

Development of Syringe Drawing Device for Reducing Insulin Injection Errors in Diabetic Patients

นิพนธ์ฉบับ

Original Article

มลธิชา ชราชาติ^{1*} และ อัษฎางค์ พลนอก^{2,3}

¹ คณะเภสัชศาสตร์ มหาวิทยาลัยนเรศวร อ.เมือง จ.พิษณุโลก 65000
² ภาควิชาเทคโนโลยีเภสัชกรรม คณะเภสัชศาสตร์ มหาวิทยาลัยนเรศวร อ.เมือง จ.พิษณุโลก 65000
³ อุทยานวิทยาศาสตร์ภาคเหนือตอนล่าง มหาวิทยาลัยนเรศวร อ.เมือง จ.พิษณุโลก 65000

* ติดต่อผู้พิมพ์: monthicha.oil@gmail.com

วารสารไทยเภสัชศาสตร์และวิทยาการสุขภาพ 2560;12(4):176-185.

Molthicha Charachit^{1*} and Assadang Polnok^{2,3}

¹ Faculty of Pharmaceutical Sciences, Naresuan University, Muang, Phitsanulok, 65000, Thailand
² Department of Pharmaceutical Technology, Faculty of Pharmaceutical Sciences, Naresuan University, Muang, Phitsanulok, 65000, Thailand
³ Science Park, the Lower North, Naresuan University, Muang, Phitsanulok, 65000, Thailand

* Corresponding author: monthicha.oil@gmail.com

Thai Pharmaceutical and Health Science Journal 2017;12(4):176-185.

บทคัดย่อ

Abstract

วัตถุประสงค์: เพื่อประเมินความพึงพอใจ ความถูกต้องและความแม่นยำของอุปกรณ์ลดความคลาดเคลื่อนในการบรรจุอินซูลินชนิดเข็มฉีดยาในผู้ป่วยเบาหวานที่โรงพยาบาลสมเด็จพระยุพราชสระแก้ว **วิธีการศึกษา:** การศึกษาแบบพัฒนาเครื่องมือดำเนินการระหว่างเดือนมีนาคม 2559 ถึงมกราคม 2560 โดยการสร้างต้นแบบของอุปกรณ์ลดความคลาดเคลื่อนในการบรรจุอินซูลินชนิดเข็มฉีดยาแล้วประเมินความพึงพอใจ ความถูกต้องและความแม่นยำในกลุ่มตัวอย่างตามลำดับคือ กลุ่มบุคลากรทางการแพทย์จำนวน 5 คน กลุ่มผู้ป่วยเบื้องต้น 10 คน กลุ่มผู้ป่วย 30 คนและกลุ่มเภสัชกร 7 คน การประเมินความพึงพอใจของผู้เข้าร่วมวิจัยจะใช้แบบสอบถามที่มี 8 ข้อคำถามซึ่งแต่ละข้อต้องได้คะแนนเฉลี่ยอย่างน้อย 3.5 ขึ้นไป (เต็ม 5 คะแนน) ความถูกต้องที่ยอมรับได้ถ้ามีความผิดพลาดสัมพัทธ์ไม่เกินร้อยละ 15, 5 และ 5 สำหรับอินซูลินที่ขนาด 10, 44 และ 82 ยูนิต ตามลำดับ และความแม่นยำที่ยอมรับได้ถ้าค่าสัมประสิทธิ์ความแปรปรวนไม่เกินร้อยละ 10 สำหรับทั้งสามขนาดยา อุปกรณ์ดังกล่าวได้รับการทดสอบและปรับปรุงจนผ่านการทดสอบทุกอย่างตามหลักเกณฑ์ที่กำหนด **ผลการศึกษา:** หลังจากการทดสอบและปรับปรุง อุปกรณ์ลดความคลาดเคลื่อนในการบรรจุอินซูลินชนิดเข็มฉีดยาผ่านการประเมินความพึงพอใจ อุปกรณ์มีความผิดพลาดสัมพัทธ์ (หรือความถูกต้อง) และค่าสัมประสิทธิ์ความแปรปรวน (หรือความแม่นยำ) ที่ยอมรับได้ตามที่กำหนด **สรุป:** การพัฒนาต้นแบบอุปกรณ์ลดความคลาดเคลื่อนในการบรรจุอินซูลินชนิดเข็มฉีดยาในขั้นต้นนี้ประสบผลสำเร็จควรมีการพัฒนาต่อไปในอนาคตให้มีคุณภาพที่ดียิ่งขึ้น

คำสำคัญ: อุปกรณ์ลดความคลาดเคลื่อน, ความคลาดเคลื่อนในการฉีดยา, การฉีดยาอินซูลิน, ผู้ป่วยโรคเบาหวาน

Objective: To assess the satisfaction, accuracy and precision of a syringe drawing device prototype for reducing insulin injection errors found in diabetic patients at Sakaeo Crown Prince Hospital. **Method:** The tool development research was conducted from March 2016 to January 2017. A prototype of the syringe drawing device was created and assessed by various groups of testers in a consecutive order, i.e. five healthcare professionals, a preliminary group of 10 patients, a group of 30 patients and a group of seven pharmacists. An 8-item questionnaire was utilized to evaluate the participant's satisfaction. To pass the satisfaction test, each item of the questionnaire had to have an average score of 3.5 points (out of 5). The accuracy was acceptable if the relative errors were not more than 15%, 5% and 5% for insulin doses of 10, 44 and 82 units, respectively. The precision was acceptable if the values of coefficient of variation (CV) were not more than 10% for all three doses. The prototype was tested and improved until all testing passed according to the criteria. **Results:** After all tests and improvements, the device prototype passed all the satisfaction tests. Relative errors (or accuracy) and values of CV (or precision) were in acceptable limits. **Conclusion:** The development of the prototype of insulin drawing device was successful. A further development is needed to improve its usability.

