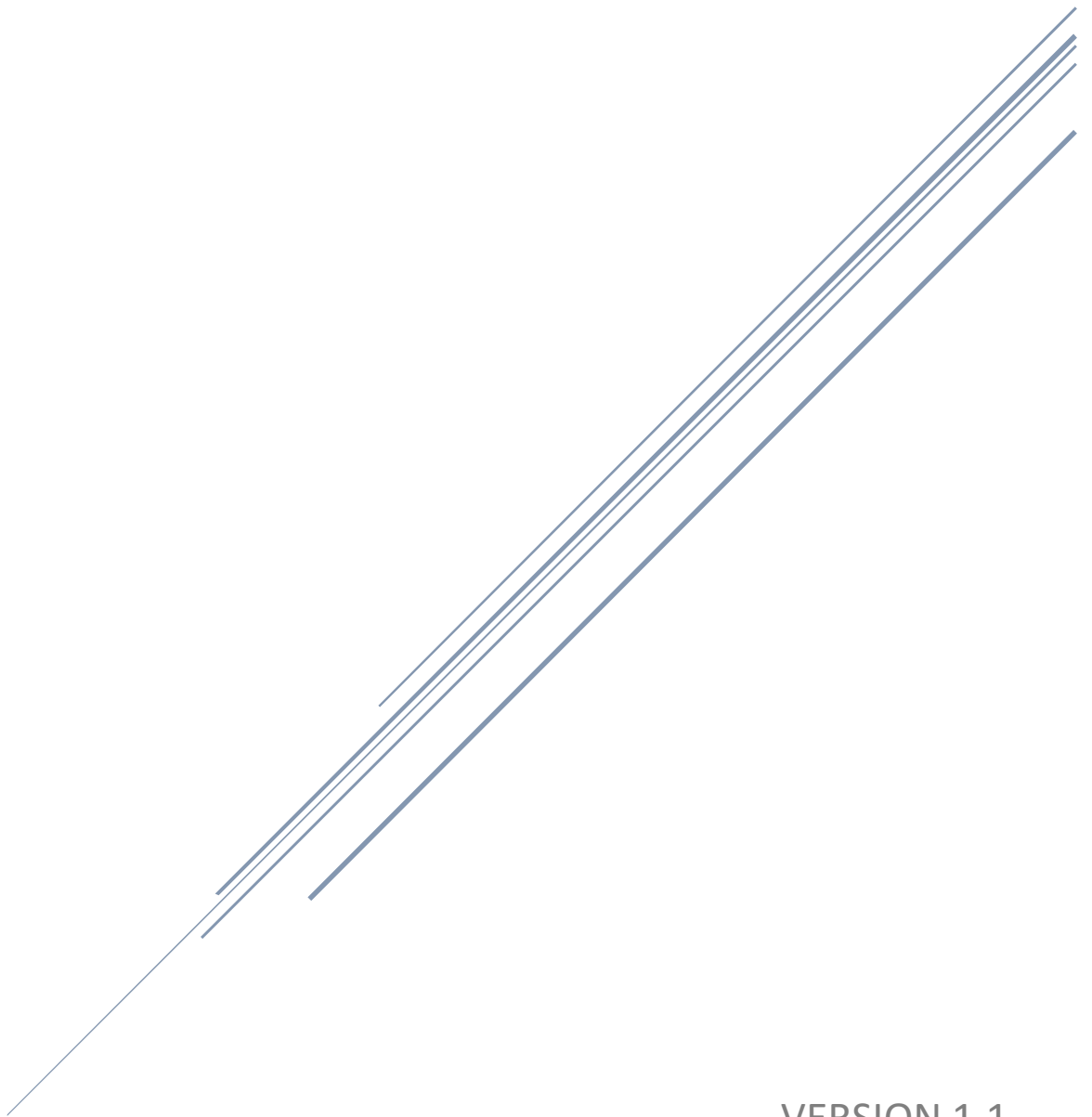


## STUDY PROTOCOL



## STUDY PROTOCOL

*I acknowledge receipt of the Clinical Study Protocol for the Study entitled “Can a montmé Coloured Pen Needle (mCPN) Intervention Improve Injection Site Rotation Habits in Established Insulin Users?” (Version 1.1; Jul 23, 2018)*

*Name*

*Signature*

*Date*

VERSION 1.1  
Jul 23, 2018

## 1. Steering Committee

- Lori D Berard RN CDE  
Chair and Principal Investigator  
Winnipeg, MB | Fax: 1-204-272-3354 | Email: mcpndata@gmail.com
- Sherri Pockett RN CDE
- Robert ROSCOE BScPharm ACPR CDE CPT
- Rick L Siemens BScPharm BSc Biology CDE CPT

## 2. Overview

The Forum for Injection Technique (FIT)<sup>1</sup> was established to provide guidance and evidence-based best practice recommendations to health care professionals working with people with diabetes who are using injectable therapies. The 3<sup>rd</sup> Edition of the Canadian FIT recommendations<sup>2</sup> states that all insulin-using patients should receive education on proper insulin injection technique including site rotation at the time of insulin initiation. Patient technique should be assessed at least annually, and education on proper insulin injection technique should be reinforced at every follow-up visit. The importance of site rotation must be underscored at these education sessions and patients should be made aware that the act of switching injection sites will help keep the injection site tissue healthy thereby promoting insulin absorption and reducing glycemic variability. The most significant complication of poor injection technique is lipohypertrophy.<sup>3-10</sup>

Lipohypertrophy is an abnormal accumulation of fat underneath the surface of the skin that usually presents as lumpy skin.<sup>11, 12</sup> Diabetes-associated lipohypertrophic lesions arise in part because insulin concurrently promotes lipogenesis, inhibits lipolysis and accordingly hinders the breakdown of adipose tissue. However, lipohypertrophy in diabetes has primarily been linked with repeated trauma due to lack of injection site rotation.<sup>12, 13</sup> While it has been posited that needle reuse may also contribute to and enhance the presentation of lipohypertrophy, this school of thought has not been validated.<sup>4-6, 8, 9</sup>

Patient education emphasizing the importance of injection site rotation as best practice is provided as a standard of care management strategy.<sup>2</sup> However, the same has not been translated into routine self-care practice. Indeed, data accumulated over the last 10 to 15 years from injection practice surveillances and a meta-analysis suggest that the incidence of lipohypertrophy<sup>4, 6-10, 14-16</sup> is on the rise despite the availability of new insulin therapies, and smaller and finer needles. Notably, participants of the Worldwide Injection Technique Questionnaire Study reported general lack of knowledge about the need for site rotation or perceived lack of education regarding the importance of site rotation.<sup>8, 15</sup>

Improving injection site health by reducing lipohypertrophy is essential for people living with diabetes. Injection of insulin into the anatomical areas, zones and/or sites affected by lipohypertrophy has been reported to increase glycemic variability, unexplained hypoglycemia as well as increased insulin doses.<sup>6</sup>

Given the rising awareness of lipohypertrophy occurrences amongst diabetes care providers, assessment of patient injection technique and education emphasizing the importance of site rotation is slowly being incorporated into diabetes-focused visits. These initiatives, however, appear to remain inconsistent across all diabetes care providers. Indeed, insulin-injecting individuals living with diabetes who do not have access to health care professionals who are aware of the importance of site rotation likely have not had their injection routines/sites assessed recently or participated in discussions about the significance of site rotation.

For a variety of reasons, access to a diabetes care provider can be extremely challenging for people with diabetes including those who are using injectable insulin therapies.<sup>17</sup> In contrast, these individuals regularly visit their pharmacies to collect prescriptions and injection-related supplies. Pharmacists are well positioned to assess and discuss injection technique when dispensing a box of insulin pen needles. Although pharmacists are rarely involved in the initiation of insulin therapy, routine follow-up of the injection practice can be quite effectively incorporated into their routine overall assessment of their clients. Granted, many pharmacists may not feel comfortable, confident nor have the necessary facilities to examine for and assess lipohypertrophy. It is quite feasible, however, for them to ask key questions at the dispensing counter to help determine if their clients may be at risk for lipohypertrophy.

A busy pharmacy may limit the time that a pharmacist is able to devote to lipohypertrophy queries and examinations. As with other diabetes healthcare providers, pharmacists are likely to also have a wide range of knowledge and experience (from very little to substantial) with lipohypertrophy and how proper injection site rotation can influence their manifestation.

