ADVANCING PATIENT SAFETY AND ACCESS TO CONCENTRATED INSULIN (U-500R INSULIN) IN THE VETERANS HEALTH ADMINISTRATION (VHA): A CLINICIAN EDUCATION PROGRAM IN THE PRIMARY CARE SETTING

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A DNP Research Project Submitted to Clarion and Edinboro Universities
In Partial Fulfillment of the Requirements for the Doctor of Nursing Practice Degree
March, 2017

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Abstract

The national epidemic of diabetes and the exposure of Vietnam veterans to Agent Orange has led to insulin resistance requiring concentrated insulin (U-500R) for glycemic control. Initiation of U-500R insulin is limited to endocrinology expertise housed at 'hub' Veterans Health Administration's (VHA's) located hours away from smaller 'spoke' facilities. To overcome the 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. We created an order template for U-500R insulin, a patient education template, and pharmacy processes to ensure that all clinicians are able to co-manage U-500R insulin. A convenience sample of clinicians at a 'spoke' VHA in northwestern Pennsylvania was evaluated. Clinicians completed an anonymous survey including: Informed consent, Perceived Competence Scale (PCS), 10-item knowledge scale (KS), and a demographics questionnaire. The post-survey included the PCS and KS.

Results from the between-within ANCOVA testing documented significant pre- to post-intervention differences on perceived competence, $F(2,52)=77.42$, $p < .001$, partial $eta^2=.598$, indicating a very large effect size. Perceived competence scores significantly increased from the pretest (M=4.06, SD=1.49) to the posttest (M=6.21, SD=0.74). A Wilcoxon Signed Ranked Z Test was used to evaluate Knowledge Scores (KS). Pretest KS scores ranged from 20% (F) to

100% (A+). At posttest, the mean KS scale score was 94.00 (SD=7.35), equivalent to an “A” grade. Post-test KS scores ranged from 70% (C) to 100% (A+). In conclusion, our program enhanced health care process and increased provider knowledge and confidence of delivery and management of U-500R insulin for veterans.

Advancing Patient Safety and Access to Concentrated Insulin (U-500R Insulin) in the Veterans Health Administration (VHA): A clinician educational program in the Primary Care Setting

Introduction

This Doctoral Project was undertaken using the Squire 2.0 Guidelines. The guidelines provide framework for reporting information to improve healthcare.

Problem Description

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

Available Knowledge

As patients age and insulin resistance increases, there is a growing need for concentrated insulin (U-500R 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 and insulin. These standard treatments are effective most of the time. However, a subset of diabetic patients has severe insulin resistance, which presents a challenge to healthcare providers (Reutrakul, Wroblewski, & Brown, 2012).

According to the Centers for Disease Control (CDC, 2016), obesity is very common, affecting more than 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. Medical costs of obese patients are an estimated $1,429 higher than those of non-obese patients. The Veterans Health Administration (VHA) estimated that 78% of veterans are overweight or obese

and more than 165,000 veterans who receive their healthcare from the VHA have a body mass index (BMI) of greater than 40, indicating morbid obesity (U.S. Department of Veterans Affairs, 2016c).

At the VHA, nearly 25% of veterans are diabetics (U.S. Department of Veterans Affairs, 2015a) due to their older age and significant co-morbidities compared to the average American population. More than 70% of patients in the VHA facilities are overweight or obese. According to Linda Kissinger, MD, MPH, chief consultant for preventive medicine at the VHA (as cited in Wahowiak, 2014), 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 one million Vietnam veterans were exposed to the herbicide and defoliant chemical Agent Orange (phenoxyl herbicides: 2, 4-dichlorophenoxyacetic acid), which increases their risk of developing diabetes (The Aspen Institute, 2010).

U-500R insulin is reserved for severely insulin-resistant patients. Primary care providers (PCPs) and other clinicians are relatively unfamiliar with this concentrated insulin formulation (Segal, Brunner, Burch, & Jackson, 2010). 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. No U-500R insulin syringe exists, and often U-100R insulin syringes are used, resulting in errors. To avoid potential errors, tuberculin syringes should be used, and the dose should be written in units and the corresponding volume written in milliliters (U.S. Pharmacist, 2010). Healthcare professionals should be well educated and vigilant about patient safety issues related to U-500R insulin prescription, dosing, and administration (Segal et al., 2010). Collaboration between primary care providers and specialists is essential for meeting diabetic goals and protecting patient safety.

Disease management should include goals for patient centeredness, safety, and clear communication (Aye & Atkin, 2014).

When patients need more than 200 units of insulin a day, they are considered to be severely insulin resistant.

> U-500 regular insulin (U-500R) is five-fold 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. (Reutrakul et al., 2012, p. 413)

Concentrated insulins have a significant impact on lowering HgA1c levels without hypoglycemia (Granata, Nawarskas, Resch, & Vigil, 2015). Grenata et al.'s (2015) study is important as it links the epidemic of obesity and diabetes with severe insulin resistance. Severe insulin resistance cannot be overcome with standard insulin regimens.

Eby et al.'s (2015) study on the efficacy of U-500R insulin confirmed the expectations that U-500R insulin decreases HgA1c values, decreases diabetic 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 until February 2013. HgA1c's were reviewed pre-conversion and at least 2 months after conversion, and a significant decrease in values was noted—namely, from 9.4% to 8.7% (Granata et al., 2015).

Valentine (2012) discussed the importance of considering the use of U-500R insulin when U-100R insulin exceeds 200 units per day. Valentine suggested that education is the most crucial aspect of initiating U-500R insulin with patients, but providers are hesitant to use it due to the potential for dosing errors and adverse outcomes. The study also discussed cost savings of

nearly half when using U-500R insulin.

The VHA currently relies on an integrated service delivery network to provide care for veterans:

> The VHA's Hub and Spoke System of Care 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. (Department of Veterans Health, 2011, p. 7)

In 2009, the VHA initiated electronic consults (e-consults) in the form of chart reviews and recommendations by the specialists at the hub medical centers for the spoke medical centers. Researchers at the VHA in Pittsburgh, Pennsylvania, conducted a quality improvement project evaluation to assess satisfaction with the e-consults process and perceived facilitators and barriers to the process (Rodriguez et al., 2015). Telephone interviews were conducted with patients, primary care providers, and specialty clinic providers from December 2009 through August 2010. Results were favorable, concluding that veterans and the VHA healthcare 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 (see Figure 1). The endocrine service is a major participant in e-consult care; however, it has 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.

Computer templates are used throughout the VHA and the private sector to document healthcare encounters and education provided. According to Swinglehurst, Greenhalgh, and

Roberts (2012), 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.