Keywords: syringe drawing device, injection error, insulin injection, diabetic patient

Introduction

Diabetes is a chronic disease that requires continuous medical care to achieve a glycemic control. Patients should be encouraged to have self-management knowledge to prevent acute complications and reduce the risk of long-term complications.^{1,2} Three groups of medicines used to control blood sugar levels include oral medicines, insulin injection and glucagon like peptide-1 (GLP-1) analogues. Type 1 diabetic patients require only insulin injections. On the other hand, type 2 diabetic patients may use oral medicines and/or injectable medicines for glycemic control.²

According to data of Sakaeo Crown Prince Hospital from October 1st, 2013 to September 30th, 2014, of the 3,020

diabetic patients, 1,556 were old individuals (over 60 years old). There were 732 diabetic patients who needed insulin injection which could be classified into 564 insulin syringe users and 168 insulin pen users. Diabetic patients or caregivers were taught how to inject insulin. However, compliance to medication use including insulin injection could be problematic. Data from our diabetes service in the fiscal year of 2013 revealed that of 1,930 services for individual patients, 113 non-compliance incidents (5.85%) were found.

Of those insulin syringe users, 194 of them were the old patients who could have some kinds of problems. With poor

memory, they could not remember the dose and administration of the insulin prescribed. With poor eyesight or diabetic retinopathy, they had difficult reading labels and number on the insulin pen. Even with these problems, these diabetic patients had to use insulin syringe by themselves. Those having help injecting insulin by their caregivers could also face problem. Some caregivers did not have the chance to learn about the process of drawing insulin into syringe by the pharmacist. Thus, many diabetic patients received insulin injection incorrectly.

A recent study has confirmed that benefits of using insulin pens were superior to using insulin syringe in terms of accuracy, ease of use, patient satisfaction, quality of life, and good adherence.³ The effort to change from insulin syringe to insulin pen has been made widely. However, many diabetic patients still have problems with insulin pen with the invisible numbers on the pen barrel. Some diabetic patients need a high dose of insulin but counting the click sound of rotating knob on insulin pen may be the cause of error for insulin dosing. For those who need more than 60 units of insulin for a given dose, insulin pen with a maximum of 60 units available for each injection is inconvenient to use. An insulin syringe with a maximum of 100 units of insulin is more applicable. In addition, with only Humulin N (NPH) in vials available, insulin syringe is inevitably needed. More importantly, the cost of insulin cartridge with insulin pen is higher than insulin in vials with insulin syringe.⁴ Therefore, the majority of diabetic patients receiving insulin injections at Sakaeo Crown Prince Hospital received insulin syringe. At present, the pharmacist is trying to solve the problem of drawing insulin into syringe for the injection by marking on the syringe barrel for the dose of insulin according to physician's order with a pen. But pen marking line is too thick which could cause an error when drawing insulin. In addition, to mark the syringe, plastic bag container had to be removed. Therefore, marked syringes could be made available to a small number of patients because of limited staff and time. At each visit, insulin dose for a given patient might be changed according to physician's order, therefore a variety of marking on the syringes are needed. In addition, since marking on the syringe is gradually faded with repeated uses over time, an error on insulin dosing is more likely.

Previous studies showed that majority of diabetic patients who used insulin injection were the elderly and had only

elementary education.⁵ They were more likely to make error in dosing insulin. It was found that the average loss of insulin was $32.90 \pm 16.84\%$. The reasons for such loss included difficulty drawing the insulin once a small dose of the suspension was left in the vial, the discarded dose when pushing the air bubbles, and the discarded dose of leftover insulin once opening the new vial.⁵ It was found that the average error of insulin syringe drawing was 14.0 ± 6.6 units per person per day. The cause of incorrect insulin syringe drawing was the incorrect reading on the syringe scale despite a correct dose reported by the patient or caregiver. This was because the scale of insulin syringe was misunderstood.⁶ For example, the patient or caregiver could state correctly that the doctor prescribed 24 units, however, they actually drew 28 units of insulin because they thought that each mark indicated one unit of insulin. They also drew 22 units instead of 20 because they placed the tip of the plunger at the unit number needed.

In terms of cost, it was found that the cost of insulin syringe was less than that of insulin pen. It is worth to note that the higher the insulin dose, the greater the cost difference. However, the loss of insulin and wrongly drawn dose were more frequent with insulin syringe. The insulin loss was due to a blurred vision among diabetic patients, a misunderstanding on the scale of the syringe, and difficulty drawing the insulin once a small suspension volume was left in the vial.⁴ In addition, the review of insulin errors by Novo Nordisk, one of the manufacturers of insulin products, found that many people developed diabetes late in life, and needed insulin when they were 60 years or older. Even medical professionals under 40 years of age also faced a 5% error with their own insulin self-administration. It was also found that 50% of the population of 60 years of age or older had dosage errors of insulin injection.⁷ The problem of the error of syringe insulin drawing caused hypoglycemia in diabetic patients.⁸ This hypoglycemia status was still a serious risk for the life and health of diabetic patients treated with insulin especially for the elderly.⁹ To reduce such error, an innovation is needed.