Each box of montméd Coloured Pen Needles (mCPN) has the following five features:

- i. *Distinctively coloured* pen needles
- ii. A user-defined *association tool* which is intended to help the patient associate each colour to a specific injection zone
- iii. A concise and intuitive educational message “*Change color, change site*” *site*<sup>TM</sup>
- iv. *Unique packaging* with educational content
- v. Four *distinctive message-in-a-box educational sound-chips* which serve to reinforce the recommended educational message on site rotation at home and come on every tenth time the pen needle box is opened

The current research study has accordingly been designed to determine if a “pharmacist-dispensed montméd Coloured Pen Needle (mCPN) intervention” will improve injection site rotation relative to the standard dispensing of non-mCPN insulin pen needles.

### **3. Background and Rationale**

The Canadian FIT<sup>2</sup> recommends considering the anatomical areas of the body, the zone (injection area divided into quadrants) and the site (point of insertion) when initiating injection site rotations. Proper rotation within a zone includes the use of the entire zone while ensuring that the new injection site is at least 1 to 2 cm from a recently used site. Currently, diagrams delineating anatomical areas and the zones within the area comprise the primary form of educational tools. However, these diagrams do not sufficiently emphasize the availability of multiple zones within the area to facilitate utilization of more of the anatomical area. Within zone site rotation is also poorly addressed.

Individuals with diabetes who use insulin tend to favour certain anatomical areas when administering their daily insulin dose. Potential, but not as yet verified, reasons for preferring these “hot spots” may include accessibility, habit or reduced discomfort due to the presence of lipohypertrophy.

FIT Canada has recently taken proactive steps to improve the available educational tools with the overarching goal to increase awareness of proper injection site rotation. These updated/new tools together with other similar initiatives have been designed to promote self-care actions and encourage insulin users to develop new injection practices. These include administering their insulin at a specific area at a particular time during the day or utilizing a rotation tool to enhance within site rotations.

Integration of a site rotation injection aid to facilitate injection site rotation should theoretically expand the injection area and injection zone. However, such a practice has never been evaluated previously. The montméd Coloured Pen Needles were specifically designed to encourage injection site rotation amongst people with diabetes. Importantly, montméd Coloured Pen Needles can be easily dispensed within the normal workflow of retail pharmacies with little additional explanation needed thereby imposing minimal disruption on the pharmacists’ other obligations.

### **4. Significance**

This 30-day research study will provide insight and evidence regarding the usability and feasibility of a mCPN intervention to improve the practice of injection site rotation. It will also evaluate the educational components that have been incorporated as part of the packaging.

The impact of the mCPN intervention will be determined by comparing the percentage of participants in the intervention (mCPN) group who has exhibited an improvement in injection site rotation at study end relative to the same measure in the group that was randomized to receive their usual insulin pen needles.

## 5. Study Design and Conduct

### 5.1. Overview

This is a 30-day, two-arm, randomized, controlled study.

Enrolled participants will be randomly assigned to one of the following study arms:

- **Control group:** participating pharmacists will dispense boxes of standard insulin pen needles to the patient participants
- **mCPN group:** participating pharmacists will dispense boxes of montméd Coloured Pen Needles to the patient participants

### 5.2. Study Sites and Participating Pharmacists

All pharmacies in Canada that provide services to individuals with diabetes who use injectable insulin therapy will be eligible to participate in this study. All participating pharmacists who will play an active role in participant enrollment and the follow-up visits will be required to complete a participation consent form and 2 surveys. The first (Pre-study survey) should be completed after they have been fully trained on the study protocol and their study obligations, and before commencement of study enrollment. The second (Post-study survey) should be completed after the last patient has completed the 30-day follow-up visit. (Refer to Section 11 for the Study Flow).

### 5.3. Randomization Process

Participating pharmacists will dispense one of the two study pen needles according to a computer-generated list that will be provided to the participating pharmacy upon site activation.

### 5.4. Hypotheses, Objectives and Endpoints

#### 5.4.1. Primary Hypothesis

A pharmacist-initiated mCPN intervention at point of dispensing will enhance injection site rotation amongst individuals with diabetes who are using insulin therapy.

#### 5.4.2. Primary Objective

To determine if a retail pharmacy-based, pharmacist-led mCPN intervention will facilitate and improve injection site rotation amongst insulin-using people with diabetes.

#### 5.4.3. Primary Endpoint

The percentage of participants in the mCPN group who demonstrate an improvement (vs

baseline performance) in the recommended site rotation techniques relative to the proportion of that in the control group.

#### **5.4.4. Secondary Hypotheses**

Pharmacists have a variable knowledge foundation on the importance of injection site rotation with injectable therapy and this dampens their comfort and confidence in providing injection site rotation counselling. A pharmacist-led mCPN intervention will promote overall good injection site rotation practices.

#### **5.4.5. Secondary Objectives**

To determine if a retail pharmacy-based, pharmacist-led mCPN intervention will

- i. improve the knowledge base of pharmacists around injection site rotation and increase their comfort and confidence in providing injection site rotation counselling
- ii. Expand the injection zone size
- iii. Increase needle change
- iv. Increase mCPN use following study completion

#### **5.4.6. Secondary Endpoints**

The change in the level of confidence in providing injection site rotation counselling (Confidence and Importance Scale), and knowledge about the importance of site rotation among pharmacists at the follow-up from baseline. Other secondary endpoints that will be assessed include the increase/change in injection zone size, percentage of participating patients who change their needles more often (patient reported), and the percentage of participating patients who decide to continue using mCPN upon study completion.

## **6. Study Population**

### **6.1. Inclusion Criteria**

- Adults (18 years or older) with type 1 diabetes mellitus or type 2 diabetes mellitus who have been using daily insulin therapy for 1 year or more
- Able to read the English text on the boxes of the pen needles

### **6.2. Exclusion Criteria**

- Individuals currently treated with a glucagon-like peptide 1 receptor agonist (GLP-1RA)
- Current or previous user of mCPN
- Individuals who are unable to understand or communicate in English
- Pregnant women
- Individuals with serious mental illnesses eg. dementia, schizophrenia disorders, bipolar disorders, major depression, etc.

## 7. Data Collection

Participating patients and pharmacists will be required to complete 2 questionnaires/surveys. The data from these 4 documents will be collated and used to inform on the potential benefits of the mCPN intervention.

The Participating Patient Questionnaires (please refer to Appendix 7 and Appendix 8) will capture basic demographic details, the number of injections the participant administers each day, the length of the needle, the injection area and the participant's injection site rotation practices. Every participant will be asked to complete the first questionnaire prior to study intervention and the second at study end (30 days after the intervention).

The Pharmacist Surveys (please refer to Appendix 9 and Appendix 10) will capture the pharmacists' perspectives on the importance of injection site rotation and their level of knowledge about lipohypertrophy. The pharmacist investigators will also be asked about their confidence around providing counseling on injection site rotation to individuals at the pre- and post-intervention visits. The first survey should be completed and submitted immediately after study training has been completed.

## 8. Sample Size

Sample size calculation was based on the primary endpoint. To ensure an 80% power to detect a difference in the proportion of 0.2 (20%) between the intervention and control group at a significance level of 5%, 90 participants are required for each study arm. Adjusting for the clustering of participants around sites via an intra-cluster correlation coefficient of 0.01 and accounting for a 5% participant dropout rate, a minimum of 117 participants per study group will be required.

Twenty pharmacies (sites) will be recruited to participate in this study and each site will be expected to enroll 12 participants. Accordingly, a total of 240 insulin-using individuals (120 per group) will be enrolled into the study. Each pharmacy site will be asked to recruit 6 individuals who are on  $\leq 2$  injections and 6 individuals who are on  $\geq 3$  injections of insulin each day. The rationale behind including these 2 specific subgroups is to ensure individuals with both type 1 and type 2 diabetes are represented in the final analyses. Of note, the education requirements and support access vary according on the type of diabetes each person lives with. The sub-grouping will therefore also facilitate the capturing of a broader scope of real-world experience with site rotation. Randomization will be facilitated at the site level versus the study level. Randomization codes for each subgroup will be scrambled and provided to the sites to be opened after consent is obtained.