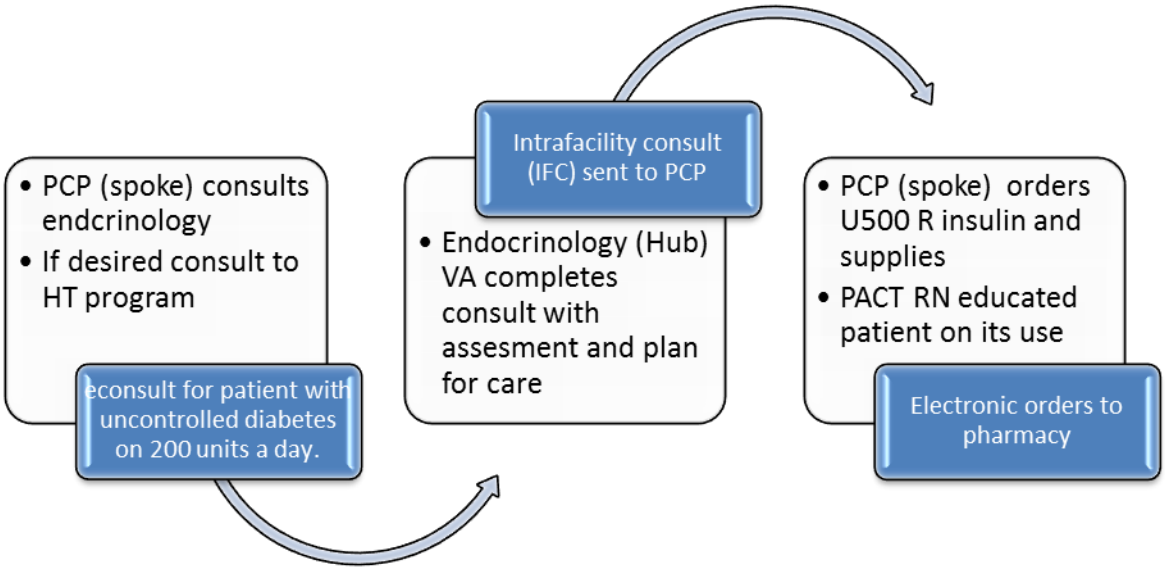

Figure 1: Intrafacility e-consult process between hub and spoke VHAs created by author

Primary care providers rely on home telehealth (HT) to care for their patients and co-manage them with specialty providers. The VHA initiated HT in 2003 with the purpose of coordinating veterans care at home related to chronic conditions with the goal of avoiding unnecessary admission to long-term care facilities (Darkins et al., 2009). HT 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 this 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 intervene when a problem occurs. In 2009, Darkins et al. analyzed data from more than 17,000 HT patients between July 2003 and October 2007 and found a 25% reduction in the number of bed days of care, 19% reduction in hospital admissions, satisfaction score or 86% for enrollees, and an average savings of $1,600 per patient. These findings indicated that the HT 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 travelling more than two hours. Decreased access to endocrinologists in the VHA can lead to increased diabetic complications and suboptimal diabetic care (see Figure 2). An estimated 20% of enrolled veterans at the VHA are diabetics, compared to 8.3% of the general population (U.S. Department of Veterans Affairs, 2014). The VHA has adopted tele-medicine 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 provides education to the veterans. An educational program to improve knowledge will 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.

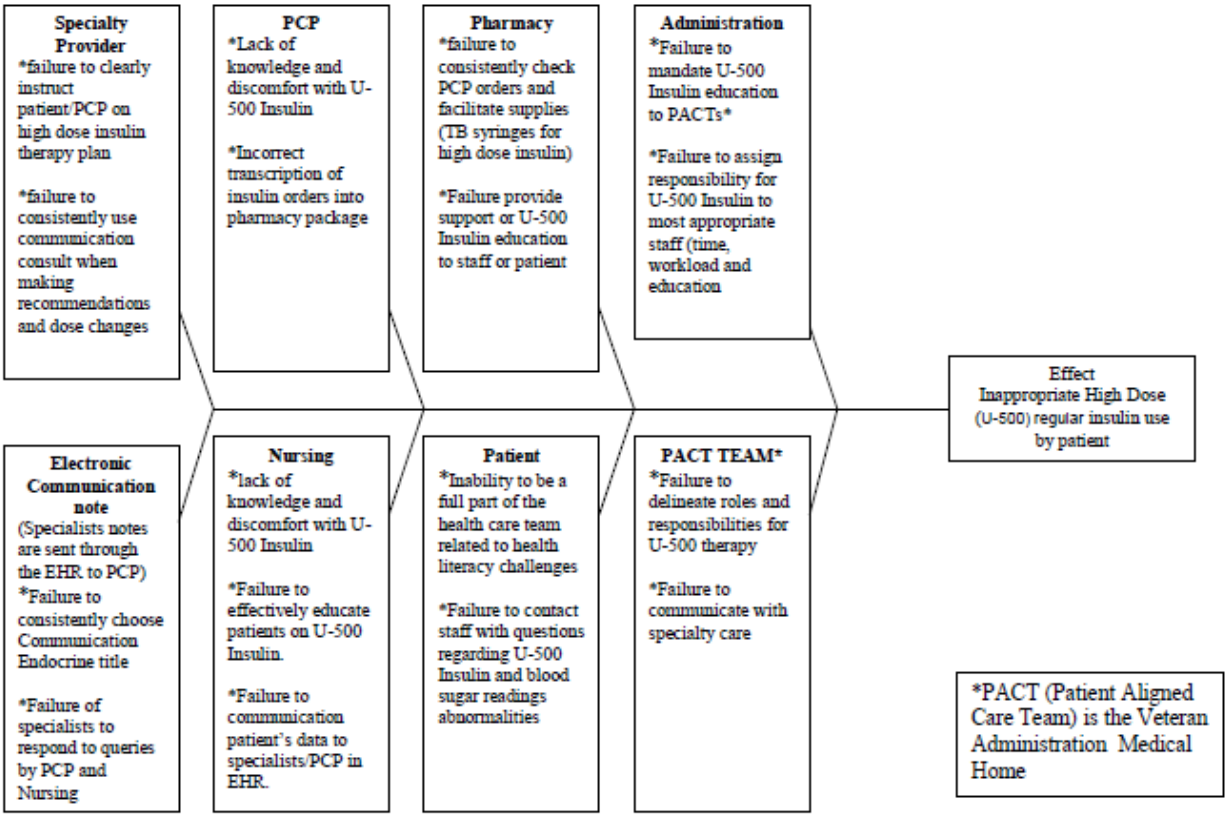

Figure 2: Root cause analysis of errors in concentrated insulin dosing analysis. Diagram constructed by author to support the need for the program evaluation.

Intended Improvement

Our intended improvement was clinicians' increased competence and knowledge of concentrated insulin, which has led to the expanded availability of U-500R insulin to more diabetic veterans and improved patient safety when using the concentrated insulin. Clinicians need to have expertise in the use of U-500R insulin in order to educate their patients and answer questions. After implementation of the education program, improved diabetic outcomes and enhanced patient safety were expected.

Study Question

Did the educational program provided to clinicians at the 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. Prior to this program evaluation, only endocrinologists at the VHA hub initiate 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 diabetic veterans was used for the study. The physicians and nurse practitioners practiced primary care at the spoke VHA or CBOCs. The nurses included were primary care nurses who were part of patient-aligned care teams (PACTs), home-based primary care nurses (HBPC), and/or home telehealth (HT) 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, HBPC, CBOC,

pharmacy, home telehealth) at the spoke VHA and CBOCs. We used a PowerPoint presentation to educate clinicians about the program and concentrated insulin (see Appendix A). The PowerPoint presentation included education about the diabetes and 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 are able to utilize the educational program's information as a reference when initiating U-500R insulin.

