowledge scale, at both pretest and posttest, displayed substantial non-normality, as indicated by $Z_{skewness}$ values that were higher than ±1.96 (Table 1); non-normality was further confirmed by significant K-S χ^2 results for the pretest knowledge scale (K-S χ^2 = 0.149, P = 0.026) and the posttest knowledge scale (K-S χ^2 = 0.320, P = 0.004). The scales were examined for outliers, and none were found; therefore, the knowledge scale could not be adjusted for skewness. Because of the violation of the normality assumption, the pretest and posttest knowledge scales were treated as ordinal variables in analyses for hypothesis testing (20). The mean knowledge scale score at pretest was 67.27 (SD 16.15); this score can be interpreted as a "D" grade. Pretest knowledge scale scores ranged from 20% (F) to 100% (A+). At posttest, the mean knowledge scale score was 94.00 (SD 7.35), which is equivalent to an "A" grade. Posttest knowledge scale scores ranged from 70% (C) to 100% (A+).

Covariate Testing

We conducted a series of analyses to determine if participants' demographic and work variables were significantly associated with the dependent variables of perceived competence (posttest) and knowledge (posttest). Specifically, potential sex differences regarding perceived competence and

knowledge were examined through independent sample *t* tests; profession, years of experience, and degree differences regarding perceived competence and knowledge were examined through one-way analysis of variance (ANOVA); and the relationship between age and perceived competence was assessed through Pearson bivariate correlations. Results from these analyses revealed only one significant finding. The one-way ANOVA showed that significant differences regarding perceived competence of concentrated insulin existed across professions [$F(2,52) = 3.80$, $P = 0.029$] (Table 2). A Tukey post hoc test showed that nurse practitioners/physicians ($n = 11$) reported significantly higher levels of perceived competence ($M = 6.16$, SD 0.72) than pharmacists ($n = 9$, $M = 5.83$, SD 0.84). The mean scores of nurse practitioners/physicians and pharmacists were not significantly higher or lower, respectively, than the mean scores reported by registered nurses ($n = 35$, $M = 6.16$, SD 0.72).

Because of the significant difference between nurse practitioners/physicians and pharmacists with regard to posttest perceived competence mean scores, profession was included as a covariate for analyses for hypothesis testing for the PCS. No significant results were found for the posttest knowledge test; as such, no covariates needed to be included in hypothesis testing for the perceived knowledge scales.

Hypothesis Testing

To determine if perceived competence regarding concentrated insulin increased from pre- to postintervention, a between-within analysis of covariance (ANCOVA) was conducted, controlling for profession. A between-within ANCOVA is used to examine between-group differences (in this case, profession) as well as within-group differences (in this case, pre- to postintervention perceived competence). Results from the between-within ANCOVA documented significant pre- to postintervention differences on perceived competence [$F(2,52) = 77.42$, $P < 0.001$, partial $Eta^2 = 0.598$], showing a very large effect size. Perceived competence scores significantly increased from pretest ($M = 4.06$, SD 1.49) to posttest ($M = 6.21$, SD 0.74). The mean perceived competence score at posttest was 3 SDs higher than the mean perceived competence pretest score. There was not a significant between-group difference with regard to profession and perceived competence [$F(2,52) = 1.73$, $P = 0.187$, partial $Eta^2 = 0.062$].

A Wilcoxon signed rank *Z* test, the nonparametric equivalent to a paired-sample *t* test (20), was conducted to determine whether concentrated insulin knowledge scores increased pre- to postintervention. A Wilcoxon signed rank *Z* test was conducted as the knowledge scores were substantially skewed, which required the use of a nonparametric statistic (20). Significant pre- to posttest increases emerged in knowledge regarding concentrated insulin (Wilcoxon $Z = -6.28$, $P < 0.001$). Knowledge scale scores increased from 67.27 (equivalent to a "D") at pretest to 94.00 (equivalent to an "A") at posttest. As with the PCS, the mean knowledge posttest scale score was more than 3 SDs higher than the mean pretest knowledge scale score.