The study will employ a convenience sampling with 1:1 randomization of eligible subjects to the standard of care education with one arm utilizing the mCPN intervention and the other maintaining the current insulin pen needle. A control group of 120 persons (60 on  $\leq 2$  injections a day and another 60 on  $\geq 3$  injections a day) will be randomized to keep using their current pen needle. An intervention group of 120 (60 on  $\leq 2$  injections a day and another 60 on  $\geq 3$  injections a day) will be randomized to receive mCPN Intervention.

Of note, the mCPN packaging contains educational information that will not be promoted but instead distributed without any direct emphasis on the instructions provided. Subjects will be asked to evaluate this information.

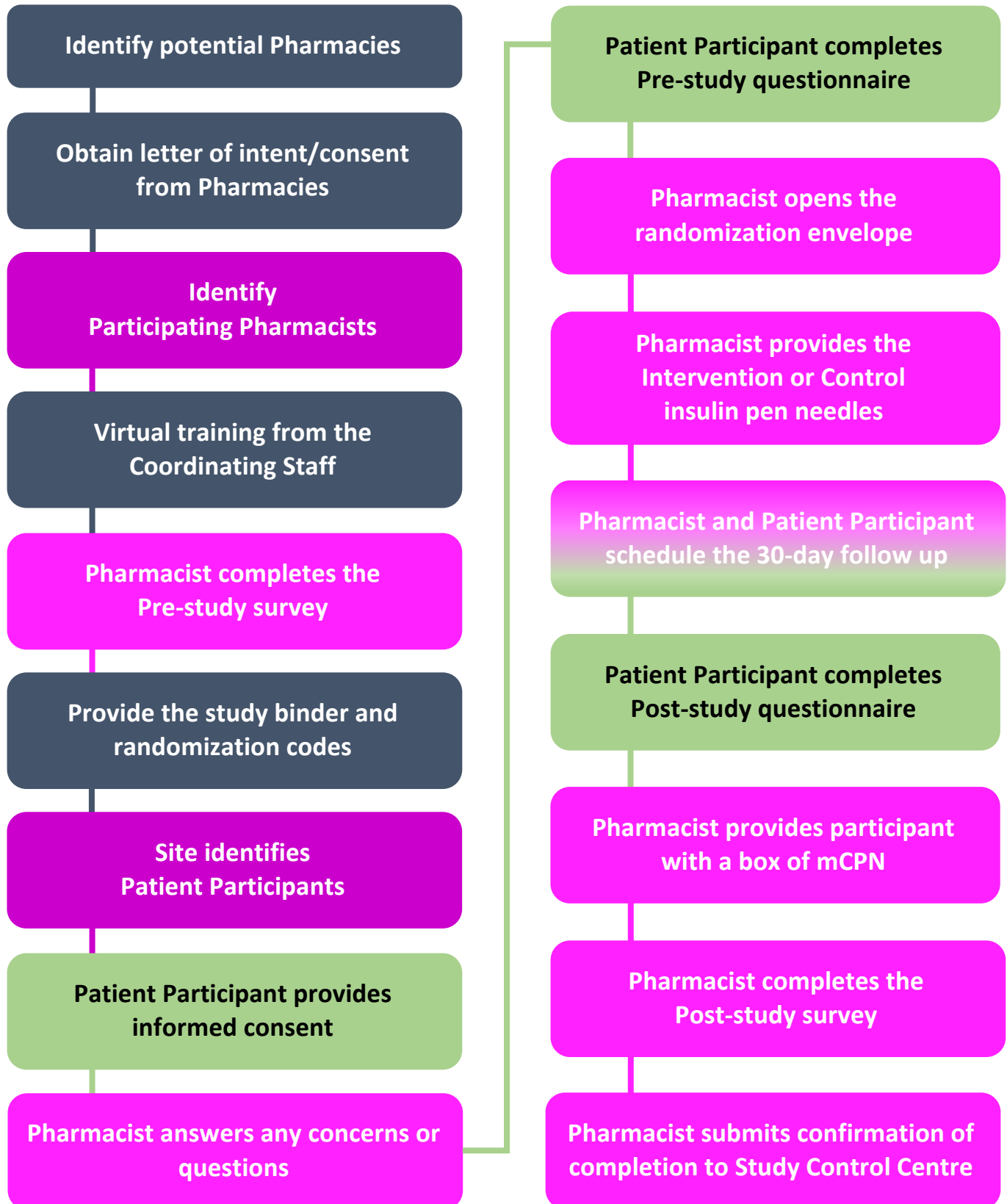
## **9. Data Analysis**

Data from the completed patient and pharmacist surveys will be entered into a Microsoft Access database. Categorical and continuous data, collected for the baseline and follow-up visits, will be evaluated by frequency distribution and univariate analysis, respectively. A generalized linear regression model will be used to compare the relative changes in the primary and secondary endpoints determined for the control and intervention groups. All data will be adjusted for baseline age, daily number of injections, duration of diabetes and duration of insulin use. All analyses will be conducted with SAS software version 9.4.

## **10. End of Study**

As an appreciation of their participation and to facilitate retention, all patient participants regardless of the study arm that they were randomized to will be invited to choose between taking home a Home Blood Pressure Monitor or a FRIO Insulin Cooling Case. Participants who were allocated to the Control Group will be eligible to receive a set of the insulin study pen needles at no cost, if they wish to try these pen needles. Participants who were allocated to the mCPN Group will have the option of continuing with the insulin study pen needle or returning to the insulin pen needle that they previously used.

### 11. Procedures and Study Flow



## 12. References

1. Hicks D, Berard L, Twamley H. Forum for Injection Technique (FIT). <http://www.fit4diabetes.com/canada-l/>
2. Berard L, Desrochers F, Hagerty D, MacNeill G, Roscoe R. FIT Forum for Injection Technique Canada. 2016
3. Al Ajlouni M, Abujbara M, Batieha A, Ajlouni K. Prevalence of lipohypertrophy and associated risk factors in insulin-treated patients with type 2 diabetes mellitus. *Int J Endocrinol Metab.* 2015;13:e20776
4. Al Hayek AA, Robert AA, Braham RB, Al Dawish MA. Frequency of Lipohypertrophy and Associated Risk Factors in Young Patients with Type 1 Diabetes: A Cross-Sectional Study. *Diabetes Ther.* 2016;7:259-267
5. Baruah MP, Kalra S, Bose S, Deka J. An Audit of Insulin Usage and Insulin Injection Practices in a Large Indian Cohort. *Indian J Endocrinol Metab.* 2017;21:443-452
6. Blanco M, Hernandez MT, Strauss KW, Amaya M. Prevalence and risk factors of lipohypertrophy in insulin-injecting patients with diabetes. *Diabetes Metab.* 2013;39:445-453
7. Deng N, Zhang X, Zhao F, Wang Y, He H. Prevalence of lipohypertrophy in insulin-treated diabetes patients: A systematic review and meta-analysis. *J Diabetes Investig.* 2017
8. Frid AH, Hirsch LJ, Menchior AR, Morel DR, Strauss KW. Worldwide Injection Technique Questionnaire Study: Injecting Complications and the Role of the Professional. *Mayo Clin Proc.* 2016;91:1224-1230
9. Ji L, Sun Z, Li Q, Qin G, Wei Z, Liu J, Chandran AB, Hirsch LJ. Lipohypertrophy in China: Prevalence, Risk Factors, Insulin Consumption, and Clinical Impact. *Diabetes Technol Ther.* 2017;19:61-67
10. Pozzuoli GM, Laudato M, Barone M, Crisci F, Pozzuoli B. Errors in insulin treatment management and risk of lipohypertrophy. *Acta Diabetol.* 2018;55:67-73
11. Thow JC, Johnson AB, Marsden S, Taylor R, Home PD. Morphology of palpably abnormal injection sites and effects on absorption of isophane(NPH) insulin. *Diabet Med.* 1990;7:795-799
12. Richardson T, Kerr D. Skin-related complications of insulin therapy: epidemiology and emerging management strategies. *Am J Clin Dermatol.* 2003;4:661-667
13. Hauner H, Stockamp B, Haastert B. Prevalence of lipohypertrophy in insulin-treated diabetic patients and predisposing factors. *Exp Clin Endocrinol Diabetes.* 1996;104:106-110
14. Frid AH, Hirsch LJ, Menchior AR, Morel DR, Strauss KW. Worldwide Injection Technique Questionnaire Study: Population Parameters and Injection Practices. *Mayo Clin Proc.* 2016;91:1212-1223
15. Kalra S, Mithal A, Sahay R, John M, Unnikrishnan AG, Saboo B, Ghosh S, Sanyal D, Hirsch LJ, Gupta V, Strauss KW. Indian Injection Technique Study: Injecting Complications, Education, and the Health Care Professional. *Diabetes Ther.* 2017;8:659-672