Measures/Analysis

The research design was a quasi-experimental matched pairs pretest–posttest design. Participating clinicians completed an anonymous survey that included the Perceived Competence Scale (PCS) (Self-Determination Theory, 2015), 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 (see Appendix B). The pre-survey also included informed consent information explaining that completion of the survey is voluntary. The post-survey was identical to the pre-survey, with the deletion of the informed consent document and demographic questions (see Appendix C). 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 (Self-Determination Theory, 2015). The reliability for the perceived competence items in a combined analysis across four studies was $\alpha = 0.90$ (Ryan, Patrick, Deci, & Williams, 2008). 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 prior to the educational program. The pre-surveys were collected prior to 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 include the anonymity of participants and full disclosure of the program evaluation. Participation was voluntary without coercion, and no patients are included in the study. There were no foreseen risks to the study participants. This program helped overcome healthcare disparities caused by decreased access to specialty care.

The Internal Review Board (IRB) at Edinboro University of Pennsylvania evaluated this study and determined it to be exempt prior to its implementation. The chief of staff at the spoke VHA in northwestern Pennsylvania approved the proposed educational program, and no IRB approval was required.

Results

Purpose of Study

The purpose of this program evaluation was to improve patient safety and access to concentrated insulin (U-500R insulin) in the VHA. An educational program to improve perceived competence and knowledge was initiated at a spoke VHA to determine if clinicians

perceived competence and knowledge of U-500R insulin increased as a result of their participation. The purpose of this chapter is to present findings from analyses. The first section provides information on the study participants; the second section provides information on the study variables. The third section reviews the testing of covariates. The fourth section reviews of the statistical findings for hypothesis testing.

Descriptive Statistics: Study Participants

The study participants were 55 predominantly female (*n* = 42, 76.4%) clinicians. Table 1 summarizes the descriptive information on study participants. The mean age of participants was 48.98 years (*SD* = 10.20), with ages ranging from 24 to 72 years of age. Almost a third (*n* = 18, 32.7%) of participants had bachelor's degrees, while a 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 a third (*n* = 19, 34.5%) of participants had 26 or more years of experience while a fifth (*n* = 11, 20.0%) of participants had between 21 and 25 years of experience. Table 1 presents additional information on years of experience.

Table 1

Descriptive Statistics: Study participants (n = 55)

	Frequency	*Percentage*
Gender		
Male	13	23.6
Female	42	76.4
Educational Degree		
Diploma Nurse	6	10.9
RN Associate's Degree	10	18.2
Bachelor's Degree (Nurse/Pharmacist)	18	32.7
Master's Degree (Nurse)	10	18.2
Doctoral Degree (Nurse/Physician/Pharmacist)	11	20.0
Profession[a]		
Registered Nurse	35	63.6
Nurse Practitioner	5	9.1
Physician	6	10.9
Pharmacist (Registered Pharmacist or Doctoral Pharmacist)	9	16.4
Years of Experience[b]		
0–5 years	4	7.3
6–10 years	7	12.7
11–15 years	4	7.3
16–20 years	10	18.2
21–25 years	11	20.0
26 or more years	19	34.5

	M	*SD*	*Minimum*	*Maximum*
Age	48.98	10.20	24.00	72.00

Note. [a] For covariate analyses, profession was recoded from a 4-category to a 3-category variable, with nurse practitioners and physicians group together (n = 11), registered nurses (n = 35), and pharmacists (n = 9). [b] For covariate analyses, years of experience were recoded from a 6-category to a 3-category: 0–15 years (n = 15), 21–25 years (n = 11), and 26 or more years (n = 19).

Descriptive Statistics: Study Variables

The study scales measured pre- to post-intervention differences in concentrated insulin, perceived competence, and knowledge among clinicians. Descriptive statistics for these scales are presented in Table 2. The 4-item Likert-type scaled Perceived Competence Scale (PCS) was used to measure perceived competence prior to 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 alphas using the respective PCS items. The Cronbach alphas for the PCS at both pretest and posttest were excellent (i.e., α =.91).

The PCS items were summed to create the composite PCS scale. To determine if the pretest and posttest PCS scales 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 (Ramsey & Schafer, 2012). Kolmogorov-Smirnov (K-S) chi-square (χ^2) tests were then conducted; a non-significant K-S χ^2 indicates that the scale displays normality (Ramsey & Schafer, 2012). The PCS scales 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 non-significant K-S chi-squares for the PCS pretest scale, K-S χ^2 = .119, p = .060, and the PCS posttest scale, K-S χ^2 = .118, p = .068. The mean PCS pretest scale score was 4.06 (*SD* = 1.49), and scores ranged from 1.00 to 7.00. The mean posttest PCS scale 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 (KS), was used to assess knowledge of topics regarding concentrated insulin. The KS utilized a true/false scoring scale. Composite pretest and posttest KSs 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%. Due to the true/false coding of the KS, Cronbach's alphas were not applicable to this scale (Ramsey & Schafer, 2012). The KS, at both pretest and posttest, displayed substantial non-normality as indicated by $Z_{skewness}$ values that were higher than +/-1.96 (see Table 2); non-normality was further confirmed by significant K-S chi-square results for the pretest KS, K-S χ^2 = .149, p = .026, and the posttest KS, K-S χ^2 = .320, p = .004. The scales were examined for outliers, and none were found; therefore, the KS could not be adjusted for skewness. Due to the violation of the normality assumption, the pretest and posttest KSs were treated as ordinal variables in analyses for hypothesis testing (Ramsey & Schafer, 2012). The mean KS score at pretest was 67.27 (*SD* = 16.15); this score can be interpreted as a "D" grade. Pretest KS scores ranged from 20% (F) to 100% (A+). At posttest, the mean KS 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+).

Table 2

Descriptive Statistics: Concentrated insulin perceived competence and knowledge scales (pretest and posttest) (N = 55)

	M	*SD*	*Min*	*Max*	$Z_{skewness}$	*Alpha*
Perceived Competence Scale (Pretest)	4.06	1.49	1.00	7.00	-0.38	.91
Perceived Competence Scale (Posttest)	6.11	0.59	4.75	7.00	-1.83	.91
Knowledge Scale (Pretest)	67.27	16.15	20.00	100.00	-2.62	N/A
Knowledge Scale (Posttest)	94.00	7.35	70.00	100.00	-3.39	N/A

Testing of Covariates

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 gender 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 ANOVAs; 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, $F(2,52) = 3.80$, $p = .029$ (see Table 3). A Tukey *post hoc* test showed that nurse practitioners/physicians ($n = 11$) reported significantly higher levels of perceived competence ($M = 6.16$, $SD = 0.72$) compared to pharmacists ($n = 9$, $M = 5.83$, $SD = 0.84$). Nurse practitioners'/physicians' and pharmacists' mean scores were not significantly higher or lower, respectively, than the mean score reported by registered nurses ($n = 35$, $M = 6.16$, $SD = 0.72$). Due to 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 perceived competence scales. 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.

