Nursing Best Practice Research Unit

Unité de recherche sur les pratiques exemplaires en soins infirmiers

The Confidence in Administering Insulin and Managing Diet Scale (CAI MDS)

NURSING BEST PRACTICE GUIDELINES

EVALUATION USER GUIDE

November 2006

Disclaimer

The opinions expressed in this publication are those of the authors. Publication does not imply any endorsement of these views by either of the participating partners of the Nursing Best Practice Research Unit, which include members of the University of Ottawa faculty and members of the Registered Nurses' Association of Ontario (RNAO).

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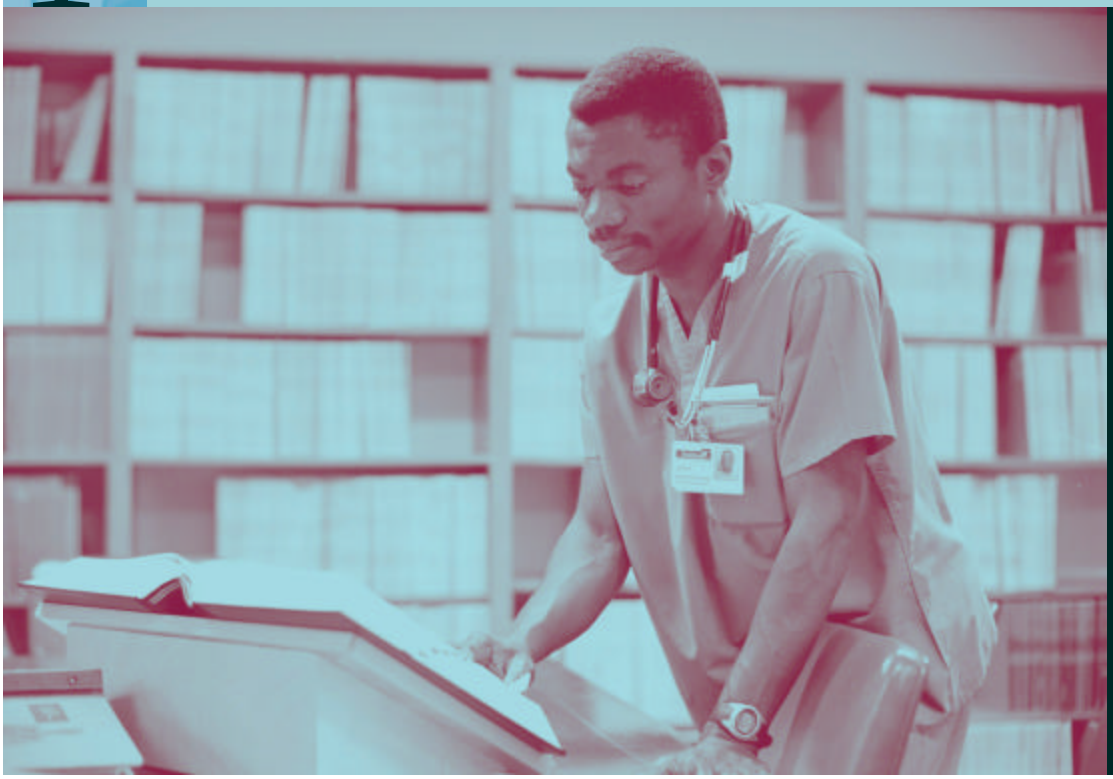


Chapter highlights

- Why evaluation tools for Best Practice Guidelines are necessary
- Process used for developing the Confidence in Administering Insulin and Managing Diet Scale (CAI-MDS)

The Nursing Best Practice Research Unit (NBPRU) was formed in January 2005 as a partnership between the University of Ottawa, School of Nursing and the Registered Nurses' Association of Ontario (RNAO). One of the research unit's objectives is to develop and pilot test tools useful in the evaluation of the implementation of clinical nursing BPGs.