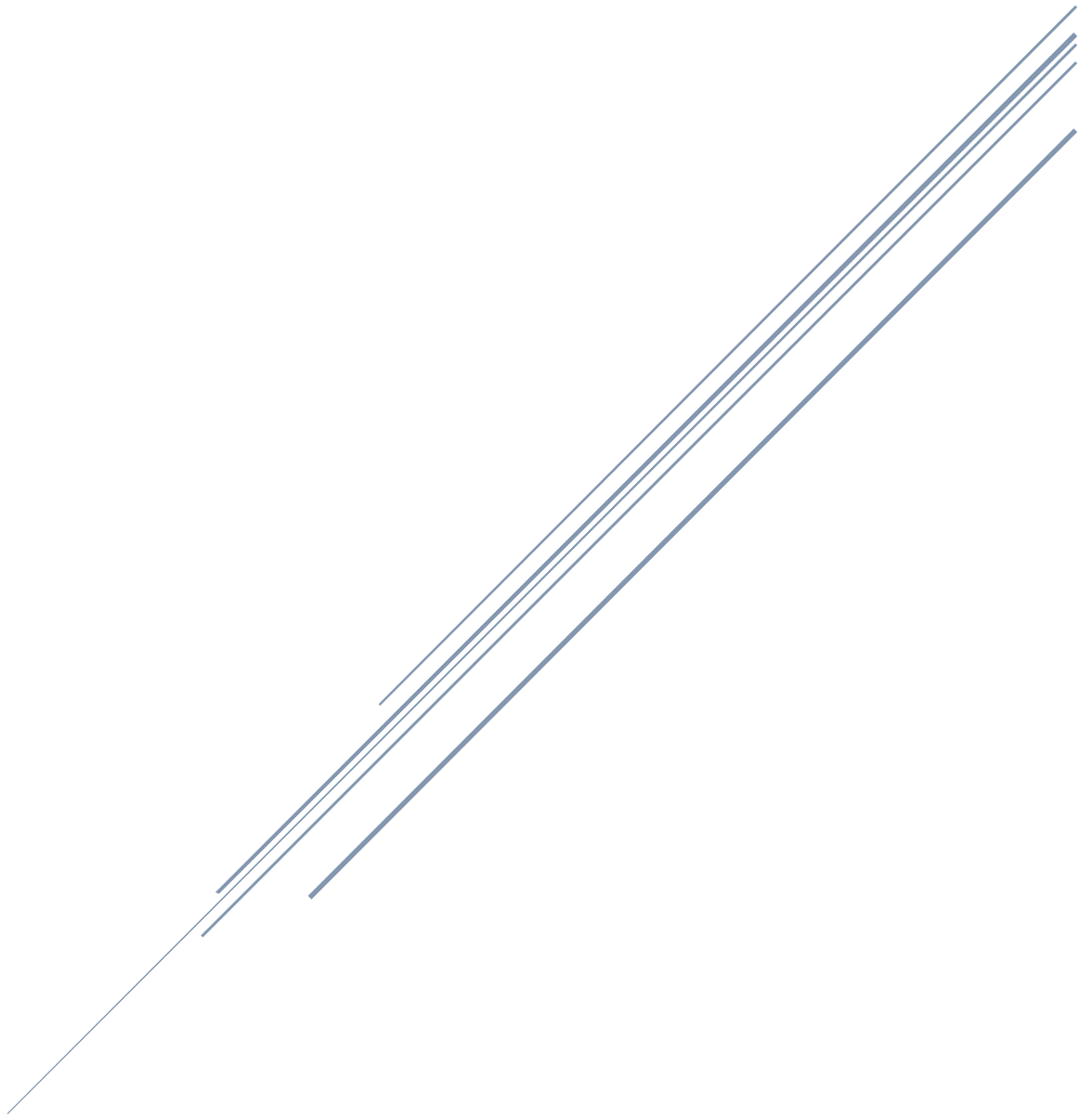
16. Kalra S, Mithal A, Sahay R, John M, Unnikrishnan AG, Saboo B, Ghosh S, Sanyal D, Hirsch LJ, Gupta V, Strauss KW. Indian Injection Technique Study: Population Characteristics and Injection Practices. *Diabetes Ther.* 2017;8:637-657
17. Canadian Diabetes Association. An economic tsunami, the cost of diabetes in Canada. 2009

## Receipt of Study Documents Checklist

- Clinical Study Protocol (Version 1.1; dated Jul 23, 2018)
- Invoice Templates (Appendix 1)
- Patient Participant Recruitment Script (Appendix 2)
- Injection Area, Zone and Site Chart (Appendix 3)
- Study Intervention (mCPN Packaging) (Appendix 4)
- Information Letter and Consent Form for Patient Participants (Appendix 5)
- Pharmacists' Letter of Agreement (Appendix 6)
- Pre-study Questionnaire for Patient Participants (Appendix 7)
- Post-study Questionnaire for Patient Participants (Appendix 8)
- Pre-study Survey for Pharmacists (Appendix 9)
- Post-study Survey for Pharmacists (Appendix 10)
- Follow up/Tracking Form (Appendix 11)
- Site Information Sheet

Please return the completed checklist to the attention of Lori Berard  
Fax: 1-204-272-3354 | email [mcpndata@gmail.com](mailto:mcpndata@gmail.com)

## APPENDICES



Jul 23, 2018

## **Appendix 1**

### **Invoice Templates**

## Invoice for Completion of Study

**Study Title: Can a Montméd Coloured Pen Needle (mCPN) Intervention Improve Injection Site Rotation Habits in Established Insulin Users?**

Site #:

Participant #:

Name of Pharmacist Investigator: \_\_\_\_\_

No. of completed patient pre-participation questionnaires:

No. of completed patient post-participation questionnaires:

No. of completed pharmacist post-participation questionnaires:

Total compensation requested: \$    .



## Invoice for Purchase Costs of Control Group Pen Needles

**Study Title: Can a Montmé Coloured Pen Needle (mCPN) Intervention Improve Injection Site Rotation Habits in Established Insulin Users?**

Site #:

Participant #:

Name of Pharmacist Investigator: \_\_\_\_\_

Type of insulin pen needles dispensed: \_\_\_\_\_

No. of boxes provided for the study period:

Cost for each box of pen needles: \$   .

Total reimbursement requested: \$    .

## **Appendix 2**

### **Patient Participant Recruitment Script**

Can a Montmé Coloured Pen Needle (mCPN) Intervention Improve Injection Site Rotation Habits in Established Insulin Users? Participant Recruitment Script

Dear XXXX,

I am currently involved in a nationwide study that is looking at whether use of a specific type of insulin pen needle will alter how individuals administer their insulin. If you decide to participate in this study after the pharmacist has reviewed with you the study goals and expectations, you will be required to provide written consent as well as complete 2 short surveys over the 30-day long study period.

As a reminder, participation in this study is completely voluntary and you may choose to withdraw from the study at any time.

You will be asked to complete the first survey today. Once you have handed in your completed survey, you will be randomly assigned to one of the following two groups:

**Group 1:** You will receive your usual insulin pen needles

**Group 2:** You will receive the insulin study pen needles instead of your usual insulin pen needles

Please note that during the 30-day study period, you will not incur any costs for the insulin pen needles that you need to use, regardless of whether they are the study pen needles or your usual pen needles.

You are required to use the assigned insulin pen needles you were given today for at least 30 days. At the end of the minimum 30-day period, you will need to complete the second survey.

Once you have completed the second survey,

1. You will be invited, as a token of our appreciation for participating in this study, to choose between taking home a *Home Blood Pressure Monitor* or a *FRIO Insulin Cooling Case*, a carrier that will help you keep and transport your insulin safely.
2. If you were in **Group 1**, you will be eligible to receive a set of the insulin study pen needles at no cost.
3. If you were in **Group 2**, you will have the option of continuing with the insulin study pen needle or returning to the insulin pen needle that you previously used.

