

A comparative analysis of pharmacists' self-confidence beliefs for regular U-500 (concentrated) insulin and U-100 insulin

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Abstract

The purpose of this research was to assess pharmacist confidence levels in the accurate and safe counseling on Humulin R regular U-500 (concentrated) insulin compared to U-100 insulin. The investigators developed a 34-item survey instrument assessing pharmacist insulin counseling confidence levels. Categories measured included demographics, common insulin patient counseling practices, pharmacist confidence levels, and perceived barriers. A survey invitation was emailed to East Tennessee State University Gatton College of Pharmacy preceptors every 2 weeks over a six-week period. Descriptive and parametric statistics were used to examine response frequencies and differences in confidence levels. A response rate of 30% (n=138) was received. Most respondents (70%) practice in an outpatient setting (i.e., ambulatory care, chain, or independent pharmacies) and over 80% indicated they have dispensed U-500. Overall, pharmacists feel less confident in their ability to dispense and safely counsel patients on U-500 insulin compared to U-100 (p<0.001). The largest perceived barriers were job-related time constraints and a lack of knowledge about U-500 insulin. Pharmacists have lower confidence in their ability to counsel patients prescribed U-500 insulin compared with U-100 insulin types. Future research is warranted to determine what training and/or resources would improve confidence levels.

Keywords: U-500 insulin; insulin; pharmacist self-confidence; counseling

Introduction

Type 2 diabetes (T2DM) accounts for approximately 95% of the 29 million cases of diabetes in America [1, 2]. The largest contributing factor is obesity and related insulin resistance [3, 4]. Severe insulin resistance requires large insulin doses that may lead to pain and reduced absorption [5]. Humulin R regular U-500 (concentrated) insulin (hereafter referred to as "U-500") is five times more concentrated (500 units/mL) than traditional U-100 (100 units/mL) and is indicated for patients requiring greater than 200 units daily [6-8]. Though commercially available as human insulin since 1997, more physicians are beginning to prescribe U-500 evidenced by a 137% increase during 2007-2009 [4]. Recent correspondence with the manufacturer has indicated U-500 is growing faster than the overall insulin analog market (Jill Vaughn, RN, BSN, email communication, January 7, 2014). As a result, pharmacists are more likely to receive prescriptions for U-500 and should be prepared to provide patient counseling to avoid errors and patient harm. The safe use of any insulin, including U-500, can be defined as improving glycemic control without increasing patient harm and achieving this goal involves intentional patient instruction by healthcare providers.

The clinical use of U-500 has several advantages. First, it is a potent anti-diabetes agent capable of reducing hemoglobin A1C about 1.0-1.8% in severely insulin resistant patients [9-12]. Second, the number of required

daily injections can be reduced compared to basal bolus insulin regimens using U-100 insulin. Insulin syringes are designed to accurately measure up to 100 units, but higher doses require additional injections. Plus, omitting or forgetting the additional injection likely results in poorer glycemic control. Third, the pharmacokinetics of U-500 gives it both prandial and basal insulin properties thus eliminating the necessity of two different insulins. One of the most common reasons for emergency department (ED) visits was insulin product mix-ups (i.e., injecting basal insulin dose for bolus insulin and vice versa). When U-500 is initiated, it replaces both the U-100 basal and bolus insulin eliminating this potential error [13]. Finally, there is less pain and absorption is improved due to the

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smaller injected volume. Yet, U-500 possesses unique challenges not associated with U-100 insulin therapy. The lack of a specific U-500 syringe necessitates use of a volumetric (e.g., tuberculin) or U-100 insulin syringe for dosing thereby increasing the risk for errors. This dose conversion can be confusing to patients and it one of the key patient counseling objectives. Recently, the Institute for Safe Medication Practices (ISMP) recommended the preferred use of volumetric syringes over U-100 syringes when measuring doses [14]. Another challenge is how the U-500 prescription order is written and labeled. Prescribers and pharmacists should include both the actual units of U-500 and "unit markings" or volume if using a U-100 or volumetric syringe, respectively [6, 14]. Also, due to its longer duration of action, secondary hypoglycemia may develop 18 to 24 hours after injection if meals are skipped or carbohydrate intake is inconsistent [8].