BACKGROUND

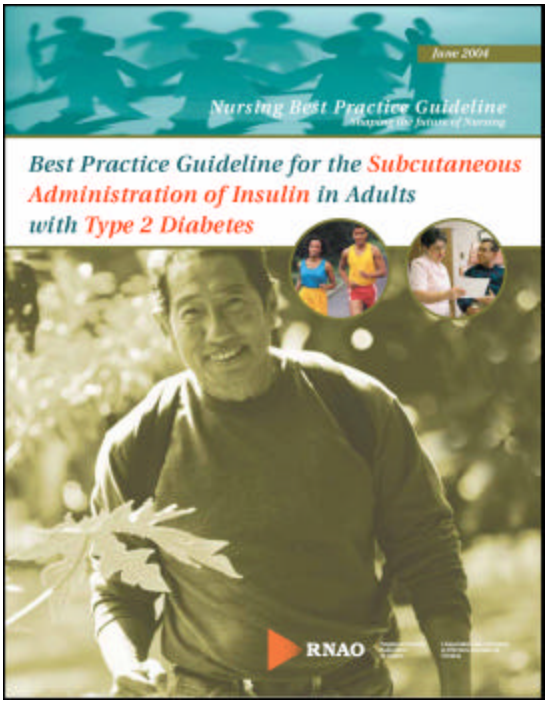
Clinical or best practice guidelines (BPGs) summarize the most up-to-date research on various clinical topics. They contain recommendations that are useful in helping healthcare providers practice evidence-informed care and improve patients' health outcomes. The Registered Nurses' Association of Ontario (RNAO), with funding from the Ontario Ministry of Health and Long-Term Care has developed 30 BPGs to date. Each BPG includes evidence-based practice, education, and organization/policy recommendations. Details about the RNAO Best Practice Guideline Program may be obtained on the RNAO website: www.rnao.org

When BPG recommendations are implemented in a healthcare organization, the evaluation of its impact needs to be linked with changes in nursing practice and improvements in patient outcomes. The measures used to evaluate the BPG implementation need to be valid and reliable so that conclusions about the relationships between the implementation and the outcomes can be established. These measures also need to be feasible, acceptable, and meaningful to healthcare providers and patients. Sound measures are crucial for effective decision-making on the implementation and evaluation of evidence-informed care.

The Nursing Best Practice Research Unit (NBPRU) was formed in January 2005 as a partnership between the University of Ottawa, School of Nursing and the Registered Nurses' Association of Ontario (RNAO). One of the research unit's objectives is to develop and pilot test tools useful in the evaluation of the implementation of clinical nursing BPGs. At a symposium held in the spring of 2005, a team of leading researchers, administrators, government funders, and policy researchers identified a gap in the availability of tools for measuring the outcomes of guideline implementation. Hence, the NBPRU has developed evaluation tools to accompany various BPGs. The psychometric properties of these evaluation tools were examined in several studies.

This user guide describes the development and psychometric properties of an evaluation tool that was developed by the NBPRU for the evaluation of patient outcomes when implementing recommendations on the RNAO BPG on Subcutaneous Administration of Insulin in Adults with Type 2 Diabetes (RNAO, 2004). It is intended for users who have experience and/or graduate training in research and evaluation.

The evaluation tool in this user guide is called the **Confidence in Administering Insulin and Managing Diet Scale (CAI-MDS)**. A brief description of its development is presented, as well as how to administer, score and interpret the scale. Its psychometric properties are also summarized. Further technical information on the study examining its psychometric properties is reported in a forthcoming paper (Danseco, Davies, Edwards, Skelly, Santos & Lybanon 2006).



THE RNAO BEST PRACTICE GUIDELINES ON SUBCUTANEOUS ADMINISTRATION OF INSULIN IN ADULTS WITH TYPE 2 DIABETES

The RNAO BPG on Subcutaneous Administration of Insulin in Adults with Type 2 Diabetes addresses critical knowledge and skills that nurses who are not specialists in diabetes care need when dealing with patients with Type