Please note that during the 30-day study period and prior to you completing the second survey, we will not be able to answer any questions related to the injection technique. However, we would be more than pleased to discuss any queries you may have once the 30-days are up and you have handed in the second survey.

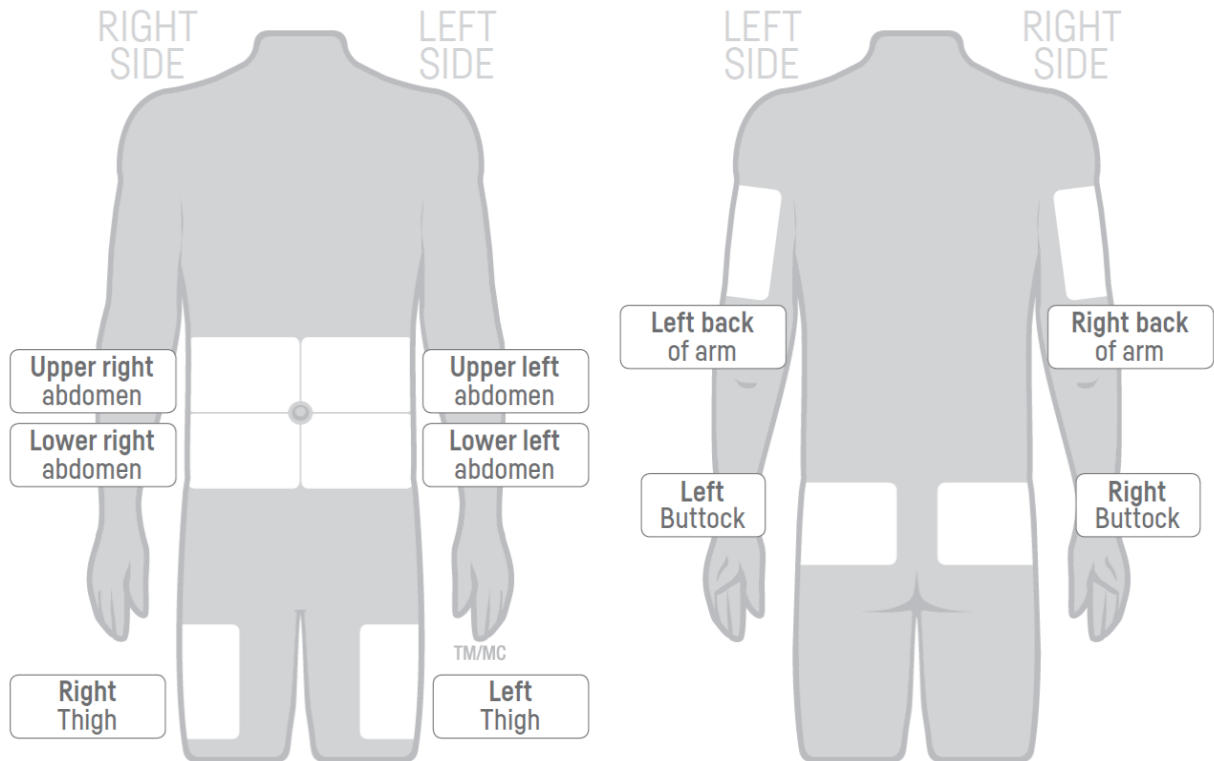
With best regards,

XXXX

## **Appendix 3**

### **Injection Area, Zone and Site Chart**

### INJECTION AREA, ZONE AND SITE CHART



## **Appendix 4**

### **Study Intervention (mCPN Packaging)**



Getting the most out of your insulin treatment requires regular injection site rotation



The only pen needle that **seemlessly reminds you** to do so!



### Why should you regularly rotate your injection site?

- leads to better blood glucose control<sup>1,2,3,4</sup>
- helps to reduce some unexplained blood sugar variation<sup>1,2,3,4</sup>
- may also help you to reduce the amount of insulin you are taking<sup>1,2,3,4</sup>



**REFERENCES**

(1) FIT Canada (Forum for Injection Techniques) <http://www.fit4diabetes.com/canada-english/>

(2) Johansson UB, et al. Impaired absorption of insulin as part from lipohypertrophic injection sites. *Diabetes Care* 2005;28(8):2025-7.

(3) Frid AH, Hirsch LJ, Menchior AR, et al. Worldwide injection technique questionnaire study. *Mayo Clin Proc.* 2016;91:1212-1223.

(4) Chowdhury TA, Escudier V. Poor glycaemic control caused by insulin induced lipohypertrophy. *BMJ.* 2003; 327:393-394.



Expertise Médicale Canadienne  
Canadian Medical Expertise

Questions?

1-866-695-1222  
[www.montmed.ca](http://www.montmed.ca)

TM Trademarks of montmédi Inc.  
© Copyright 2017 montmédi Inc., all rights reserved

Tirez le maximum de votre traitement d'insuline en assurant la rotation régulière des sites d'injection.



La seule aiguille à stylo qui **vous rappelle naturellement** cette recommandation clé!



### Pourquoi régulièrement alterner les sites d'injection?

- assure un meilleur contrôle glycémique<sup>1,2,3,4</sup>
- contribue à réduire des fluctuations du taux de sucre<sup>1,2,3,4</sup>
- peut aider à réduire la quantité d'insuline que vous vous administrez<sup>1,2,3,4</sup>



**RÉFÉRENCES**

(1) FIT Canada (Forum for Injection Techniques) <http://www.fit4diabetes.com/canada-francais/>

(2) Johansson UB, et al. Impaired absorption of insulin as part from lipohypertrophic injection sites. *Diabetes Care* 2005;28(8):2025-7.

(3) Frid AH, Hirsch LJ, Menchior AR, et al. Worldwide injection technique questionnaire study. *Mayo Clin Proc.* 2016;91:1212-1223.

(4) Chowdhury TA, Escudier V. Poor glycaemic control caused by insulin induced lipohypertrophy. *BMJ.* 2003; 327:393-394.



Expertise Médicale Canadienne  
Canadian Medical Expertise

Questions?

1-866-695-1222  
[www.montmed.ca](http://www.montmed.ca)

MC Marques de commerce de montmédi Inc.  
© Copyright 2017 montmédi Inc. Tous droits réservés



**The messages below will be played one at a time each time the box is opened followed by 15 silent box openings. The cycle will repeat thereafter.**

**Message 1**

Site Rotation matters!

Did you know that always injecting into the same place can damage the tissues?

This can affect your blood sugar levels.

It can increase your risk of low blood sugars and it can even increase how much insulin you take.

Unique color coding of SiteSmart pen needles reminds you to rotate injection site.

Change color, Change Site.

For more information ask your pharmacist.

**Message 2**

Change color change site

Check your SiteSmart packaging.

Use of the 2 readymade popular injection plans or develop your own plan that works for you by assigning a color to each of the recommended injection site. Every time you grab a needle simply inject it to the site matching the color of the pen needle.

It is as simple as that.

**Message 3**

Injection Technique Best Practice Tip

In addition to performing regular site rotation, Canadian injection technique experts recommend using a pen needle once, discarding it, and using a new one for each injection to keep your tissues healthy.

**Message 4**

Congratulations!

I hope you have appreciated these few educational sound bites, and that by now SiteSmart has helped you to adopt a healthy injection site rotation routine that easily fits into your daily life.

Keep going!

## **Appendix 5**

### **Information Letter and Consent Form for Patient Participants**

## INFORMED CONSENT TO PARTICIPATE IN A RESEARCH STUDY

---

**STUDY NAME:** Can a Montméd Coloured Pen Needle (mCPN) Intervention Improve Injection Site Rotation Habits in Established Insulin Users?

**SPONSOR AND FUNDER:** montméd Canada

**PRINCIPAL INVESTIGATOR:** Lori D Berard, RN, CDE | Winnipeg Regional Health Authority

You are invited to consider taking part in a research study. Participation is voluntary. If you choose to participate, you will need to sign the consent document and you will receive a copy of this signed document for your records. You may withdraw from the study at any time. Before you decide to participate, please take as much time as you need to read this document carefully.

### **Declaration of Conflicts**

montméd Canada will be paying the pharmacy and pharmacists to conduct the study.