Table 3

One-way ANOVA: Concentrated insulin perceived competence differences across profession

Variable	*n*	*M*	*SD*	*F*	*Df*	*P*
Profession				3.80	2,52	.029
Registered Nurse	35	6.16	0.72			
Nurse Practitioner/Physician	11	6.68*	0.50			
Pharmacists	9	5.83*	0.84			

Note. * Indicates significant differences between nurse practitioners/physicians and pharmacists.

Hypothesis Testing

To determine if perceived competence regarding concentrated insulin increased from pre- to post-intervention, a between-within 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 post-intervention perceived competence. Results from the between-within ANCOVA, shown in Table 4, documented significant pre- to post-intervention differences on perceived competence, $F(2,52) = 77.42$, $p < .001$, partial $eta^2 = .598$, 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 three standard deviations higher than the mean perceived competence pretest score. There was not a significant between-group difference with regard to profession and perceived competence, $F(2,52) = 1.73$, $p = .187$, partial $eta^2 = .062$.

Table 4

Between-Within ANCOVA: Pre- to posttest concentrated insulin perceived competence differences controlling for profession (n = 55)

Variable	*M*	*SD*	*F*	*Df*	*P*	*Partial Eta²*
Profession			1.73	2,52	.187	.062
Perceived Competence			77.42	2,52	<.001	.598
Pretest	4.06*	1.49				
Posttest	6.21*	0.74				

Note. * Indicates significant differences between pretest and posttest perceived competence scale scores.

A Wilcoxon signed rank *Z* test, the nonparametric equivalent to a paired-sample *t*-test (Ramsey & Schafer, 2012), was conducted to determine whether concentrated insulin knowledge scores increased pre- to post-intervention. A Wilcoxon signed rank *Z* test was conducted as the

knowledge scores were substantially skewed, which required the use of a non-parametric statistic (Ramsey & Schafer, 2012). Results from the test are presented in Table 5. Significant pre- to posttest increases emerged in knowledge regarding concentrated insulin, *Wilcoxon Z* = -6.28, $p < .001$. 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 perceived competence scales, the mean knowledge posttest scale score was more than three standard deviations higher than the mean pretest Knowledge Scale score.

Table 5

Wilcoxon Signed Rank Z Test: Pre- to posttest concentrated insulin perceived knowledge differences (n = 55)

Variable	*M*	*SD*	*M Rank*	*Sum of Ranks*	*Wilcoxon Z*	*p*
Perceived Knowledge			4.50	4.50	-6.28	<.001
			26.93	1373.50		
Pretest	67.27*	16.15				
Posttest	94.00*	7.35				

Note. * Indicates significant differences between pretest and posttest perceived Knowledge Scale scores.

Discussion

Summary

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 more than 200 units of insulin a day. This situation has created the need for Insulin U-500R and other complex medication regimens to help veterans achieve their 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 healthcare 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 use of U-500R insulin. This program can be used as a model for other VHAs nationally and institutions that use unified electronic medical record systems for care delivery for U-500R insulin. The program could also be adapted to ensure the safe use of other high risk specialty medications. The program did not lead to increases in resource utilization or opportunity costs.

Limitations

The VHA has its own communication network between spoke and hub VHAs. This program would be easily generalizable to the VHA nationally. In order to implement such a program in the private sector, several components would be needed—namely, a robust electronic medical record (EMR) that communicated across the healthcare system, the availably of specialty care willing to work closely with primary care clinicians, primary care clinicians willing to take on this responsibility, and possible changes to fee-for-service billing.

All spoke VHATHE VHA clinicians might not have as large an effect in perceived competence and knowledge scores pre- and post-test 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 diabetic 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 pre-filled U-500R KwikPen and a U-500R specific syringe. The pre-filled 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 PACT team enhanced knowledge and endocrinology support needed to deliver safe and complex diabetic 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 EMR process with decision support.

This program was the first step in improving the local management of complex diabetic patients. In the long run, it remains to be seen if patients' diabetic measures improve with local support. We hope this program and those like it will improve the collaboration between specialty and primary care to enhance best practice and patient safety. Further evaluation of the program should be undertaken to evaluate the utilization, diabetic control and clinical outcomes of patients who meet the criteria for U500 insulin.

Definition of Terms

Clinician. A clinician is "a health professional, such as a physician, psychologist, or nurse, who is directly involved in patient care, as distinguished from one who does only research or administrative work" (Clinician, 2007, para. 1).

Community-based outpatient clinic (CBOC). A CBOC "is a VA-operated clinic or a VA-funded or reimbursed health care facility or site that is geographically distinct or separate from the parent medical facility" (U. S. Department of Veterans Affairs, 2016b, para. 4).

Concentrated insulin. Concentrated insulin (i.e., U-500R) "is five times concentrated regular insulin used to improve glycemic control in adults and children with diabetes mellitus requiring more than 200 units of insulin per day" (Eli Lilly, 2016, para. 2).

Diabetes mellitus. The *Gale Encyclopedia of Medicine* (Diabetes Mellitus, 2008, para. 1) defines diabetes mellitus as:

> a condition in which the pancreas no longer produces enough insulin or cells stop responding to the insulin that is produced, so that glucose in the blood cannot be absorbed into the cells of the body. Symptoms include frequent urination, lethargy, excessive thirst, and hunger. The treatment includes changes in diet, oral medications, and in some cases, daily injections of insulin.

E-consult. Electronic consultations (e-consults) are "asynchronous, consultative, provider-to-provider communications within a shared electronic health record (EHR) or web-based platform (Vimalananda et al., 2015, p. 323).

Endocrinologist. An endocrinologist "is a medical specialist who treats endocrine (glands that secrete hormones internally directly into the lymph or bloodstream) disorders" (Endocrinologist, 2008, para. 8).

Hemoglobin (HgA1c). The *Gale Encyclopedia of Medicine* defines hemoglobin A1c as

"a test that measures the amount of hemoglobin bound to glucose. It is a measure of how much glucose has been in the blood during the past two to four months" (Glycosylated Hemoglobin, 2008, para. 6).

Home-based primary care (HBPC). HBPC refers to healthcare services that veterans receive in their homes. "A VA physician supervises the health care team who provides the services. Home Based Primary Care is for veterans who have complex health care needs for whom routine clinic-based care is not effective" (U.S. Department of Veterans Affairs, 2016a, para. 1).

Home telehealth (HT). HT "can connect a veteran to a VA hospital from home using regular telephone lines, cellular modem (these act as doors for transmission of information) and cell phones (using an interactive voice response system)" (U.S. Department of Veterans Affairs, 2015b, para. 3).

Hub and spoke VHAs. According to the Department of Veterans Health (2011, p. 7):

> The VHA's Hub and Spoke System of Care is an integrated service delivery network. Tertiary care centers (hub) provide primary and specialty care for veterans. All of the VHA medical centers without special care (spoke) have responsibility for the provision of basic medical care by designated and trained providers.