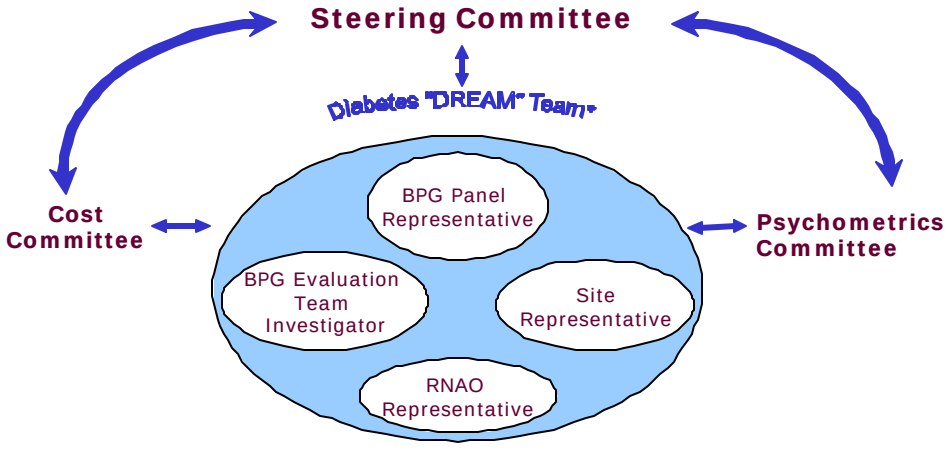
2 diabetes who require subcutaneous insulin. The recommendations consist of information that registered nurses (RNs) and registered practical nurses (RPNs) in various practice settings can apply to assist patients in self-care. These self-care components include assessment of psychosocial factors such as self-efficacy, stressors and beliefs about insulin initiation, and tailoring initial and follow-up patient education on topics such as hypoglycemia and blood glucose monitoring.

Key patient outcomes associated with the implementation of this guideline include improved quality of life, demonstration of safe insulin administration, satisfaction with treatment and diabetes education, and self-efficacy relating to diabetes self-care. The panel development team that worked on this BPG included experts on diabetes care, and stakeholders that reviewed the BPG included practitioners in medicine, pharmacy, social work and nutrition.

APPROACH TO SCALE DEVELOPMENT

The development of the evaluation measure for the BPG on the subcutaneous administration of insulin followed a collaborative process involving representatives from the guideline development panel, implementation sites, and the guideline evaluation team (see Figure 1). This collaborative team identified priority recommendations of the BPG, selected an area for developing an evaluation measure, and reviewed relevant tools identified during a literature review. We called this team the Diabetes "DREAM" Team (**D**eveloping, **R**eviewing, **E**valuating and **A**nalyzing **M**easures).

Figure 1. Evaluation Team Structure.



*DREAM: Developing, Reviewing, Evaluating and Assessing Measures

The priority recommendations we identified as well as clinical expert advice led to the selection of self-efficacy as an outcome of implementing this BPG. We then conducted a review of the literature for existing measures on self-efficacy and other similar patient outcome measures that were relevant to diabetes self-management.

From our review of the literature, we found 35 instruments measuring different aspects of diabetes self-management. We selected one scale, the Insulin Management Diabetes Self-Efficacy Scale (IMDSES) developed by Hurley (1990) for extensive review. The IMDSES scale measures patients' beliefs in several areas where these beliefs could help or hinder self-management activities.
During our review and discussion, we observed that the response format used (i.e., Likert scale from "Strongly Disagree" to "Strongly Agree") did not follow Bandura's (1994, 1997) recommended format for measuring self-efficacy. Albert Bandura developed the concept of self-efficacy (1977), and many researchers have found the role of self-efficacy as key in the results of many health programs.

We also noted that problems are often encountered by persons completing the negatively-worded items in the IMDSES. For example, disagreeing with the statement, "I'm not sure I can recognize when my blood sugar is low" implies that one can recognize when blood sugar is low. However, some persons check off that they agree with the statement rather than disagree. This is a common problem with negatively worded items (DeVellis, 2003).

We developed the CAI-MDS by constructing items similar to those in the IMDSES (Hurley, 1990) and the Self-Efficacy for Diabetes scale (Stanford Patient Education Centre). We focused only on patients' beliefs in two major areas: insulin administration and management (12 items) and diet management (9 items). The subscale on insulin administration and management included various situations or contexts where a person's self-efficacy on insulin management can vary.

While the RNAO BPG on insulin administration does not focus on teaching patients about diet management, items on diet management were included because being able to manage diet has been shown to have an impact on blood glucose levels (Franz, et al., 2002). Self-efficacy with following dietary recommendations may play a role in overall diabetes self-management.