The National Innovation Agency provides the definition of innovation as something new through the use of knowledge and creativity that is beneficial to the economy and society.¹⁰ Everette M. Rogers provides the definition of innovation as an idea, practice, or object that is perceived as new by an individual or other unit adoption.¹¹ Summarily, it can be said

that innovation means ideas, practices, and new inventions that never existed before or the betterment of the existing entities. And when innovation is used, it will help to work better, more efficient and effective. Diffusion of innovations is the process of bringing innovation to the test and deployment to develop community, society and organization. Diffusion of innovations begins with the creation of acceptance, innovation, and transformation. The performance of diffusion of innovations depends on factors such as individual, social system, communication, time and the nature of innovation. There are five main factors that influence adoption of an innovation including relative advantage, compatibility, complexity, trialability and observability. Positive innovation will widespread, while negative innovation will not recognize such as innovation that the users perceive as not better than the original, not compatible with the values and culture of the user, complex or difficult to understand, difficult for trial and not obvious example.¹¹⁻¹³

Based on the problems of error of insulin syringe drawing from Sakaeo Crown Hospital and previous studies, pharmacists have an important role in reducing such errors to prevent the harm of insulin administration in the diabetic patients. A successful insulin use could help improve clinical outcomes and hence quality of life of diabetic patients. To have a better equipment for insulin injection, an innovation to improve the insulin syringe was needed. Thus, the objective of this study was to develop syringe drawing devices for reducing error of insulin injection for diabetic patients at Sakaeo Crown Prince Hospital. Specific objectives of the study were to examine satisfaction, accuracy and precision of the syringe drawing device.

Methods

This was a research and development (R&D) research. The concept of developing the syringe drawing devices for reducing error of insulin injection for diabetic patients at Sakaeo Crown Prince Hospital was originated from the Design Thinking Process which consisted of five stages including Empathize, Define, Ideate, Prototype, and Test.^{14,15} The study was conducted from March 2016 to January 2017.

The study flow and related samples

The device prototype was firstly tested for satisfaction, accuracy and precision by five healthcare providers. The suggestions were obtained and used to improve the prototype. Once improved, the prototype was then tested for satisfaction, accuracy and precision by 10 patients. Again, the suggestions obtained were used for improving the prototype. In the next step, the improved prototype was tested by a sample of 30 patients for satisfaction, accuracy and precision. All suggestions gathered were again used to improve the prototype. Finally the prototype was tested for satisfaction, accuracy and precision by seven out-patient pharmacists. At each step of evaluation, items with less than 3.5-point satisfaction score were improved and re-tested by the participants in that step.

For the five participants of healthcare providers, they were selected by purposive sampling. These included two out-patient pharmacists, two in-patient nurses and one out-patient nurse responsible for advising the patients on injecting insulin using the syringe.

The patient participants were divided into two groups. The first 10 patients were for a preliminary test. They were those who were able to prepare the dose in the syringe correctly based on the evaluation by the research team (error within an acceptable limit). The next group of 30 patients was used to gain a more reliable result among patients. These two groups of patients were selected by convenience sampling method. Inclusion criteria included age of 20 years of older, using insulin at home at least once a day with a dose in the range of 10 to 82 units. They had to prepare the insulin syringe by themselves. They were also able to communicate and willing to participate in the study. The exclusion criteria were the cessation of insulin therapy, change from insulin syringe to insulin pen as prescribed by the doctor, hospitalization, follow-up discontinuation, eyesight disorder or blindness, disorder of extra-pyramidal and movement systems.

For the sample of seven out-patient pharmacists, they were selected using purposive sampling method. They needed to have an experience in advising the patients to use insulin syringe for at least two years.

The development of the device prototype

To help diabetic patients to receive correct does of insulin by the use of insulin syringe, an innovative device

was created by the researcher to reduce drawing error to an acceptable level. With the universal design concept¹⁶, the device was designed to be reusable, less costly, easy and convenient to use, and ready for use. Even though drawing devices specific to various doses of insulin in specific patients could not be made, the device was designed to easily adjust for specific insulin doses. Nurses or pharmacists could adjust the device according to the insulin dose prescribed specifically for given patients. The device was designed to attach on and detach from the syringe barrel easily so it can be reused effectively. Since the insulin injection is supposed to be a sterile procedure, the device was also expected not to damage sterility of the process.¹⁷

The device was made from a plastic straw and colored sticky paper tape. The tape was widely commercially available with various colors to apply for different doses prescribed (Figure 1).



Figure 1 Prototype of the syringe drawing device to reduce dosing made of plastic straw and colored sticky paper tape.

The process of creating the device prototype was as follows. First, plastic straw with a diameter of 8 mm was used since it could be attached on the 100-unit insulin

syringe barrel [Nipro® insulin syringe, 0.33 x 13 mm², Nippon (Thailand) Co., Ltd.]. The straw was cut lengthwise to the length of the syringe with the syringe plunger pulled to its full length (15 cm). The straw was further cut along the length of 0.5 cm wide and wrapped around with the sticky tape to increase the strength and highlight the color which contrasted with the syringe color.

Second, the length of the straw from the first step was measured from the “0” unit to the finger grips of 7-cm long. An area 0.3 x 0.5 cm² on both edges of the straw was cut and removed.