### **Information on the Research**

**I. Study Background, Purpose and Description:** You have been using insulin for more than 1 year to manage your diabetes. Previously, you may or may not have been advised that it is important you rotate your injection sites to ensure that your insulin dose is delivered effectively every time. You are now invited to participate in this 30-day long study that will assess if montméd Coloured Pen Needles will help individuals like yourself remember to always rotate your injection site. This study will enroll approximately 240 people from about 20 retail pharmacies across Canada. As part of the study, you will be asked to complete 2 questionnaires, the first on the day you sign this consent form and the second on day 30 of the study.

**II. Restrictions and Potential Risks/Benefits:** There are no restrictions. There are no potential risks. You are unlikely to experience any additional discomfort relative to your usual pen needles. You may or may not benefit from your participation in this study.

**III. Who Should Not Participate in this Study:** Do not participate in this study if you are pregnant, trying to get pregnant, or if you think you may be pregnant. Please speak to your pharmacist if you think you may be pregnant, or if you are unsure.

### **Protecting Your Privacy**

Any personal identifying information that is recorded or stored for study purposes will be “de-identified” by replacing your personal identifying information with a “unique code/number”.

### **Study Results**

The study results may be presented at a scientific conference or published in a scientific journal. If the study results are published, your identity will NOT be disclosed in any of the publications.

**Costs of Study Needles and Reimbursement**

You will not be charged for the cost of any of the insulin pen needles you will need during the 30-day long study. You will not receive any payment for taking part in this study. As an appreciation of your participation, you will be invited to choose between taking home a Home Blood Pressure Monitor or a FRIO Insulin Cooling Case, after you have completed the second survey at the end of the 30-day study. If you are allocated to the group that will continue with your usual pen needles during the study and you wish, upon completion of the study, to try the montméd Coloured Pen Needles, you will be eligible to receive a set of these insulin pen needles at no cost.

**STATEMENT OF CONSENT** to participate in the study entitled:

***Can a Montméd Coloured Pen Needle (mCPN) Intervention Improve Injection Site Rotation Habits in Established Insulin Users?***

By signing this consent form, I acknowledge that:

- The research study has been explained to me, and my questions have been answered to my satisfaction.
- I know that I have the right not to participate and the right to withdraw.
- The potential harms and benefits (if any) of participating in this research study have been explained to me.
- I have been told that I have not waived my legal rights nor released the investigator, sponsor, or involved pharmacy from their legal and professional responsibilities.
- I know that I may ask now, or in the future, any questions I have about the study.
- I have been told that records relating to me and my care will be kept confidential and that no information will be disclosed without my permission unless required by law.
- I have been given sufficient time to read the above information.
- I will be given a copy of the signed and dated consent form.

I consent to participate in this study.

\_\_\_\_\_  
**Printed Name of Participant**

\_\_\_\_\_  
**Signature of Participant**

/   /

**Date/Time**

\_\_\_\_\_  
**Printed Name of Person Obtaining Consent**

\_\_\_\_\_  
**Signature of Person Obtaining Consent**

/   /

**Date/Time**

## **Appendix 6**

### **Pharmacists' Letter of Agreement**

**STATEMENT OF AGREEMENT** to participate in the study entitled:

*Can a Montmé Coloured Pen Needle (mCPN) Intervention Improve Injection Site Rotation Habits in Established Insulin Users?*

By signing this consent form, I acknowledge that:

- The research study has been explained to me, and my questions have been answered to my satisfaction.
- I have received all the necessary study documents and I will sign, date and return all the relevant acknowledgement pages to the office of the Principal Investigator
- I understand that I will receive training on my responsibilities in this study.
- I will conduct the study ethically, to the best of my abilities and as per detailed in the training that I will receive.
- I will be provided with a copy of the signed and dated agreement letter.

I consent to participate in this study.

\_\_\_\_\_  
**Printed Name of Participating Pharmacist**

\_\_\_\_\_  
**Signature of Participating Pharmacist**

/   /

**Date**

\_\_\_\_\_  
**Printed Name of Participating Pharmacy Manager**

\_\_\_\_\_  
**Signature of Participating Pharmacy Manager**

/   /

**Date**

**Appendix 7**  
**Pre-study Questionnaire for Patient Participants**  
*(To be completed during pharmacy visit)*



## PARTICIPANT PRE-STUDY QUESTIONNAIRE

Site #:

Participant #:

Thank you for agreeing to participate in the mCPN Intervention Study. The information you provide in this questionnaire will be used to improve training and education for all people using injections to manage their diabetes.

1) How old are you?

\_\_\_\_\_ years

2) Please indicate your gender

Male       Female       Prefer not to answer

3) What type of diabetes do you have?

Type 1       Type 2       Do not know

4) How many years have you been living with diabetes?

\_\_\_\_\_ years

5) How many years have you been using insulin to manage your diabetes?

\_\_\_\_\_ years

6) How many total insulin injections do you use per day?

1       2       3       4       5 or more

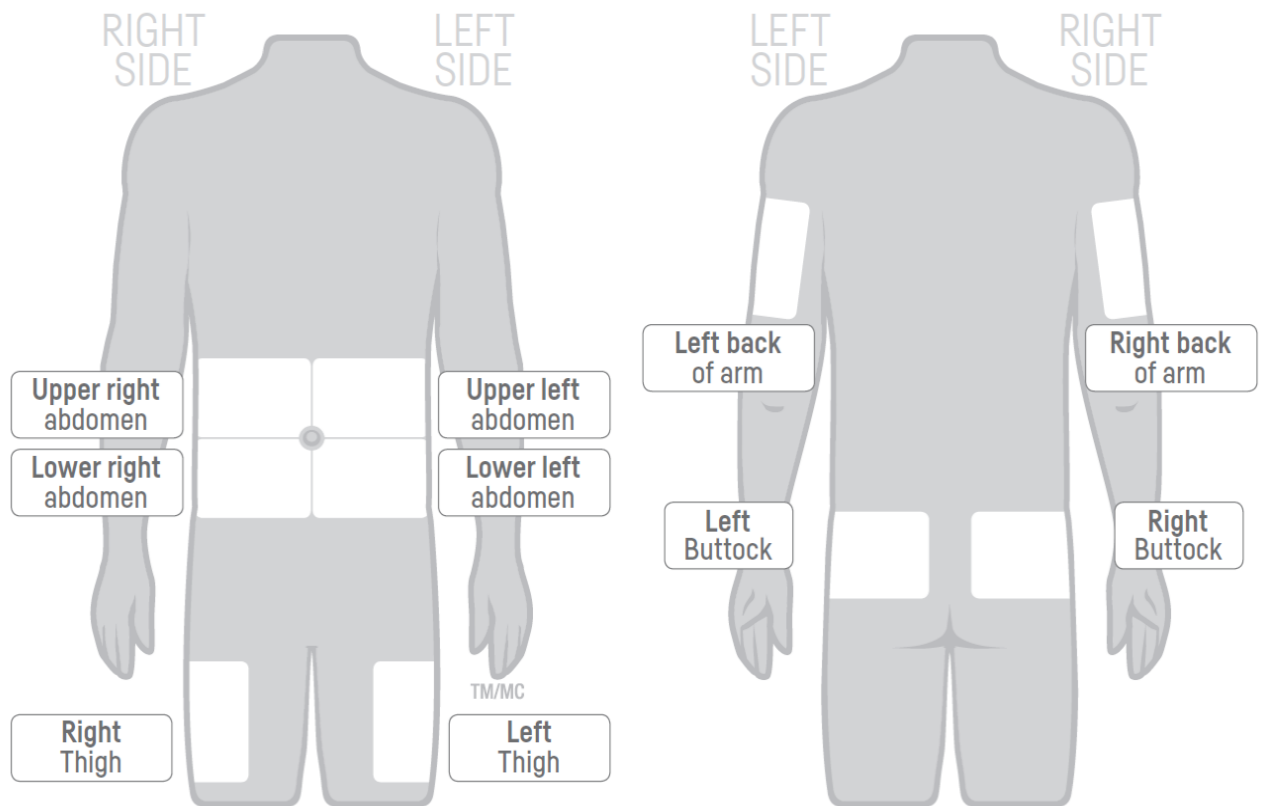
7) What is the length of the needle you currently use to inject your insulin (tick all that apply)?

>8 mm       8 mm       6 mm       5 mm       4 mm

8) What was the total number of units of all insulins you injected yesterday?