The CAI-MDS uses a 5-point Likert rating scale ranging from 1 ("not at all confident") to 5 ("extremely confident") as endpoints. A response format using a "disagree to agree" format would not follow the recommended format for measuring self-efficacy based on Bandura's framework and other more widely used self-efficacy scales (Crawford et al., 2004; DiClemente, Carbonari, Montgomery & Hughes, 1994; Velicer, DiClemente, Rossi & Prochaska, 1990).

Initial drafts of the CAI-MDS were reviewed by a panel of experts, which included nurses with expertise in diabetes care and psychologists with expertise in measurement and in self-efficacy. Their feedback and suggestions were integrated in the field-test version. One of the suggestions included using an Arial font, size 14 to assist in readability, considering the potential vision problems that may occur for people with diabetes.

The CAI-MDS was pilot-tested in two healthcare organizations located in Ontario from July to December 2004. The sites included a large metropolitan university-affiliated hospital and a community care agency. A total of 45 participants took part in this study. A more detailed description of the sample and procedures is presented in Danseco et al. (2006).

2 Administration, Scoring and Interpretation of the CAI-MDS

Chapter highlights

In this section, we describe:

- The two subscales of the CAI-MDS;
- How to use the CAI-MDS; and
- How to score and interpret the tool.

DESCRIPTION OF THE CONFIDENCE IN ADMINISTERING INSULIN AND MANAGING DIET SCALE (CAI-MDS)

The current user guide presents the **Confidence in Administration of Insulin and Managing Diet (CAI-MDS**, see Appendix A) a self-efficacy scale relating to insulin self-administration, monitoring of blood glucose levels and managing one's diet. The CAI-MDS can be used by nurses who are providing diabetes care and wish to evaluate the effectiveness of diabetes-related education, as a result of implementing the RNAO BPG on subcutaneous administration of insulin. The CAI-MDS can also be used to monitor improvements in self-efficacy over time, for example to see if clients' self-efficacy is related to changes in nursing practice as nurses fully implement recommendations in the BPG on insulin administration.

It is preferable that the CAI-MDS be administered *two to four weeks after patient education*, when patients or clients have had some degree of familiarity with self-administration of insulin.

The CAI-MDS can also be adapted for use by managers within various healthcare organizations interested in using the tool in quality improvement programs, where the benefits of educational activities need to be measured. Graduate students and others may also wish to adapt the CAI-MDS patient self-report scale for their own diabetes self-efficacy–related research.

The CAI-MDS was designed to assess self-efficacy, which is the **perception of one's ability to perform diabetes–related self-care activities** (van der Ven et al., 2003) like preparing and administering insulin, as well as how well a person manages one's diet. There are two subscales: the Insulin Administration and Glucose Monitoring subscale with 12 items, and the Diet Management subscale with 9 items.

Each item describes a situation or context where self-efficacy with self-administration of insulin or diet management can vary. For example, one question asks about a person's level of confidence in completing activities related to their insulin treatment and management ("How confident do you feel with doing these activities related to your insulin treatment?"). Another

question asks about the level of confidence in practising activities related to managing diet and corresponding blood glucose control ("How confident do you feel doing these activities based on the dietary advice given by a health professional for your diabetes?").

ADMINISTRATION

Patients or clients are provided with the self-report questionnaire and are asked to circle the response that most closely indicates their level of confidence when doing a certain task or activity. In some cases, it may not be possible to have patients/ clients complete the questionnaire immediately. This may be the case for patients in a rural setting or in a home care agency. In these situations, patients/ clients may complete the questionnaire in their homes and return it by mail preferably in a pre-paid, pre-addressed envelope (provided by researcher or healthcare provider).

The questionnaire may also be completed by telephone or in person, with the interviewer/ researcher reading out the statements and response options, and the patient or client orally providing the answers. It is a good idea to keep in mind that patients or clients may tend to give socially desirable answers when the questionnaire is given in an interview format. One advantage of the interview format is that the provider can ask for the client to clarify their responses to an item and gain more insights into the client or patient's self-efficacy.