Self-efficacy beliefs influence pharmacists' interpersonal communication. According to Bandura's self-efficacy theory, a positive relationship exists between task-specific communication and the extent that individuals engage in communication [15, 16]. Conversely, individuals with low task-specific self-efficacy beliefs are more likely to avoid participating in communicative behaviors [17]. In theory, pharmacists who lack confidence are less likely to communicate with patients' prescribed U-500 therapy and consequently may not ensure patient understanding or verify the patient's skill level needed to accurately use and administer the concentrated insulin. The primary objective of the study was to assess pharmacist confidence levels on the accurate and safe counseling on U-500 compared to U-100 insulin.

Materials and methods

The authors developed a 34-item, survey instrument formatted in four sections: i. pharmacist and practice setting characteristics, ii. insulin counseling and dispensing characteristics, iii. pharmacists' confidence levels with insulin counseling, and iv. perceived barriers. A 5-point Likert response scale (5=strongly agree; 1=strongly disagree) was used to measure confidence levels. Elements of insulin counseling measured included drawing up the correct dose, timing of injection, injection technique, storage, when to monitor sugar, and hypoglycemic symptoms and treatment. A skip pattern question was used if respondents had never dispensed U-500. A ranked order question with randomized choice order was used to determine perceived barriers. U-100 insulin was defined as any other dispensed insulin besides U-500. The instrument was pretested by faculty including one with expertise in survey instrument development and modified prior to administration. The survey took approximately 10 minutes to complete and completion served as informed consent. An exempt status IRB designation was granted by the East Tennessee State University (ETSU).

An email invitation explaining the research objective was sent to all ETSU pharmacy preceptors (N=459) on March 17, 2014. The email contained a personalized cover letter and a link to the survey instrument. Follow-up emails were resent to all preceptors, one every two weeks over the six-

week study period modeled after Dillman's tailored design method [18]. Survey Monkey was utilized for administration and data collection. All survey responses received were considered usable. The survey instrument is available as a supplemental (Appendix I).

Data were analyzed using SPSS version 22 (SPSS/IBM; Armonk, NY). An a priori level of significance was set at $\alpha=0.05$. Assuming a 50% response rate, an estimated sample size of 210 was calculated to achieve a 5% margin of error with 95% confidence. Descriptive statistics were calculated for all items. Survey scale reliability was determined using Cronbach's alpha. Individual survey item scores were combined for U-100 and U-500 items to create a scale score. Paired t test was employed for comparing scaled score confidence levels between U-100 and U-500.

Results

A total of 138 responses were received by the researchers yielding a response rate of 30% (Table 1). The majority of pharmacists (70%) practice in the outpatient setting (i.e., ambulatory care, chain, or independent pharmacies). Over 83% of respondents indicated dispensing U-500 at least once and a mean of 3.4 prescription orders for U-500 was received over the last six months. Internal reliability of the survey instrument comparing pharmacist confidence levels was 0.959 and 0.896 for U-100 and U-500 items, respectively. Pharmacist confidence scale scores for U-100 and U-500 insulin (mean \pm standard deviation) was 4.72 ± 0.41 and 4.23 ± 0.65 , respectively [absolute difference 0.49 (95% CI 0.36, 0.57), ($p<0.001$)]. Overall, pharmacists are less confident in their ability to dispense and safely counsel patients on U-500 compared to U-100. The distribution of results comparing U-100 and U-500 items is summarized in Table 2. Volumetric syringes are recommended by ISMP to dose U-500 insulin yet pharmacist confidence levels on how to counsel patients using volumetric syringes are lower compared with traditional U-100 insulin syringes. Seventy seven percent of pharmacists felt confident (strongly agree or agree) in counseling a patient using an insulin syringe to dose U-500 while 68% reported confident (strongly agree or agree) in counseling using a volumetric syringe. Pharmacists also reported a minority (23%) of patients use volumetric syringes. To avoid dosing errors, both units and volume should be included on the prescription order. Yet, 73% of pharmacists reported that prescribers never or seldom include both actual units and volume on U-500 prescription orders. For perceived barriers to counseling, job-related time constraints (42%) were the largest reported barrier followed by lack of knowledge (23%). Almost half (41%) of respondents reported they either were self-taught or never taught about U-500. Other barriers were prescriber already counseled patient (20%), no patient counseling resources available (10%), and patient refusing counseling (5%).