\_\_\_\_\_ Units (add up the units of all the doses given)

- 9) On the body charts below, please mark with an "X" exactly where you have injected over the last 7 days. Place as many X's per site to represent the last 7 days of injections. You should make as many X's as injection per day for 7 days – example – 2 injections per day – 14 X's.



- 10) Thinking of each of the injection areas that you have marked in the body charts in Question 9, please read and choose one of the following responses that most closely reflects the size of your injection area:

- I usually use an area the size of a **post card** to give my injections
- I usually use an area the size of a **playing card** to give my injections
- I usually use an area the size of a **credit card** to give my injections
- I usually use an area the size of a **postage stamp** to give my injections

11) How many occurrences of "low blood sugars" have you had over the last 30 days?

- None
- 1 to 3
- 4 to 7
- 8 to 13
- 14 to 28
- more than 1 per day

12) Over the past 7 days, how many times did you use a needle before replacing it with a new needle?

- Once
- 2 to 3
- 4 to 5
- 6 or more

13) How do you think your diabetes may change if you were to inject in the same spot over a long period of time? Choose all that apply.

- Don't know
- My injection site does not hurt
- I may need more insulin
- I may need less insulin
- I may have higher blood sugars
- I may have lower blood sugars
- I might experience more "swings" of blood sugars from lows to highs
- Nothing will happen

**To be completed by the Pharmacist Investigator:**

Has the participant reviewed and signed the Informed Consent Form?

Yes       No

Has the participant completed the questionnaire?

Yes       No

The participant has been randomized to:

Group 1 (usual pen needles)       Group 2 (mCPN needles)

**Appendix 8**  
**Post-study Questionnaire for Patient Participants**  
***(To be completed during pharmacy visit)***

## PARTICIPANT POST-STUDY QUESTIONNAIRE

Site #:

Participant #:

Thank you for participating in the mCPN Intervention Study. The information you provide in this questionnaire will be used to improve training and education for all people using injections to manage their diabetes.

1) Did you have any difficulty using the needle that was provided to you for this study?

No

Yes, please explain

---

---

2) Since completing the first questionnaire, has anyone spoken to you about your insulin injection technique?

No

Yes

3) How many insulin injections do you use each day?

1

2

3

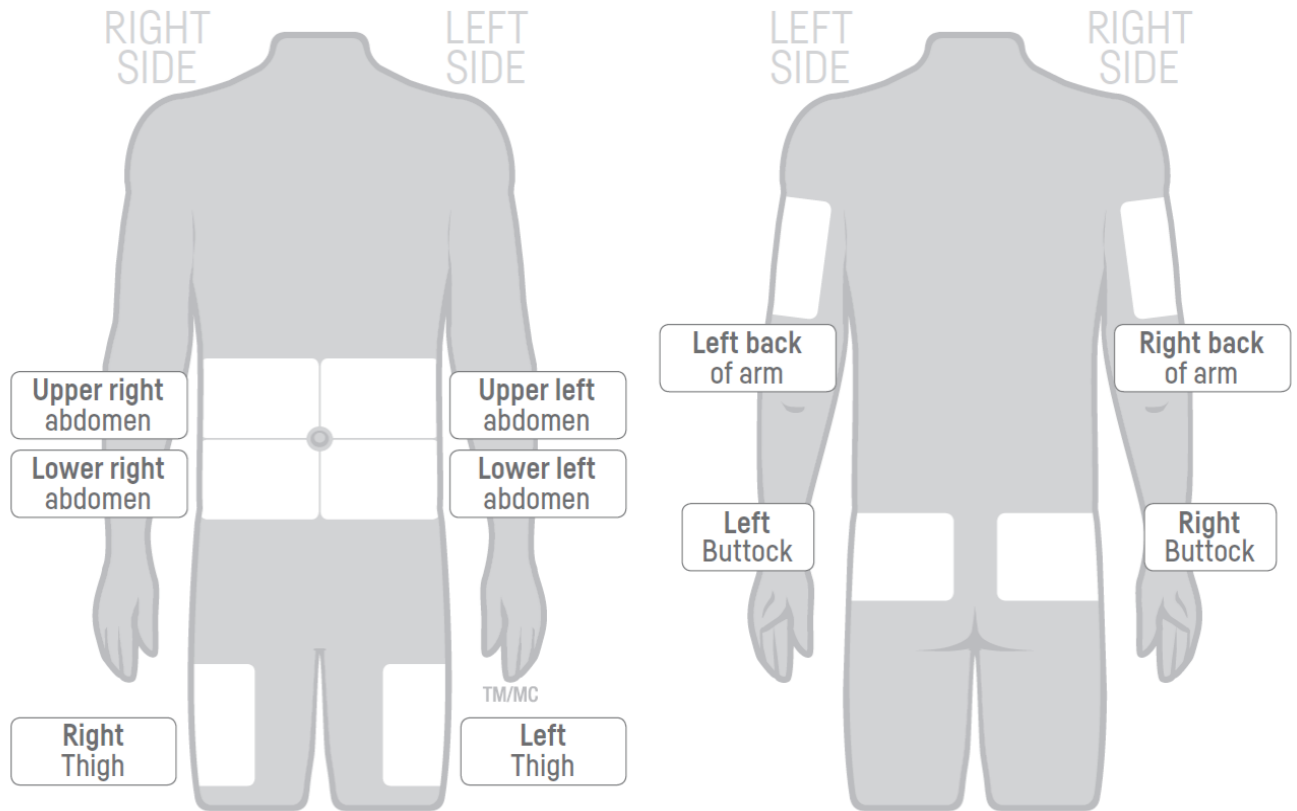
4

5 or more

4) What was the total number of units of all insulins you injected yesterday?

\_\_\_\_\_ Units (add up the units of all the doses given)

- 5) On the body charts below, please mark with an "X" exactly where you have injected over the last 7 days. Place as many X's per site to represent the last 7 days of injections. You should make as many X's as injection per day for 7 days – example – 2 injections per day – 14 X's.



- 6) Over the last 30 days do you believe you have changed sites
- More frequently than previously
  - Less frequently than previously
  - About the same
- 7) Thinking of each of the injection areas that you have marked in the body charts in Question 5, please read and choose one of the following responses that most closely reflects the size of your injection area:
- I usually use an area the size of a **post card** to give my injections
  - I usually use an area the size of a **playing card** to give my injections
  - I usually use an area the size of a **credit card** to give my injections
  - I usually use an area the size of a **postage stamp** to give my injections

- 8) How many occurrences of “low blood sugars” have you had over the last 30 days?
- None
  - 1 to 3
  - 4 to 7
  - 8 to 13
  - 14 to 28
  - more than 1 per day
- 9) Over the past 7 days, how many times did you use a needle before replacing it with a new needle?
- Once
  - 2 to 3
  - 4 to 5
  - 6 or more
- 10) How do you think your diabetes may change if you were to inject in the same spot over a long period of time? Choose all that apply.
- Don't know
  - My injection site will not hurt
  - I may need more insulin
  - I may need less insulin
  - I may have higher blood sugars
  - I may have lower blood sugars
  - I might experience more “swings” of blood sugars from lows to highs
  - Nothing will happen



If you were assigned to **Group 2 (you received a box of the coloured pen needles)**, please answer the following questions:

1) How would you compare the coloured pen needles to your usual pen needles?

	Strongly Agree	Agree	Neither Agree nor Disagree	Disagree	Strongly Disagree
I found it easier to remember to rotate my injection site	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
I varied my injection site more often	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
I changed my pen needle more often	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
The phrase "Change colour, change site" was a helpful reminder to consider changing injection site more often	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
The coloured pen needles helped remind me consider other injection sites for my injections	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

2) The packaging of the coloured pen needles includes an educational message about injection site rotation. Please rate your satisfaction with receiving this type of diabetes care education tool from your pharmacist.

	Very Satisfied	Satisfied	Neither Satisfied nor Dissatisfied	Dissatisfied	Very Dissatisfied
Impact of the educational message about injection site rotation on the packaging of the coloured pen needles	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

3) How would you rate the coloured pen needles against your usual pen needles?

	Very Satisfied	Satisfied	Neither Satisfied nor Dissatisfied	Dissatisfied	Very Dissatisfied
Compared to my usual pen needles, I was _____ with the coloured pen needles.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

4) If the cost for the coloured pen needles is comparable and not more expensive than your current pen needles, would you consider switching to the coloured pen needles?