Insulin. The *American Heritage Medical Dictionary* defines insulin as:

> a polypeptide hormone that is secreted by the beta cells of the islets of Langerhans in the pancreas and functions in the regulation of carbohydrate and fat metabolism, especially the conversion of glucose to glycogen, which lowers the blood glucose level. It consists of two linked polypeptide chains called A and B. (Insulin, 2007, para. 2)

Insulin resistance. According to the *Gale Encyclopedia of Medicine*, insulin resistance

(Insulin Resistance, 2008, para. 1):

> is not a disease as such but rather a state or condition in which a person's body tissues have a lowered level of response to insulin, a hormone secreted by the pancreas that helps to regulate the level of glucose (sugar) in the body. As a result, the person's body produces larger quantities of insulin to maintain normal levels of glucose in the blood. There is considerable individual variation in sensitivity to insulin within the general population, with the most insulin-sensitive persons being as much as six times as sensitive to the hormone as those identified as most resistant. Some doctors use an arbitrary number, defining insulin resistance as a need for 200 or more units of insulin per day to control blood sugar levels.

Obesity. Obesity refers to the "abnormal accumulation of body fat, usually 20% or more over an individual's ideal body weight. Obesity is associated with increased risk of illness, disability, and death" (Obesity, 2008, para. 1).

Primary care provider (PCP). A PCP includes "the health care provider (the nurse practitioner, physician's assistant, or physician) to whom a patient first goes to address a problem with his or her health" (Primary Care Provider, 2012, para. 1).

Tuberculin syringe (TB). A tuberculin syringe is a small syringe with a fine needle for injections into the skin. The syringes can hold up to 3 milliliters of medication. Markings of 0.1 milliliters on the syringe allow for more precision in dosing than regular insulin syringes (BD Worldwide, 2016, para. 1).

Telehealth. According to *Segen's Medical Dictionary* (Teleheath, 2011), telehealth can be defined as:

> A generic term for remote delivery of healthcare by a range of options, including by

> landline or mobile phones and the internet. Telehealth can improve patients' experience by reducing the need to travel to hospitals when remote monitoring (e.g., ECG) and videoconferencing is equally effective and cheaper. (para. 3)

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Appendix A

Concentrated Insulin (U500-R) Education Program 2016

* Stacey Lutz-McCain, MSN, FNP-C Doctoral Candidate Edinboro/Clarion Universities of PA
* Dr. Archana Bandi –Endocrinologist Pittsburgh VHA
* Meg Larson, DNP Erie VHA

Learning Objectives

* Clinicians will:
  * Recognize the differences between Concentrated (U-500R) insulin and standard insulins
  * Identify safety concerns related to U-500R insulin
  * Analyze benefits vs. risk of U-500 R insulin
  * Understand insulin resistance and treatment
  * Evaluate patient education needs related to concentrated insulin
  * Remember how to safely prescribe and educate patients on U-500R insulin

Why Use U500-R Insulin?

* Increasing obesity epidemic and increasing occurrence of insulin resistance with uncontrolled diabetes
* 25% of the Veteran population is obese
* Escalating insulin dose requirements, usually associated with poor diabetes control
* Absorption of high insulin volumes becomes unpredictable

(U.S. Department of Veterans Affairs, 2015a)

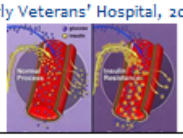
Benefits of U-500

* Decreased number of injections per day
  * Usually 2-3 doses per day
  * Simplifying regimen with only 1 type of insulin
* Decreased volume of insulin injection (so no leakage at injection site)
* Improved compliance
* Improved diabetes control
* Subcutaneous use only
* Cost savings
* Allows large doses of insulin to be administered in a smaller volume

Who qualifies for U-500R insulin?

* Patients with severe insulin resistance with high dose insulin requirements
  * Greater than 200 units of insulin a day
* Patients on multiple daily injections
* Demonstration of medication adherence
* Patient or caregiver can clearly see all markings on tuberculin syringe

(James A. Haverly Veterans' Hospital, 2011)



Who Does NOT Qualify for U-500R Insulin

* Patients admitted to the Erie VHA (inpatient)
* History of hypoglycemia unawareness
* Inability to read or interpret markings on Tuberculin syringe
* Failure to adhere to medical directions (non-adherence)

(James A. Haverly Veterans' Hospital, 2011)

What is Concentrated Insulin (U-500R)?

* U-500R insulin has been available since the 1950's
  * It was first used for patients with extreme insulin resistance caused by antibodies against animal derived insulins
  * Later used for patient with extreme insulin resistance
* It is 5 times more concentrated than U-100R insulin

(Cochrane et al., 2013)

What is it?

U500R	Standard Insulin
500 units/mL	100 units/mL
10,000 units per 20mL	1000 units per 10mL Vial

What is it?

- Pharmacokinetic profile:
  - Onset of action within 30 minutes
  - Peak action 4-8 hours
  - Duration of action 13 hours up to 24 hours
- Onset of action similar to Regular (U-100) Insulin
- Duration of action similar to NPH
- Has actions resembling both regular and NPH inulin.

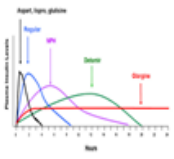
(Eli Lily, 2016)

Comparing Insulin Preparations

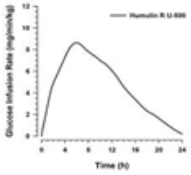
	Onset	Maximum Duration
Regular U-100 Insulin	30-60 min	6-8 hours
NPH	2-4 hours	14-18 hours
Regular U-500	<30 min	6-22 hours

Insulin Duration of action

Standard Insulins



U-500R insulin



What is Insulin Resistance

- According to the *Gale Encyclopedia of Medicine*, insulin resistance (Insulin resistance, 2008):
- It is not a disease as such but rather a state or condition in which a person's body tissues have a lowered level of response to insulin
- The patient produces larger quantities of insulin to maintain normal levels of glucose in the blood.
- There is considerable individual variation in sensitivity to insulin within the general population, with the most insulin-sensitive persons being as much as six times as sensitive to the hormone as those identified as most resistant.
- Most clinicians define insulin resistance as a need for 200 or more units of insulin per day to control blood sugar levels.

What Causes Insulin Resistance

* Obesity is the biggest factor
* High fat diet
* Lack of exercise

Who Prescribes U-500R insulin

* Endocrinologist at HUB VHAs: Pittsburgh
* The Endocrinologist or Diabetes specialist at the hub VHA assesses the patient to determine if they are a candidate and their ability to properly monitor and manage the concentrated insulin
* A consult is sent to the spoke VHA (Erie) to initiate the insulin
* Education will be provided by the spoke VHA with support from hub VHA.
* The Veterans diabetes will still be managed by the hub VHA.