Third, a sticky tape with a size of 0.5 x 4 cm² and the color different from that previously described was prepared. The width of 0.5 cm of the sticky tape was equal to the length of the syringe seal (0.5 cm).

Fourth, the pharmacist took the straw from the second step to wear on the insulin syringe. The plunger was then pulled to reach the insulin dose prescribed. Sticky tape prepared in the third step was attached onto the syringe according to the prescribed dose.

Fifth, the part of the straw that was beyond the push button was cut.

This prototype of syringe drawing devices for reducing error of insulin injection for diabetic patients then underwent the tests for satisfaction, accuracy and precision.

Data collection instrument

A questionnaire to evaluate the participant's satisfaction was created by the researcher. The first part collected the participant's demographic information. The second part asked the participant about their satisfaction and opinion about the device prototype. The questionnaire consisted of 8 items measuring various aspects of the device prototype including practical use (3 items), safety (1 item), appearance (beauty, durability) (2 items), cost-effectiveness (1 item) and overall satisfaction (1 item). The satisfaction response was a rating scale ranging from 1 (lowest) to 2 (low), 3 (moderate), 4 (high) and 5 (highest). Additional comments and suggestions from the participants were allowed with open-ended questions.

Content validity of the satisfaction questionnaire was evaluated using the index of item-objective congruence (IOC). The IOC is usually used for evaluating the content validity on measure at the development stage. We asked three experts to validate the questionnaire. These experts

included one physician specialized in diabetes care for at least one year, and two hospital pharmacists with at least two years of experience in drug use counseling and had a professional level of academic position of the Ministry of Public Health. Based on the IOC validation method, for a given item, a score of +1 was given if the expert agree that the item measured what it was expected to measure, a score of 0 if undecided, and a score of -1 if not measuring what it was expected to measure. The IOC of each individual item was then calculated by summing scores from the three experts and divided by three. With a possible IOC of -1 to +1, items with IOC values of +0.5 or greater were considered acceptable while those with IOC values of less than +0.5 should be revised or eliminated.

In terms of the criteria for acceptable satisfaction in R&D innovation, the average satisfaction score for each aspect of the device prototype should be at least 3.5 out of the total of 5 points.^{18,19} If any of the aspect did not meet the criteria, the prototype should be improved and re-evaluated.

The evaluation of accuracy and precision of the device prototype

The accuracy of the insulin drawing device prototype was evaluated using the relative error. It was calculated by comparing the dose measured by the device prototype compared with that measured by the standard method as guided by the Pharmacy Council of Thailand.²⁰ Based on the ISO standard 11608-1:2012²¹, 3 insulin doses of 1, 40 and 80 units were used for the validation of accuracy and precision of the device. However, the dose of 1 unit was problematic to measure by syringe. Studies showed that for a dose below 10 units, insulin pens were more accurate than syringes; while for a dose of 10 units or higher, pens and syringes offered similar accuracy.^{22,23} Based on the causes of errors mentioned previously^{6,22,24}, this study therefore evaluated accuracy and precision of 3 doses of insulin ranging from low (10 units), medium (44 units) and high (82 units).

The criteria of accuracy testing for insulin doses of 10, 44, and 82 units were relative errors of $\leq 15\%$, $\leq 5\%$ and $\leq 5\%$, respectively.^{22,24} If any of the test doses did not meet the accuracy criteria, the device prototype should be improved and re-evaluated.

In terms of precision, it was evaluated using the coefficient of variation (CV). The CV was calculated by

comparing the standard deviation (SD) of the mean dose of insulin that was drawn by the device with its mean. Three doses of insulin, 10, 44 and 82 units, were tested. The criteria for precision testing was the CV of less than 10%.^{22,24,25} If any of the test doses did not meet the precision criteria, the device prototype should be improved and re-evaluated for precision.

The test procedure of accuracy and precision of the device

To test the accuracy and precision of the insulin, the insulin was drawn by the standard method (standard syringe only) and the syringe drawing device. The standard method was guided by the Pharmacy Council of Thailand²⁰ as follows. First, the vial of insulin was gently rolled in the palm of the hand to disperse the insulin. The vial was not shaken since it would cause bubbles. Second, the insulin syringe was taken out of the container. The air volume equal to the dose of the insulin required was infused into the syringe to prevent a vacuum. Third, the vial of insulin with the syringe was turned upside down. Gradually, a required dose of insulin was drawn from the vial into the syringe. Fourth, the insulin-filled syringe was checked for bubbles. If any, the insulin in the syringe was injected back into the vial and gently redrawn. The bubbles were not harmful, but could be a cause of receiving a dose lower than prescribed.

Insulin drawing using the prototype of syringe drawing device was similar to the standard method previously described. The differences were in the second step. Before injecting the air into the vial, the drawing device was attached to the syringe. The seal of the syringe was in the same plane as the sticky tape.

The test was conducted for three days. On each day, the participants started insulin syringe drawing at 12:30 pm. Each participant drew the insulin by both methods with all three test doses, 10, 44 and 82 units. The participant was told to have a one-minute break between drawings to relax the muscle and eye strain.

Measurement of the test insulin doses

The insulin dose drawn into the syringe was measured by weighing on the analytical balance of digital scale with 4 decimal places. The insulin-filled syringe was rolled gently to disperse the suspension. The beaker was placed on the top of the balance. The balance was then tared to read zero.