Discussion

Pharmacists are very confident with counseling on U-100 insulin, but significantly less confident in their ability to counsel on U-500. The lower confidence was even observed with tasks not related to a specific insulin type such as counseling how to treat hypoglycemia. Based

Table 1 Demographic and practice characteristics of respondents (N=138).

Demographic/practice characteristics	Numeric value
Gender, no. (%)	
Female	73 (52.6)
Male	65 (47.4)
Setting, no. (%)	
Ambulatory Care Clinic	16 (11.6)
Chain	56 (40.6)
Independent	24 (17.4)
Institutional	39 (28.3)
Other	3 (2.1)
Age, Mean (SD)	39.8 (11.3)
Years in practice, Mean (SD)	14.6 (12.2)
Pharmacists with post-graduate training, ^a %	28
Prescriptions filled per day, ^b Mean (SD)	291.8 (161.0)
Pharmacists who have dispensed U-500 insulin, %	83.3
Prescriptions dispensed for U-500 insulin in last 6 months, Mean (SD)	3.4 (4.1)

Abbreviations: SD = standard deviation; U-500 = Humulin R regular U-500 (concentrated) insulin; ^aPost-graduate training = PGY1/PGY2 pharmacy residency, MBA, PhD, etc.; ^bCalculated using data from chain and independent pharmacists only.

Table 2 Pharmacist perceptions of confidence in ability to counsel on the safe use of regular U-500 insulin compared with U-100 (N=121)^a.

Item	U-100 insulin Mean (SD)	U-500 insulin Mean (SD)
I feel confident in my ability to dispense insulin	4.8 (0.6)	4.3 (0.9)
I feel confident in my ability to counsel a patient on how to accurately draw up the correct dose in an insulin syringe	4.8 (0.6)	4.1 (1.0)
I feel confident in my ability to counsel a patient on proper injection technique	4.7 (0.7)	4.2 (1.0)
I feel confident in my ability to counsel a patient on storage of insulin	4.7 (0.6)	4.5 (0.8)
I feel confident in my ability to counsel a patient on the proper timing of an insulin dose	4.6 (0.6)	4.2 (0.9)
I feel confident in my ability to counsel a patient when to check his/her blood sugar based upon insulin type to determine blood sugar control	4.6 (0.6)	4.0 (1.0)
I feel confident in my ability to counsel a patient on symptoms of hypoglycemia caused by insulin	4.7 (0.6)	4.4 (0.7)
I feel confident in my ability to counsel a patient on how to treat hypoglycemia caused by insulin	4.7 (0.6)	4.3 (0.8)
Scale score (p < 0.001)	4.7 (0.7)	4.2 (0.7)

Abbreviations: U-500 = Humulin R regular U-500 (concentrated) insulin; U-100 = Humalog® (lispro), Novolog® (aspart), Apidra® (glulisine), Humulin R® (regular), Novolin R® (regular), Humulin N® (NPH), Novolin N® (NPH), Lantus® (glargine), Levemir® (detemir), Humulin 70/30®, Novolin 70/30®, Humalog Mix 75/25®, Humalog Mix 50/50®, Novolog Mix 70/30®; IQR = Interquartile range; ^aResponded to using a 5-point Likert scale; 5 = strongly agree, 4 = agree, 3 = neutral, 2 = disagree, 1 = strongly disagree.