Patient Safety Alert: High Potential for Error

* Only use tuberculin syringe for administration
* Dose should be expressed by both units and volume
* FDA issued safety label changes to express the prescribed dose in actual units of U-500R along with corresponding volume marking on the syringe

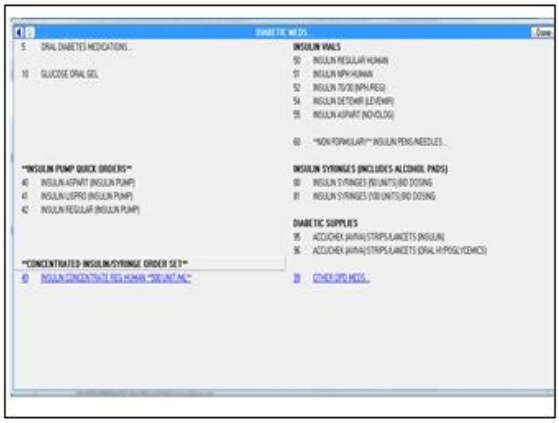
(Eli Lilly, 2016)

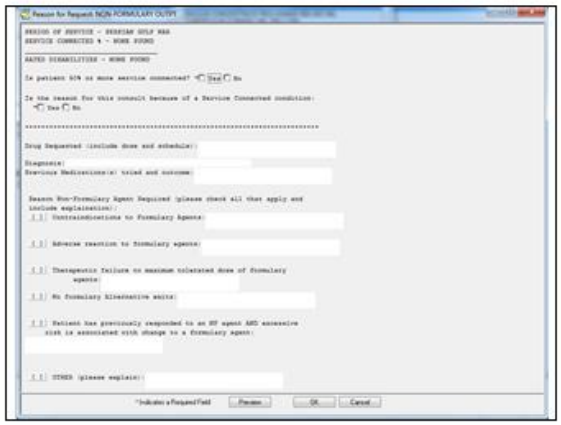
VA Central Office Response to Patient Safety Alert 2009

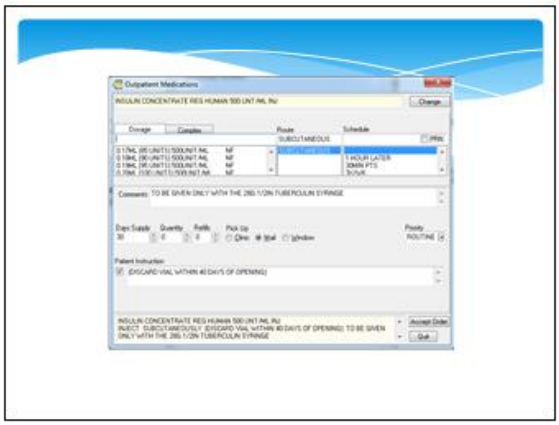
* Only Use tuberculin syringe
* Total doses should be expressed in terms of both units and volumes (ex:100 units is .4mL)
* U-500R insulin should be prescribed only using a quick order through pharmacy
  * Labeling U-500R insulin as concentrated insulin
  * Including tuberculin syringes in the order set
  * Standardize SIC line to reflect total dose in terms of units and volume

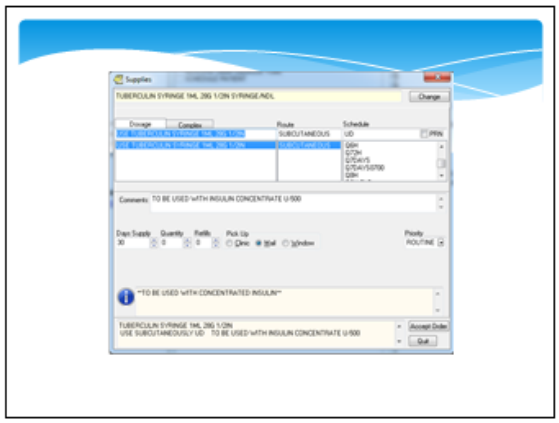
(VA National Center for Patient Safety, 2009)

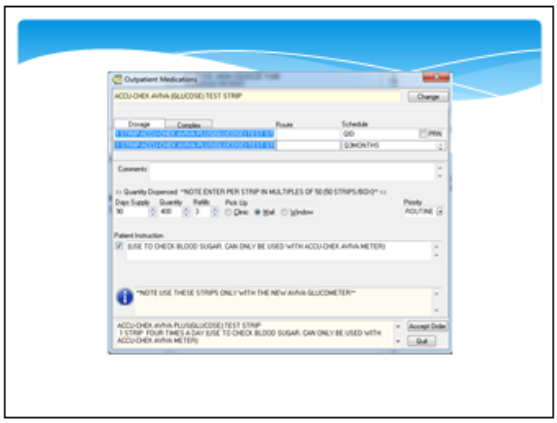

U-500R Quick Order
Erie VHA Pharmacy

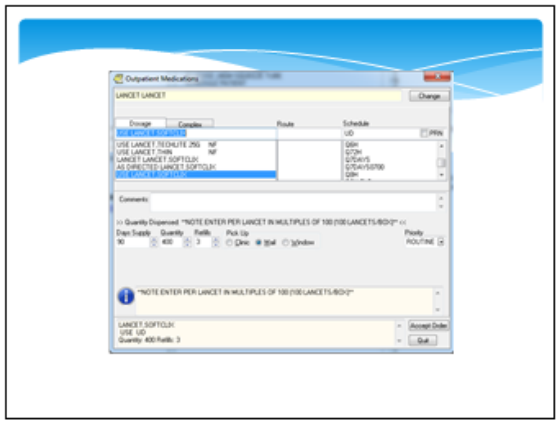

INSULIN VIALS
"INSULIN PUMP QUICK ORDERS"
INSULIN SYRINGES (INCLUDES ALCOHOL PADS)
DIABETIC SUPPLIES
"CONCENTRATED INSULIN/SYRINGE ORDER SET"