The plunger was pushed to expel all insulin suspension into the beaker. The weight was read and recorded.^{22,26}

Data analysis

General information of participants and the results of the evaluation of the satisfaction on the prototype of syringe drawing devices for reducing error of insulin injection were analyzed by descriptive statistics using frequency with percentage and mean. To pass the evaluation of satisfaction, score of each aspect of the device prototype had to be 3.5 points or higher.^{18,19}

For accuracy determination of the drawing device prototype, relative errors were calculated by dividing the difference between weighed insulin doses of the standard method and the drawing device method by the weighed dose of the standard method. All relative error values were converted to percent values by multiplying by 100. Based on the three test doses, specifically 10, 44 and 82 units, relative error values as previously described had to not exceed 15%, 5% and 5%, respectively, to have an acceptable accuracy.^{22,24}

For precision determination of the drawing device prototype, coefficient of variation (CV) value was calculated by dividing standard deviation of the mean of the weighed insulin dose drawn by the device prototype with its mean. All CV values were converted to percent values by multiplying by 100. The CV values had to be less than 10% to have an acceptable precision.^{22,24,25}

Results

The results of this research and development project were divided into two parts: the development of the insulin drawing device prototype and the evaluation on satisfaction, accuracy and precision.

The improvement of the syringe drawing device prototype based on satisfaction of five healthcare providers

The majority of these five healthcare providers had been working in healthcare for 0 – 5 years (60.00%), while the rest had been working for at least 16 years (40.00%). The majority were in their 20 – 29 years of age (60.00%), and female (80.00%).

Among a total eight items, two items were rated lower than 3.5 points including the beauty (3.40 points) and durability (3.00) (Table 1).

Table 1 Satisfaction results of the first evaluation by five healthcare providers.

Topic	Mean score (total of 5 points)	Evaluation result*
1. Practical use		
1.1 Offering a correct dose	4.20	Passed
1.2 Suitable size	3.60	Passed
1.3 Easy to use	4.20	Passed
2. Safety		
2.1 Safe to use	4.20	Passed
3. Appearance		
3.1 Visually pleasant	3.40	Failed
3.2 Durable	3.00	Failed
4. Cost-effectiveness		
4.1 Cost-effective	4.00	Passed
5. Overall satisfaction	3.80	Passed

* A passing cutoff of 3.5 points or higher.

With these rating measures and suggestions obtained from the open-ended questions, the prototype was improved as follows.

To improve the prototype, the silicone tube with a size of 5/16" was used instead of the plastic straw. The researcher had considered a few alternative materials including balloon stick, PVC pipe and silicone tube to replace the plastic straw. The balloon stick was durable, stable, and not rolling onto itself. It was cheap and widely available with various colors and sizes. The drawback was that the balloon stick was too hard to cut with scissors or knife. This difficulty, even though trivial, could make this innovation less likely to be accepted and adapted. Like balloon stick, PVP pipe was durable, stable, not rolling onto itself, cheap, and widely available. It was also hard to cut like the balloon stick, and it could be broken more easily. Finally, silicone tube, a single layer of silicone rubber, was clear with smooth surface, with a good resistance to heat and cold. It was medically safe, odorless and highly flexible. It was durable, stable, not rolling onto itself, cheap and widely available. The clear silicone tube could allow for the easy inspection of the bubble while drawing insulin. Based on the advantages of silicone tube over balloon stick and PVC pipe, the clear silicone tube was chosen for improving the prototype. The colored sticky paper tape was still used in the prototype.

The steps to improve the prototype were as follows. We used the silicone tube with a size of 5/16" with inner and outer diameters of 8 and 12 mm, respectively. This size of silicone tube was compatible with the size of the U-100 insulin syringe available at Sakaeo Crown Prince Hospital, specifically the Nipro® U-100 insulin syringe (a size of 0.33 x 13 mm², manufactured by Nippon (Thailand) Co., Ltd.). First, the clear silicone tube was cut at the length of 8.3 cm. The tube was cut along its length so it became a silicone patch with a width of 5 - 7 mm (Figure 2). At the two edges of the silicone patch, an area of 0.3 x 0.5 cm² on both edges of the patch was cut and removed. The length from one end to the other was 7 cm. A stick tape with a size of 0.5 x 4 cm² and the color different from that previously described was prepared. The width of 0.5 cm of the sticky tape was equal to the length of the syringe seal (0.5 cm). The pharmacist then took the silicone patch to wear on the insulin syringe. The plunger was then pulled to reach the insulin dose prescribed. The sticky tape was attached onto the syringe according to the prescribed dose (Figure 2).



Figure 2 Improved prototype of the syringe drawing device to reduce dosing made of the clear silicone tube after the first round of satisfaction test by five healthcare providers.

This improved prototype was then evaluated for satisfaction by the same five healthcare providers. It was found that all items passed the criteria of 3.5 points with scores ranging from 4.00 to 4.60 points. The item with the lowest score of 4.00 was "suitable size."

The accuracy and precision of the device prototype as tested by five healthcare providers

Once the improved device passed all aspects of satisfaction, accuracy and precision were tested. It was found that accuracy values of insulin doses of 10, 44 and 82 units were 2.63%, 1.42% and 1.84%, respectively (Table 1). With criteria of ≤ 15%, ≤ 5% and ≤ 5% for doses of 10, 44 and 82 units, respectively, accuracy of the device was acceptable. Values of precision of the three doses were 3.23%, 1.82% and 0.44%, respectively, which were acceptable by the cutoff of < 10% for all three doses.