In some situations where patients or clients may not be familiar with reading English, it is preferable that an interpreter be available. In this case, it is important to note that there may be cultural factors to consider. Self-efficacy may not be a culturally important construct in other cultures.

This questionnaire has not been tested in languages other than English, or in various ethnic groups. We have also not examined differences in responses when the questionnaire is given in an interview format, a self-administered format.

Appendix B provides some suggestions on how to use the CAI-MDS or other evaluation measures when conducting research in a healthcare organization.

SCORING AND INTERPRETATION

Respondents are asked to indicate their level of confidence in being able to perform or complete the behaviour/task on a five-point Likert scale ranging from 1 ("not at all confident") and 5 ("extremely confident"). A total score is obtained by summing across all items.

The two separate subscale scores are obtained by summing across each subscale's corresponding items (e.g. summing across the 12 items for the Administration and Glucose Monitoring subscale, and summing across the 9 items for the Diet Management subscale). In general, higher scores indicate that a person feels very confident in their ability to perform the specific task.

Appendix C provides some guidelines for entering data using SPSS, and **Appendix D** illustrates sample programs for scoring the CAI-MDS.

3 Overview of Psychometric Properties of the CAI-MDS

Chapter highlights

In this chapter, we briefly report on the psychometric properties of the Confidence in Administering Insulin and Managing Diet Scale. The properties described include:

- Feasibility
- Acceptability
- Reliability
- Content and Convergent validity.

Table 1 summarizes the psychometric properties assessed and the procedures used to evaluate them.

Table 1. Statistical Procedures Used to Evaluate Psychometric Properties of the Chart Audit Tool.

Psychometric Property	Statistical Procedure Used
Feasibility	Response rates, changes to the data collection period
Acceptability	Examined the percentage of missing data for each item
Reliability	Calculated Cronbach's alpha for each subscale to assess internal consistency
Content Validity	Comments and suggestions from expert reviewers
Convergent Validity	Examined the correlations of the CAI-MDS with a diabetes attitude scale and a diabetes self-care scale.

Feasibility *(whether a measure can actually be used in a particular setting given the resources, demands of testing and complexity of administration)* was low due to the low response rates. Of 112 eligible participants, only 45 or 40% took part in the study. The team recruited participants for 14 weeks during the summer of 2004. It was noted that it is harder to get people to participate in studies during the summer. It was also difficult to recruit patients once they were discharged from the hospital.

Acceptability *(whether a measure and its items are acceptable to end-users)* appears to be good. Twenty-nine questionnaires or 71% had no missing data. Only one item (monitoring my blood sugar more often when I have a bad cold or flu) from the Insulin Administration subscale

had missing responses (n = 7). For the item "Knowing what to do if my blood sugar is high" five participants indicated that they couldn't answer the questions because they didn't feel they had enough experience with the diabetes self-management routines, since they had only recently begun their insulin treatment program.

Reliability *(internal consistency; whether the items of a scale "hold together" and measure the construct)* was assessed with a statistic called the Cronbach's alpha. This index ranges from 0 to 1.0, with the higher numbers reflecting higher reliability. In general, a Cronbach's alpha of at least .70 is considered adequate.

The Cronbach's alpha for the two CAI-MDS subscales were high, with a = .90 for the Insulin Administration and Glucose Monitoring subscale, a = .94 for the Diet subscale. These results show that the subscales have very good reliability.

Content validity *(whether a measure's scales or dimensions captures constructs in a comprehensive manner)* was assessed by seven clinician experts on diabetes care, self-efficacy, and change behaviour measurement.

Feedback from the reviewers on such issues as clarity of wording, instructions, readability (including size and quality of fonts for ease of reading), and comprehensiveness of topics covered, consistency with self-efficacy theories, and the appropriateness of items with the proscribed subscales was incorporated into the current version of the CAI-MDS.

Convergent validity *(correlations with related measures or constructs)* was assessed by calculating Pearson correlation coefficients between the CAI-MDS total and two subscale scores and the Diabetes Attitude Scale (DAS-3, Anderson, Fitzgerald, Funnell & Gruppen 1998) and the Summary of Diabetes Self-Care Activities-Revised (SCSCA-R, Toobert, Hampson & Glasgow, 2000).