TABLE 2. One-Way ANOVA: Concentrated Insulin Perceived Competence Differences Across Profession

	n	*M*	SD	*F*	df	*P*
Profession				**3.80**	**2,52**	**0.029**
Registered nurse	35	6.16	0.72			
Nurse practitioner/physician	11	6.68*	0.50			
Pharmacist	9	5.83*	0.84			

**Significant differences between nurse practitioners/physicians and pharmacists.*

Discussion

The national epidemic of diabetes ,fueled by obesity as well as aging Vietnam veterans' exposure to Agent Orange, has led to a greater number of veterans requiring >200 units/day of insulin. This situation has created the need for U-500R insulin and other complex medication regimens to help veterans achieve glycemic goals. Endocrinology support is crucial to meet this need; however, such services are housed in hub VHAs that are often located several hours away from local service providers. To overcome the potential health care disparities and improve patient safety in treatment for spoke veterans, a program was introduced to a spoke VHA in northwestern Pennsylvania.

Interpretation

Our program included clinician education, the introduction of a new ordering process for U-500R insulin, and an electronic template to consistently educate veterans. The results were significantly favorable, with clinicians reporting increased perceived competence and demonstrating improved knowledge of U-500R insulin management. This program enhanced the availability and patient safety in the use of U-500R insulin and can be used as a model for other VHAs nationally, as well as institutions that use unified electronic medical record systems for care delivery. Although developed for U-500R insulin, the program could be adapted to ensure the safe use of other high-risk specialty medications. Increases in resource utilization or opportunity costs did not occur.

Limitations

The VHA has its own communication network between spoke and hub VHAs. This program would be easily generalizable to VHA facilities nationally. To implement such a program in

the private sector, several components would be needed—namely, robust electronic medical record software that communicates across the health care system, the availability of specialists who are willing to work closely with primary care clinicians, primary care clinicians who are willing to take on this responsibility, and possible changes to fee-for-service billing.

All spoke VHA clinicians might not have as large an effect in perceived competence and knowledge scores pre- and posttest depending on the clinicians' life experiences and educational background before the evaluation. The spoke VHA sample in the current study did not include any certified diabetes educators or clinicians with endocrine specialty experience.

Since completion of this study, patient safety with U-500R insulin has been enhanced with the introduction of a prefilled U-500R KwikPen and a U-500R–specific syringe. The prefilled U-500R KwikPen and syringe will likely improve clinicians' confidence when prescribing the U-500R insulin recommended by the endocrinology specialist.

Conclusion

This program offered the patient-aligned care team enhanced knowledge and endocrinology support needed to deliver safe and complex diabetes care to veterans, removing the barrier of long-distance travel. To our knowledge, this is the first time a program was delivered to a VHA facility to improve the local provision of high-risk specialty medication and management, including clinical education as well as an electronic medical record process with decision support.

This program was the first step in improving the local management of complex diabetes patients. In the long run, it remains to be seen if patients' diabetes measures improve with local support. We hope this program and those like it will improve the collaboration between specialty and primary care to promote best practices and enhance patient safety. Further evaluation of the program should be undertaken to evaluate its use and effects in terms of diabetes control and clinical outcomes of patients who meet the criteria for U-500R insulin.

Duality of Interest

No potential conflicts of interest relevant to this article were reported.

Author Contributions

S.J.L.-M. researched data, contributed to discussion, and wrote, reviewed, and edited the manuscript. A.B. and M.L. contributed to the discussion, assisted in writing, and reviewed and edited the manuscript. S.J.L.-M. is the guarantor of this work and, as such, had full access to all the data in the study and takes full responsibility for the integrity of the data and the accuracy of the data analysis.

Prior Presentation

An abstract for this study was selected for poster presentation at the American Diabetes Association's 77th Scientific Sessions, 9–13 June 2017, San Diego, Calif.

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