For the dosing using the standard syringe method, accuracy and precision was also acceptable.

Table 1 The accuracy and precision of the syringe drawing device for reducing tested by five healthcare provider based on doses of 10, 44 and 82 units.

Insulin dose (units)	Mean (SD)		Accuracy (Relative error, %)			Precision (Coefficient of variation, %)		
	Test device	Standard method	Criteria	Test device	Standard method	Criteria	Test device	Standard method
10	0.1085 (0.0035)	0.1114 (0.0043)	≤ 15	2.63	0.00	<10	3.23	3.85
44	0.4489 (0.0082)	0.4554 (0.0038)	≤ 5	1.42	0.00	<10	1.82	0.83
82	0.8354 (0.0037)	0.8511 (0.0069)	≤ 5	1.84	0.00	<10	0.44	0.81

Satisfaction, accuracy and precision of the device as tested by 10 patients

Of all 10 patients with correct dosing using insulin syringe, there were more women (60.00%) than men. The majority was in their 40 – 49 years of age (40.00%). Half of them had been using insulin for at least 3 years (50.00%). Most of them had primary education (70.00%). The satisfaction of all items by these 10 patients was established with scores ranging from 4.00 to 4.80 points. The item with the lowest score of 4.00 was "easy to use."

It was found that accuracy values of insulin doses of 10, 44 and 82 units were 6.56%, 4.65% and 4.74%, respectively (Table 2). With criteria of $\leq 15\%$, $\leq 5\%$ and $\leq 5\%$ for doses of 10, 44 and 82 units, respectively, accuracy of the device was acceptable. Values of precision of the three doses were 5.98%, 2.10% and 3.64%, respectively, which were acceptable by the cutoff of $< 10\%$ for all three doses.

For standard dosing method using insulin syringe, accuracy and precision was also acceptable with percent of errors lower than those of the test device.

Table 2 The accuracy and precision of the syringe drawing device for reducing tested by 10 patients based on doses of 10, 44 and 82 units.

Insulin dose (units)	Mean (SD)		Accuracy (Relative error, %)			Precision (Coefficient of variation, %)		
	Test device	Standard method	Criteria	Test device	Standard method	Criteria	Test device	Standard method
	10	0.1041 (0.0062)	0.1106 (0.0029)	≤ 15	6.56	0.76	<10	5.98
44	0.4342 (0.0091)	0.4492 (0.0046)	≤ 5	4.65	1.36	<10	2.10	1.03
82	0.8107 (0.0208)	0.8201 (0.0189)	≤ 5	4.74	2.56	<10	3.64	2.31

Satisfaction, accuracy and precision of the device as tested by 30 patients.

Of all 30 patients, there were more women (80.00%) than men. The majority was in their 60 years of age or older (53.33%). More than half of them had been using insulin for at least 3 years (70.00%). Most of them had primary education (73.33%). The satisfaction of all items by these 10 patients was established with scores ranging from 4.10 to 4.80 points. The item with the lowest score of 4.10 was "durable."

It was found that accuracy values of insulin doses of 10, 44 and 82 units were 5.40%, 3.51% and 4.15%, respectively (Table 3). With criteria of $\leq 15\%$, $\leq 5\%$ and $\leq 5\%$ for doses of 10, 44 and 82 units, respectively, accuracy of the device was acceptable. Values of precision of the three doses were 7.97%, 3.74% and 1.96%, respectively, which were acceptable by the cutoff of $< 10\%$ for all three doses.

Among these 30 patients with considerably older than the groups of 10 patients and of five healthcare providers, coefficient of variation (CV) values which reflected less precision were higher than those found in the test device (16.44%, 6.22%, and 3.67%, for doses of 10, 44 and 82

units, respectively). In addition, at the dose of 10 units, 16.44% CV did not pass the 10% cutoff.

Table 3 The accuracy and precision of the syringe drawing device for reducing tested by 30 patients based on doses of 10, 44 and 82 units.

Insulin dose (units)	Mean (SD)		Accuracy (Relative error, %)			Precision (Coefficient of variation, %)		
	Test device	Standard method	Criteria	Test device	Standard method	Criteria	Test device	Standard method
	10	0.1054 (0.0084)	0.1186 (0.0195)	≤ 15	5.40	6.45	<10	7.97
44	0.4394 (0.0164)	0.4539 (0.0283)	≤ 5	3.51	0.32	<10	3.74	6.22
82	0.8158 (0.0160)	0.8204 (0.0301)	≤ 5	4.15	3.60	<10	1.96	3.67

Satisfaction, accuracy and precision of the device as tested by seven out-patient pharmacists.

Of the 10 out-patient pharmacists, there were slightly more men (57.14%) than women. The majority was in their 20 – 29 years of age (71.43%). The majority had been working in the out-patient department for 0 – 5 years (85.71%). The satisfaction of all items by these 10 patients was established with scores ranging from 4.00 to 4.71 points. The item with the lowest score of 4.00 was "visually pleasant."

It was found that accuracy values of insulin doses of 10, 44 and 82 units were 1.06%, 0.49% and 1.57%, respectively (Table 4). With criteria of $\leq 15\%$, $\leq 5\%$ and $\leq 5\%$ for doses of 10, 44 and 82 units, respectively, accuracy of the device was acceptable. Values of precision of the three doses were 6.89%, 1.25% and 0.83%, respectively, which were acceptable by the cutoff of $< 10\%$ for all three doses.