Correlations range from -1.00 to 1.00. A positive value means a positive relationship between two variables, and a negative correlation coefficient means a negative relationship between the two variables. The "magnitude" of the correlation (the closer to +1.00 or to -1.00) shows how strong the relationship is. For a positive relationship, a correlation that is less than .40 is generally considered low, those between .40 and .60 is moderate, and those above .60 shows a high correlation.

Significant moderate to high correlations were found between the Insulin Administration and Glucose Monitoring subscale and the DAS-3 seriousness of Type 2 Diabetes subscale ($r = .41$, $n = 29$ $\underline{p} < .05$) and the Value of tight control subscale ($r = .38$, $n = 32$, $\underline{p} < .05$). This means that the more confident (self-efficacious) patients felt about their ability to administer insulin and monitor their blood glucose levels, the more likely they are to believe in the seriousness of their disease and the value of having tight glucose control.

The Diet subscale was also significantly correlated with the DAS-3 Value of Tight Control subscale ($r = .41$, $n = 30$, $\underline{p} < .05$). This suggests that patients who felt more confident in their ability to control their diets were also more likely to value tight blood glucose control. Finally, a significant correlation was found between the Diet subscale and the DAS-3 Patient Autonomy subscale ($r = .43$, $n = 32$, $\underline{p} < .05$). This shows that patients who are more confident in their ability to control their diet (or

follow dietary recommendations) are also more likely to feel in control and empowered in their decision-making in relation to their disease.

The CAI-MDS total score was not significantly correlated with any subscales of the DAS-3 or SDSCA-R. The two CAI-MDS subscales were found to be strongly correlated with each other ($r = .51$, $n = 24$, $\underline{p} < .05$) indicating that the more confident a patient feels about ability to administer insulin and monitor blood glucose levels, the more confident they feel about their ability to control their dietary intake.

No significant correlations were found between the CAI-MDS total and subscale scores and the SDSCA subscale scores.

4 Summary

The current user guide presents the Confidence in Administering Insulin and Managing Diet Scale (CAI-MDS), a self-report questionnaire designed to measure a patient's confidence in self-administering insulin, monitoring blood glucose levels and managing one's diet. This self-efficacy scale was developed to measure one aspect of patient outcomes when implementing recommendations from the RNAO BPG on the subcutaneous administration of insulin, among adults with Type 2 diabetes.

We used a collaborative approach with representation from the team that developed the guideline, two organizations implementing the guidelines, and the evaluation team at the University of Ottawa. A self-efficacy tool with two subscales on insulin administration and on diet management was constructed. A pilot version that integrated comments from clinical expert reviewers in diabetes care, on measurement of behaviour change, and on self-efficacy was tested in an acute care hospital and in a community care nursing organization.

A total of 45 patients/clients completed the CAI-MDS. They also completed a questionnaire on diabetes attitudes and self-care activities. Initial results on the psychometric properties of the CAI-MDS show that it has good content validity, acceptability, and high reliability (Danseco et al. 2006). Results on the scale's convergent validity were likewise promising, based on the correlations with the attitudes on diabetes and scores on self-care activities.

The CAI-MDS can be valuable in knowing patients or clients' self-efficacy confidence in their self-administration of insulin, blood glucose monitoring and diet management. The CAI-MDS can be used as a baseline and post-intervention measure, providing clinically relevant information before and after education on subcutaneous insulin administration and other diabetes-related self-care activities.

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Appendix

LIST OF APPENDICES

Appendix A: The Confidence in Administering Insulin and Managing Diet Scale (CAI MDS)

Listed on the following two pages are different situations and activities relating to diet and insulin management.

Section A: How confident do you feel with doing these activities related to your insulin treatment?