on Bandura's self-efficacy theory, pharmacists who with lower confidence are less likely to counsel patients. The pharmacist is often the last healthcare professional that patients will encounter prior to beginning any drug

therapy. Thus, the pharmacist's role in patient education and counseling is vital. The difference observed may be due to fewer counseling opportunities for U-500 since it is only reserved for patients with severe insulin resistance. Of note, a minority of respondents had never dispensed U-500 thus it is a task they have never performed. The lower confidence may also be due to a relative lack of knowledge about U-500 since almost half the respondents were never formally educated about U-500 or trained by others. In comparison, education programs and resources for U-100 are abundant and easily accessible.

Pharmacists are in a position to educate other health providers about medication therapies. Based on our results, prescribers need more education how to order the concentrated insulin as they rarely include both actual units and volume on U-500 prescription orders. Our survey instrument did not directly measure confidence in teaching prescribers on insulin, but pharmacists presumably would be less likely in educating other healthcare providers if their self-confidence is lacking. The use of volumetric syringes to dose U-500 is low compared with insulin syringes. Reasons could be due to higher device familiarity, comfort with use, availability and less cost associated with insulin syringes. Access to patient education tools may improve confidence, however our survey instrument did not measure if pharmacists use any tools or resources when counseling patients on insulin. To minimize errors, pharmacists should keep a dose conversion chart accessible for patient education and dispense copy with each U-500 prescription. Due to the increased number of errors reported with using U-500, the manufacturer is developing a U-500 pen to minimize dosing errors [19].

The largest barrier to counseling patients on U-500 is job-related time constraints. The majority of respondents (73%) believe it is more difficult to counsel patients receiving U-500 than U-100 and therefore instruction time will take longer. Pharmacy busyness reduces patient counseling and assessment of patient understanding [20]. One strategy to counsel efficiently on insulin products is utilizing demo syringes via the teach-back technique [21]. Using this strategy, the patient demonstrates how to draw up his/her prescribed insulin dose to verify accuracy and understanding. This method also allows the pharmacist to preferentially concentrate on areas of misunderstanding or inaccuracies. Lack of knowledge was perceived as the second most common barrier. To increase knowledge, schools and colleges of pharmacy should evaluate their curricula on U-500 to assess the quantity and quality of education provided. Specifically, patient counseling laboratory activities with the focus of explaining how to dose and inject U-500 using both syringe types could improve knowledge and self-confidence and deserves research attention. In addition, offering more continuing education programs and/or education materials would increase knowledge for the practicing pharmacist.

Several factors limit the interpretation of the data. First, a nonprobability sample selection approach was employed. Pharmacists were recruited by using current preceptors at one institution due to convenience sampling and may not be representative of all pharmacists or other healthcare

professionals. Second, the lower than expected response rate leads to a potential response bias. Even though the characterization of respondents appears to be a fair representation of all preceptors based on practice setting, it is impossible to determine the individual confidence levels of nonresponders and what impact it may have had on the results. In addition, pharmacists responding in a social desirable behavior might overestimate their confidence levels. Third, since all preceptors received multiple emails modeled after the Dillman method, the survey platform tool could not discriminate between repeated responses from different computers or ISP addresses. Finally, with all survey-based research, self-report methodological and limitations may exist as the survey instrument was created by the investigators.

Conclusion

With the increasing epidemic of diabetes, prescription orders for U-500 are increasing and pharmacists need to be confident in counseling patients on its accurate and safe use. Our findings indicate that pharmacists have lower confidence in their ability to counsel patients prescribed U-500 compared with U-100. Future research is warranted to determine what training and/or resources would improve confidence levels.

Conflicts of interest

Authors declare no conflicts of interest.

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Supplementary data

Supplementary data associated with this article can be found, at <http://nobleresearch.org/Doi/10.14312/JDE-2015003>. These data include Appendix I i.e. Surveying pharmacists' confidence in patient counseling on the safe use of regular U-500 (concentrated) insulin.

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