The accuracy and precision based on the standard method was also acceptable.

Table 4 The accuracy and precision of the syringe drawing device for reducing tested by seven pharmacists based on doses of 10, 44 and 82 units.

Insulin dose (units)	Mean (SD)		Accuracy (Relative error, %)			Precision (Coefficient of variation, %)		
	Test device	Standard method	Criteria	Test device	Standard method	Criteria	Test device	Standard method
	10	0.1103 (0.0076)	0.1110 (0.0048)	≤ 15	1.06	0.41	<10	6.89
44	0.4532 (0.0057)	0.4540 (0.0056)	≤ 5	0.49	0.31	<10	1.25	1.23
82	0.8377 (0.0069)	0.8370 (0.0036)	≤ 5	1.57	1.66	<10	0.83	0.43

From Table 5, it was found that by using the insulin drawing device, the patients were more likely to cause errors than healthcare providers including the pharmacists both in accuracy and precision.

Table 5 Accuracy and precision of the syringe draw device by various groups of participants.

Insulin dose (units)	Criteria for acceptance	Accuracy and precision by groups of participants			
		Five healthcare providers	10 patients	30 patients	7 out-patient pharmacists
Accuracy (Relative error, %)					
10 units	< 15%	2.63	6.56	5.40	1.06
44 units	< 5%	1.42	4.65	3.51	0.49
82 units	< 5%	1.84	4.74	4.15	1.57
Precision (Coefficient of variation, %)					
10 units	< 10%	3.23	5.98	7.97	6.89
44 units	< 10%	1.82	2.10	3.74	1.25
82 units	< 10%	0.44	3.64	1.96	0.83

Discussions and Conclusion

In this research and development research, we aimed to develop the syringe drawing devices for reducing error of insulin injection for diabetic patients at Sakaeo Crown Prince Hospital. Specifically we tested the satisfaction, accuracy and precision of the device using various groups of testers including healthcare providers, patients and pharmacists. The syringe drawing devices for reducing error of insulin injection passed the tests of satisfaction, accuracy and precision.

This device was finally made of silicone tube with a size of 5/16" (inner diameter 8 mm, outer diameter 12 mm). The silicone tube was chosen because it was clear so the bubbles can be seen easily. The size of the tube made attaching onto the U-100 insulin syringe easily. The syringe of this size was available at Sakaeo Crown Prince Hospital. It was Nipro[®] U-100 insulin syringe with the size of 0.33 x 13 mm², manufactured by Nippon (Thailand) Co., Ltd. With the bright color of the sticky paper tape attached on the device, the patient was able see the mark of the prescribed dose clearly.

In terms of satisfaction, the improved device was acceptable in all aspects. However, the lowest scores were found in items of "suitable size" (score of 4.00 points) by healthcare providers, "easy to use" (4.00 points) by 10 patients, "durable" (4.10 points) by 30 patients, and "visually pleasant" by seven out-patient pharmacists. This subjective judgment led to different opinion among different groups of

testers. However, all aspects with low score, even though meeting the criteria of 3.5 points cutoff, need a closer look for improvement.

The accuracy and precision of the drawing device passed all the criteria by all groups of testers. However, errors were usually higher with the device than the standard syringe method. The lower does was more likely to be associated higher errors. As expected, patients were more likely to cause higher levels of errors than healthcare providers including pharmacists.

In terms of reducing errors, the device helped reducing errors as shown by coefficient of variation (precision) among 30 patients. The values of coefficient of variation (CV) by standard method were 16.44%, 6.22% and 3.67% for insulin doses of 10, 40 and 82 units, respectively. While CV values by the test device were 7.97%, 3.74% and 1.96%, respectively, which were lower than those by the standard method. Therefore, this drawing device could have been useful for the patients. We could conclude that the prototype of the insulin drawing device was useful in reducing the errors.

The device prototype development based on the concept of Design Thinking Process which consisted of five stages including Empathize, Define, Ideate, Prototype, and Test was possible.^{14,15}

Compared with the standard drawing method, it seems that the device did not reduce errors in most tests. This was consistent with the study of Gnanalingham et al. (1998).²² This relatively disappointing results could be due to the fact that, in most part, participants were professionals who had an extensive experience in insulin drawing by the standard method. The performance could also depend on the size of the silicone tube and the color sticky tape together with how accurate the colored sticky tape was put on the silicone tube by the pharmacist. It also depended on the participants' technique on the device prototype. Compared with the standard method, most participants were unfamiliar with the device prototype. Therefore, this device might need a certain amount of skill training for the patient. Video for training could also be helpful for skill build-up.

The application of the device has another limitation. If the size of the insulin syringe is different from the one tested in this study (Nipro[®] U-100 insulin syringe, with the size of 0.33 x 13 mm, manufactured by Nippon (Thailand) Co., Ltd.), it will be necessary to change the size of the silicone tube and

the colored sticky paper tape. In addition, the application of insulin dose out of the range of 10 to 82 units was not supported by this study. Furthermore, one should consider insulin pen for doses lower than 10 units for a better accuracy.

With our relatively inconclusive results, we suggest studies with larger sample sizes and various sizes of the syringe to accommodate a wide variety of insulin syringe. We also recommend creating the devices using other concepts and materials, such as polymers.