Yes

Not sure

No

5) Please provide any additional comments you would like to share below:

---

---

---

---

---

**Appendix 9**  
**Pre-study Survey for Pharmacists**  
***(To be completed and submitted via Fax/Scan to email)***

### PRE-PARTICIPATION IN THE mCPN INTERVENTION STUDY

Site #:

Pharmacist Study Code #:

- 1) Prior to agreeing to participate in this study, on a scale of 1 to 5 how important is **injection site rotation education** in insulin therapy (1 = unimportant and 5 = very important)?

Unimportant	Slightly Unimportant	Neither	Slightly Important	Very Important
1	2	3	4	5

- 2) Prior to agreeing to participate in this study, on a scale of 1 to 5 how confident are you in **providing education about proper injection site rotation** for insulin therapy (1 = not confident and 5 = very confident)?

Not confident	Little Confidence	Neither	Somewhat Confident	Very confident
1	2	3	4	5

- 3) We are interested in knowing your current knowledge regarding insulin injection techniques. Please answer the following.

a. Have you heard the term **lipohypertrophy**?  Yes  No

- b. On a scale of 1 to 5 (1 = no knowledge to 5 = excellent understanding), how would you rate your knowledge of the **effect of lipohypertrophy**?

No Knowledge (None)	Somewhat Aware (Poor)	Aware of some information (Adequate)	Aware and have a useable background of information (Good)	Very Aware and Knowledgeable (Excellent)
1	2	3	4	5

- c. On a scale of 1 to 5, what is your level of comfort **in pen needle tip selection and use** (1 = uncomfortable to 5 = very comfortable)?

Uncomfortable	Somewhat Uncomfortable	Neither	Somewhat Comfortable	Very Comfortable
1	2	3	4	5

- d. On a scale of 1 to 5, what is your level of comfort **discussing injection site rotation** (1 = uncomfortable to 5 = very comfortable)?

Uncomfortable	Somewhat Uncomfortable	Neither	Somewhat Comfortable	Very Comfortable
1	2	3	4	5

- 4) When providing insulin pen needles, what percentage of the time do you discuss proper site rotation?

0-20%       21-40%       41-60%       61-80%       81 – 100%

- 5) What percentage of your insulin-injecting patients do you believe properly rotate their sites?

0-20%       21-40%       41-60%       61-80%       81 – 100%

- 6) What percentage of your insulin-injecting patients do you believe reuse their needles more than once?

0-20%       21-40%       41-60%       61-80%       81 – 100%

- 7) OPTIONAL QUESTION

Approximately, what percentage of patients that purchase insulin pen needles are provided with counselling regarding proper injection rotation technique?

0-20%       21-40%       41-60%       61-80%       81 – 100%

Please return the completed form to the attention of Lori Berard  
Fax: 1-204-272-3354 | email [mcpndata@gmail.com](mailto:mcpndata@gmail.com)

**Appendix 10**

**Post-study Questionnaire for Pharmacists**

*(To be completed and submitted via Fax/Scan to email)*

**POST-PARTICIPATION IN THE mCPN INTERVENTION STUDY**

Site #:

Pharmacist Study Code #:

- 1) After participating in this study, on a scale of 1 to 5, how important is **injection site rotation education** in insulin therapy (1 = unimportant and 5 = very important)?

Unimportant	Slightly Unimportant	Neither	Slightly Important	Very Important
1	2	3	4	5

- 2) After participating in this study, on a scale of 1 to 5, how confident are you in **providing education about proper injection site rotation** for insulin therapy (1 = not confident and 5 = very confident)?

Not confident	Little Confidence	Neither	Somewhat Confident	Very confident
1	2	3	4	5

- 3) We are interested in knowing your current knowledge (after participating in the study) regarding insulin injection techniques. Please answer the following.

a. Have you heard the term **lipohypertrophy**?  Yes  No

- b. After participating in this study, on a scale of 1 to 10 (1 = no knowledge to 10 = excellent understanding), how would you rate your knowledge of the **effect of lipohypertrophy**?

No Knowledge (None)	Somewhat Aware (Poor)	Aware of some information (Adequate)	Aware and have a useable background of information (Good)	Very Aware and Knowledgeable (Excellent)
1	2	3	4	5

- c. After participating in this study, on a scale of 1 to 10, what is your level of comfort **in pen needle tip selection and use** (1 = very uncomfortable to 10 = extremely comfortable)?

Uncomfortable	Somewhat Uncomfortable	Neither	Somewhat Comfortable	Very Comfortable
1	2	3	4	5

- d. After participating in this study, on a scale of 1 to 10, what is your level of comfort **discussing injection site rotation** (1 = very uncomfortable to 10 = extremely comfortable)?

Uncomfortable	Somewhat Uncomfortable	Neither	Somewhat Comfortable	Very Comfortable
1	2	3	4	5

- 4) After participating in this study, when providing insulin pen needles in the future, what percentage of time do you foresee discussing proper site rotation?

0-20%       21-40%       41-60%       61-80%       81 – 100%

- 5) After participating in this study, what percentage of your study participants using the mCPN, do you believe properly rotate their sites?

0-20%       21-40%       41-60%       61-80%       81 – 100%

- 6) After participating in this study, what percentage of your study participants using the mCPN, do you believe reuse their needles more than once?

0-20%       21-40%       41-60%       61-80%       81 – 100%

- 7) OPTIONAL QUESTION

After participating in this study, approximately what percentage of patients that purchase insulin pen needles do you anticipate will be provided with counselling regarding proper injection rotation technique?

0-20%       21-40%       41-60%       61-80%       81 – 100%



**Thinking of the mCPN intervention, please complete these questions,**

- 1) Does this intervention improve injection technique with regards to:
- a. Site rotation?  Yes  No
  - b. Increased number of zones?  Yes  No
  - c. Increased area of use within zones?  Yes  No
  - d. Needle re-use?  Yes  No
  - e. Do you believe that simply providing patients using insulin, with pen needles with educational tools, like the mCPN packaging may change patient behavior regarding needle re-use?  
 Yes  No
  - f. Do you believe that simply providing patients using insulin, with pen needles with educational tools, like the mCPN packaging may change patient behavior regarding proper site rotation?  
 Yes  No
- 2) Do you believe that the mCPN intervention may change pharmacy staff behavior regarding assessment of proper injection technique?  
 Yes  No

**POST-PARTICIPATION IN THE mCPN INTERVENTION STUDY**

Since receiving the education provided during the site training:

1) Do you feel that your pharmacy staff have acquired skills that can be incorporated into everyday practice?

Yes             No

2) Not considering patients included in the 30-day trial period, have you begun to assess insulin pen needle users when they come for refills?

Yes             No

3) After completion of the study, do you plan on providing the option of providing patients with proper injection site educational tools like the Site Smart system to your patients?

Yes             No

4) Does having an educational tool on your shelves help your staff to consider discussing proper injection technique with patients? (ie seeing coloured needle beside the conventional insulin pen needle packaging)?

Yes             No

5) Do you feel that counselling on proper insulin injection technique would be as effective for patients without the use of colored needles?

Yes             No

Please provide any additional comments/learnings/customer comments you would like to share below:

---

---

---

---

---

Please return the completed form to the attention of Lori Berard

Fax: 1-204-272-3354 | email [mcpndata@gmail.com](mailto:mcpndata@gmail.com)

**Appendix 11**  
**Follow up/Tracking Form**

## Follow up/Tracking Form

Site #:

### Pharmacist

Study Code #:

Pre-study survey completion date:

/ /

Post-study survey completion date:

/ /

### Patient

Name (for site use only): \_\_\_\_\_

Telephone Number (for site use only):

Study Code #:

Pre-study questionnaire completion date:

/ /

Reminder Call Date for Second Visit:

/ /

2<sup>nd</sup> Vist and

Post-questionnaire completion date:

/ /

## **Appendix 12**

### **Study Binder Contents**

1. Final Study Protocol
2. Protocol signature page
3. LOI
4. Invoice Template – Completion of study
5. Invoice Template – Standard of Care Pen needles
6. Question and Answer documents for Pharmacist Investigators
7. Study flow chart
8. Participant recruitment script
9. Pre- and Post-Participation Questionnaires for the Pharmacist Investigators
10. Randomization list
11. Subject files – 12 per site – Consents, pre- and post-participation questionnaires – tracking forms
12. Enrollment and Dropout log
13. Training documents and Signature log