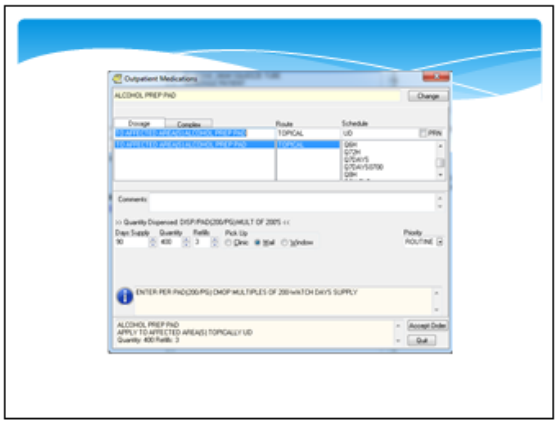


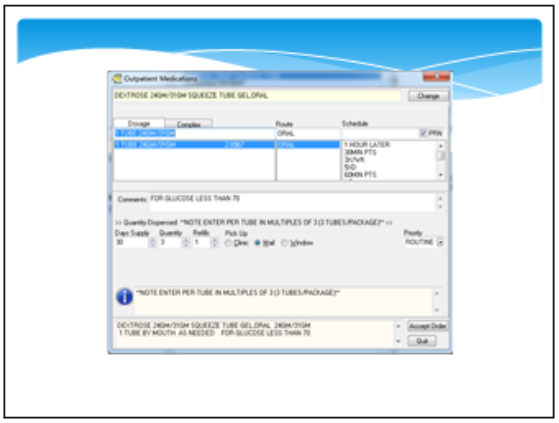


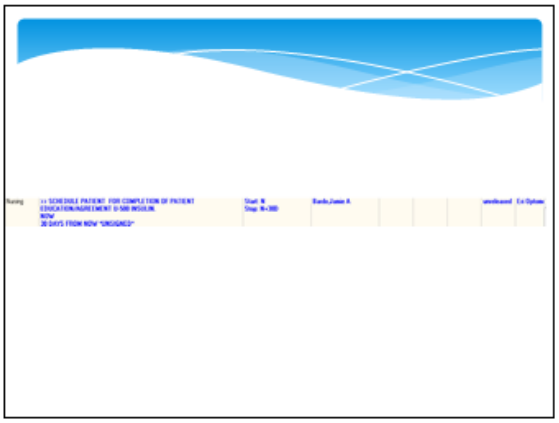


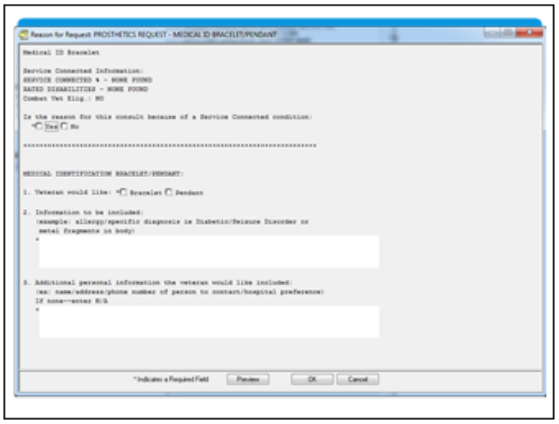


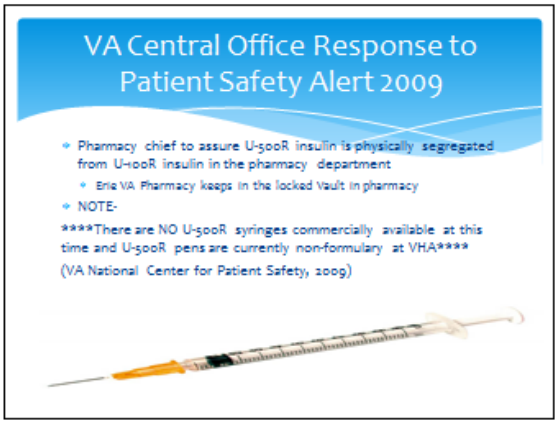











VA Central Office Response to Patient Safety Alert 2009
Pharmacy chief to assure U-500R insulin is physically segregated from U-100R insulin in the pharmacy department
Erie VA Pharmacy keeps in the locked Vault in pharmacy
NOTE-
****There are NO U-500R syringes commercially available at this time and U-500R pens are currently non-formulary at VHA****
(VA National Center for Patient Safety, 2009)

Erie VA Pharmacy Process for U-500R Insulin initiation

- The pending order for U-500R is reviewed by a pharmacist and processed
- A prescription label and patient information is printed in pharmacy
- Vials of U-500R insulin are kept in the vault because of the medications LASA (Look Alike, Sound Alike) designation and the high concentration of the product compared to other insulins.
- A technician procures the number of vials and affixes the prescription label.
- A pharmacist checks the insulin and assures drug information handouts are included.
- Only Tuberculin syringes are ordered for use with concentrated insulin

LASA

Only Use a Tuberculin Syringe (TB) with U-500R insulin

Tuberculin (TB) Syringe

NEVER use: Regular Insulin Syringe!!!!!!

U-500R insulin Side-effects

* Hypoglycemia: due to prolonged duration of action. Can develop 18-24 hours after injection
* Potential for weight gain (similar to regular insulin)
* Potential for syringe confusion

(Ely Lily, 2016)

U-500 Safety

Weight Gain

U-100	U-500
4.0-4.5 kg	4.2 kg

Patient Education

- Review signs of hypoglycemia (low blood sugar)
- Mild symptoms-sugar less than 70
  - Fast heartbeat, change in vision, hunger, headache, irritability, weakness/fatigue, anxious, dizziness, sweating, shaking
- Severe symptoms – sugar less than 50
  - Can have rapid onset: seizures, unconsciousness, combative behaviour

Patient Education

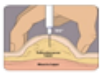
- It is a clear liquid, comes in a larger bottle (20mL) and has a RED triangle to mark it as U-500R Insulin.
- Do NOT use if cloudy or discolored.
- Store U-500R Insulin away from other insulin products to decrease confusion
- Always use tuberculin syringes to draw up appropriate amount and precise amount of insulin
- Educate on possibility of hypoglycemia and treatment
- Hold U-500R Insulin if a meal is skipped.
- Advise patients to call if any questions.

(Ely Lily, 2016)

Patient Education

- Do NOT mix with other insulins
- Always inject subcutaneously (not in a vein or muscle)
- Change injection sites with each dose
- Remember to eat after injection within 30 minutes after injection
- Try to avoid drinking alcohol on this medication as it can affect your blood sugar and cause low readings.

(Ely Lily, 2016)



Patient Education

- Educate patient/caregivers on U-500R Insulin. Ensure awareness that it is five times more concentrated than regular insulin U-100R
- Demonstrate how to draw up the exact dose using a tuberculin syringe and have patient demonstrate
- Teach the correct dosage in volume and units of insulin
- Advise patients to NEVER self-adjust this insulin

(Ely Lily, 2016)

How to Store U-500R Insulin

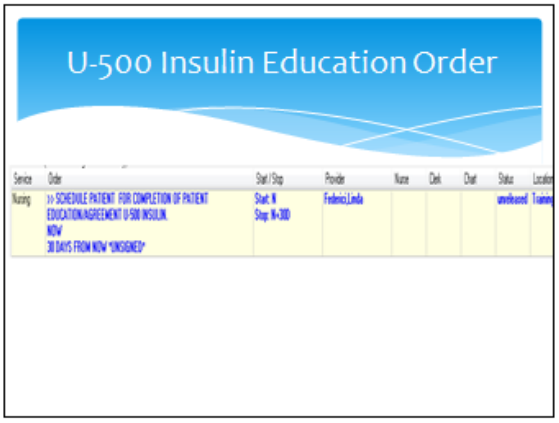
* Discard if:
  * Expired, cloudy or discolored, or open longer than 40 days
* Unopened Vials:
  * Keep in a refrigerator 36-46 degrees Fahrenheit
  * Do not freeze
* Opened Vials:
  * Keep in refrigerator or at room temperature
  * Keep away from heat and direct sunlight