References

- American Diabetes Association. Standards of medical care in diabetes-2014. *Diabetes Care* 2014;37(Suppl 1):S14-80.
- Diabetes Association of Thailand under the Patronage of Her Royal Highness Princess Maha Chakri Sirindhorn. Clinical practice guideline for diabetes 2014. Bangkok. Aroonkarpim Publishing, 2014: pp.17-18. (in Thai)
- Selam JL. Evolution of diabetes insulin delivery devices. *J Diabetes Sci Technol* 2010;4(3):505-513.
- Sincharoenmanee A. Comparison of cost and outcomes between reusable pen and syringe/vial for diabetics with insulin therapy at Nakhonchaisi Hospital. M.Pharm. (Clinical Pharmacy) degree thesis. Nakhonpathom. Silpakorn University, 2005.
- Panichcharoen N. The evaluation of insulin wastage by diabetes mellitus patients in Promburi Hospital. *J Gov Pharm Org* 2014;40(2): 20-26. (in Thai)
- Pawasuthipaisit A, Chunsrisuriyawong A. The evaluation for the error of insulin drawing up into the syringe in diabetic patients at Nong Bua Lamphu Hospital. Research report. The Association of hospital Pharmacy (Thailand). 2006. (Accessed on Sep. 11, 2014, at http://www.thaihp.org/index.php?option=other_detail&lang=th&id=43&sub=26) (in Thai)
- Diabetes in Control: News and Information for Medical Professionals. A review of insulin errors. 2014. (Accessed on Aug. 1, 2015, at <http://www.diabetesincontrol.com/-a-review-of-insulin-errors/>)
- Ruangsrri N. A study of hypoglycemia in diabetic patients at Phichit Hospital. *Phichit Hosp J* 2008;23(2):133-140. (in Thai)
- Stepka M, Rogala H, Czyzyk A. Hypoglycemia: A major problem in the management of diabetes in the elderly. *Aging Clin Exp Res* 1993;5(2): 117-121.
- Public Sector Innovation Center. Definition of Innovation. (Accessed on Feb. 4 2016, at [http://www.opdc.go.th/psic/main.php?url=content &gp=1 &mn=3](http://www.opdc.go.th/psic/main.php?url=content&gp=1 &mn=3)) (in Thai)
- Rogers EM. Diffusion of innovations, 3th ed. New York. Free Press, 1983: pp.10-12.
- Pittayapitak T, Vicheanpant T. Innovation diffusion: Concept and model. *J Lib Info Sci Srinakharinwirot Univ* 2012;5(1):107-118. (in Thai)
- Popaiboonwong P. Factors affecting the acceptance of team work system innovation in employees performance of Kanok Sin Export Co., Ltd. The 6th Conference of Graduate Studies Research, Sep. 18, 2010. (in Thai)
- Hassoplattner Institute of Design at Stanford. An introduction to design thinking process guide. (Accessed on Sep. 30, 2015, at http://waag.org/sites/waag/files/public/media/publicaties/design_thinking_process_guide-by-nc.pdf)
- Dam RF, Siang TY. 5 stages in the design thinking process. 2017. (Accessed on May 15, 2017, at <https://www.interaction-design.org/literature/article/5-stages-in-the-design-thinking-process>)
- Thai Health Promotion Foundation. Universal design: Design for all people. 2011. (Accessed on Aug. 14, 2015, at <http://goo.gl/BRpsfO>) (in Thai)
- Notification of Ministry of Public Health. Single-use disposable insulin syringes. *The Royal Thai Government Gazette* 2010;127 (special issue 151):26-28. (in Thai)
- Jiraro P. Objective, Indicator and criterion for project evaluation. *J Educ* 2013;24(3):25-36. (in Thai)
- Kampiriyapong N. Project performance report "Innovative Teaching of Diabetes Injection of Insulin." 2013. (Accessed on Sep. 2, 2015, at http://hospital.tu.ac.th/PlanTUHosWeb/data/Project%20CQI/CQI_2556/56_076.pdf) (in Thai)
- Chutimaworapan P, Wongpoowarak P, Hemajutha A (eds.). The manual of skills on professional qualifications of pharmacy professionals. Nonthaburi. The Pharmacy Council of Thailand, 2011: pp.104-105. (in Thai)
- International Organization for Standardization. Needle-based injection systems for medical use-requirements and test methods-part 1: needle-based injection systems. ISO 11608-1:2012. 2012.
- Gnanalingham GM, Newland P, Smith CP. Accuracy and reproducibility of low dose insulin administration using pen-injector and syringes. *Arch Dis Child* 1998;79(1):59-62.
- Lteif AN, Schwenk FW. Accuracy of pen injectors versus insulin syringes. *Diabetes Care* 1999;22:137-140.
- Ginsberg BH. Clinical use and evaluation of insulin pens. *J Diabetes Sci Technol* 2016;10(1):162-163.
- Puxty JA, Hunter DH, Burr WA. Accuracy of insulin injection in elderly patients. *Br Med J (Clin Res Ed)* 1983;287:1762.
- Notification of the Ministry of Industry No. 4029 (BE 2552) issued under the Industrial Product Standards Act BE 2511. Cancellation and standardization of industrial products: Single-use disposable insulin syringes. *The Royal Thai Government Gazette* 2009;126 (special issue 150):12. (in Thai)

Editorial note

Manuscript received in original form on April 20, 2017;
accepted in final form on June 17, 2017