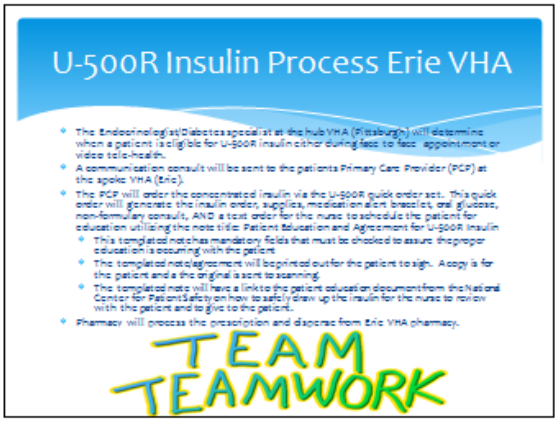
(Ely Lily, 2016)

Patient Education Materials

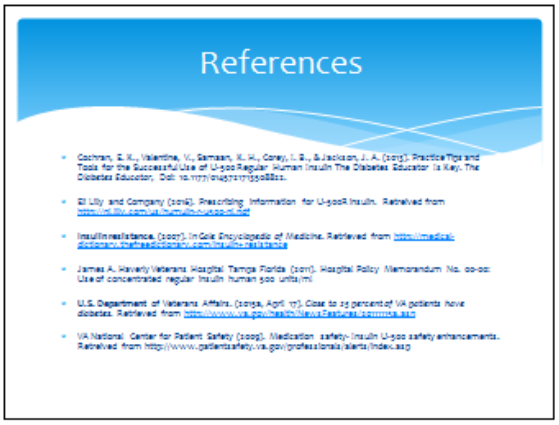
* How to draw up U-500 (Concentrated) Insulin with a Tuberculin Syringe: http://www.patientsafety.va.gov/docs/U500InsulinBrochure.pdf
* PowerPoint for clinical/staff review in Patient Education Link on CPRS toolbar
* Patient education documentation and agreement template

Template for Nursing documentation note title: Patient Education/Agreement U-500 Insulin


U-500 Insulin Education Order
Service
Order
Start / Stop
Provider
Nurse
Clerk
Chart
Status
Location
Nursing
>> SCHEDULE PATIENT FOR COMPLETION OF PATIENT EDUCATION/AGREEMENT U-500 INSULIN.
NOW
30 DAYS FROM NOW "ONGOING"
Start: N
Stop: N-300
Fredrick,Linda
unreleased


U-500R Insulin Process Erie VHA
The Endocrinologist/Diabetes specialist at the hub VHA (Pittsburgh) will determine when a patient is eligible for U-500R insulin either during face to face appointment or video tele-health.
A communication consult will be sent to the patients Primary Care Provider (PCP) at the spoke VHA (Erie).
The PCP will order the concentrated insulin via the U-500R quick order set. This quick order will generate the insulin order, supplies, medication alert bracelet, and glucose, non-formulary consult, AND a text order for the nurse to schedule the patient for education utilizing the note title: Patient Education and Agreement for U-500R Insulin
This templated note has mandatory fields that must be checked to assure the proper education is occurring with the patient
The templated note/agreement will be printed out for the patient to sign. A copy is for the patient and a the original is sent to scanning.
The templated note will have a link to the patient education document from the National Center for Patient Safety on how to safely draw up the insulin for the nurse to review with the patient and to give to the patient.
Pharmacy will process the prescription and dispense from Erie VHA pharmacy.
TEAM
TEAMWORK


Conclusion
We can co-manage U-500R insulin safely with a collaborative approach with Endocrinology and Diabetes specialists.
SAFETY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Appendix B

Pre-Survey: Concentrated Insulin (U500R insulin) Education

Note: By completing the survey, you are consenting to participate in the study.

1. Age: _____

2. Gender: _____

3. Profession:

Physician Nurse Practitioner Registered Nurse Physician Assistant Pharmacist

4. Years of experience:

0–5 6–10 11–15 16–20 21–25 25+

5. Degree:

Diploma Associate Baccalaureate Master's Doctoral

6. Have you worked in endocrinology as a specialty?

Yes No

Please respond to each of the following items in terms of how true it is for you with respect to dealing with Concentrated (U-500R) insulin.

1	2	3	4	5	6	7
Strongly Disagree			Neutral			Strongly Agree

1. I feel confident in my ability to understand U-500R insulin (concentrated) management.

1	2	3	4	5	6	7

2. I am capable of handling patients prescribed U-500R insulin.

1	2	3	4	5	6	7

3. I am able to effectively participate in the management of patients prescribed U-500R insulin.

1	2	3	4	5	6	7

4. I feel able to meet the challenge of caring for patients prescribed U-500R insulin.

1	2	3	4	5	6	7

Concentrated Insulin Education Evaluation: Circle True or False for each question

1. U-500R insulin is 5 times as concentrated as regular insulin.

True False

2. U-500R insulin is recommended when patients are on > 100 units of insulin a day.

True False

3. A tuberculin syringe is used with U-500R insulin.

True False

4. The main reason patients are prescribed U-500R insulin is insulin resistance caused by obesity.

True False

5. Primary care providers can independently initiate U-500R insulin at the VHA.

True False

6. U-500R insulin is dispensed like any other medication by the pharmacy at the VHA.

True False

7. Patient education for U-500R insulin should be conducted over the phone to ensure patients' safety.

True False

8. Dosing of U-500R insulin occurs once daily.

True False

9. When ordered, U-500R insulin dosage should be expressed in both units and volume.

True False

10. If a tuberculin syringe is not available, a concentrated U-100R insulin syringe may be used to measure the U-500R insulin dose.

True False

Appendix C

Post-Survey: Concentrated Insulin (U500R insulin) Education

Please respond to each of the following items in terms of how true it is for you.

1	2	3	4	5	6	7
Strongly Disagree			Neutral			Strongly Agree

1. I feel confident in my ability to understand U-500R insulin (concentrated) management.

1	2	3	4	5	6	7

2. I am capable of handling patients prescribed U-500R insulin.

1	2	3	4	5	6	7

3. I am able to effectively participate in the management of patients prescribed U-500R insulin.

1	2	3	4	5	6	7

4. I feel able to meet the challenge of caring for patients prescribed U-500R insulin.

1	2	3	4	5	6	7

Concentrated Insulin Education Evaluation: Circle True or False after each question

1. U-500R insulin is 5 times as concentrated as regular insulin.

True False

2. U-500R insulin is recommended when patients are on > 100 units of insulin a day.

True False

3. A tuberculin syringe is used with U-500R insulin.

True False

4. The main reason patients are prescribed U-500R insulin is insulin resistance caused by obesity.

True False

5. Primary care providers can independently initiate U-500R insulin at the VHA.

True False

6. U-500R insulin is dispensed like any other medication by the pharmacy at the VHA.

True False

7. Patient education for U-500R insulin should be conducted over the phone to ensure patients' safety.

True False

8. Dosing of U-500R insulin occurs once daily.

True False

9. When ordered, U-500R insulin dosage should be expressed in both units and volume.

True False

10. If a tuberculin syringe is not available, a concentrated U-100R insulin syringe may be used to measure the U-500R insulin dose.

True False