Please circle only one answer for each question using the following scale:

NA - Not Applicable
1 - Not at all confident
2 - Not very confident
3 - Moderately confident
4 - Very confident
5 - Extremely confident

1. Preparing a dose of insulin by myself	NA	1	2	3	4	5
2. Giving myself an insulin injection	NA	1	2	3	4	5
3. Safely disposing of used needles or syringes	NA	1	2	3	4	5
4. Doing a blood sugar test with a meter	NA	1	2	3	4	5
5. Testing my blood sugar as often as recommended by my nurse/doctor	NA	1	2	3	4	5
6. Knowing what to do if my blood sugar is high	NA	1	2	3	4	5
7. Knowing what to do if my blood sugar is low	NA	1	2	3	4	5
8. Monitoring my blood sugar more often when I have a bad cold or flu	NA	1	2	3	4	5
9. Following instructions from my nurse/ doctor on caring for myself when I am sick with a bad cold or flu	NA	1	2	3	4	5
10. Preventing low blood sugar (hypo-glycemia)	NA	1	2	3	4	5
11. Recognizing when my blood sugar is low	NA	1	2	3	4	5
12. Knowing when to contact my doctor or health care team for assistance	NA	1	2	3	4	5

Section B: How confident do you feel with doing these activities based on dietary advice given to you by a health professional for your diabetes?

Please circle only one answer for each question using the following scale:

NA - Not Applicable
1 - Not at all confident
2 - Not very confident
3 - Moderately confident
4 - Very confident
5 - Extremely confident

13. Making healthy food choices when eating in familiar places	NA	1	2	3	4	5
14. Making healthy food choices when eating in unfamiliar places	NA	1	2	3	4	5
15. Making healthy food choices with people who don't know I have diabetes[3]	NA	1	2	3	4	5
16. Choosing from recommended snack foods when I want to have a snack	NA	1	2	3	4	5
17. Choosing foods from different food groups	NA	1	2	3	4	5
18. Spacing meals apart as recommended	NA	1	2	3	4	5
19. Reducing fat content as recommended	NA	1	2	3	4	5
20. Reducing sweets	NA	1	2	3	4	5
21. Eating the recommended amount of starchy foods	NA	1	2	3	4	5

Appendix B: How to Collect Data in Healthcare Settings

This is intended to generally outline for the novice researcher (allied health care workers, managers of quality improvement programs, and others) steps on how to obtain research information or data within a healthcare setting. A sample flow chart of the research process is provided. This guideline focuses on conducting research in the context of a hospital setting. The clinical context of a particular research setting needs to be considered when determining whether these procedures need to be adapted.

Before conducting any research, you will need to seek ethical approval for your study from the appropriate research ethics board(s), such as at the healthcare facilities where you plan to conduct the research and/or your educational institution (if you are a student or instructor). Data collected for quality improvements purposes within a facility may not need ethical approval; however, this should be checked with your facility's research ethics board. The following steps address the most common ethical issues. Your research ethics board may have additional ethical concerns.

Step 1: **Communication of the Study Approach to the Research Assistant**

When conducting research at a healthcare centre, you will likely have to rely on a Research Assistant (RA) based at the site to help with the particular facility REB application and process requirements, recruitment of participants and data collection. The RA must be properly informed and trained on the study protocol to ensure he/she follows approved ethics procedures that protect participant rights, privacy and confidentiality. The RA will be your key contact at the healthcare setting and will alert staff about the research study to assist with the recruitment of participants and collection of data.

The healthcare organization that has agreed to participate in your research usually selects the RA who will be working with you based on direction from you on the skills and credentials required to conduct the research. Participating research personnel should be regular employees of the healthcare centre with access to potential participants on a daily basis, but not providing direct patient care. It is critical that the research personnel do not have direct supervision or influence over potential participants (either patients or staff). This provision is a requirement for conducting ethical research. The concern is that if patients are approached by their attending care personnel or if staff are approached by a direct supervisor, they may feel that they have to participate in the research out of fear that not participating might affect their treatment or employment. This is referred to as coercion. The potential for coercion is minimized and/or eliminated if research staff are not directly involved in the patient's care and/or are not in a direct supervisory role or position of influence over potential participants.

The following should be provided to the RA to ensure that the study's purpose, procedures, and his/her role is understood:

- Research study information (e.g., what is being studied; how participants are to be recruited; the RA role during the recruitment and data collection phases; how participant informed consent will be obtained; how and what data will be collected; the estimated time it will take for recruitment, data collection and study completion).
- Patient eligibility criteria (see Step 2).
- How the RA is to communicate study information to all nursing staff on participating units and/or to appropriate staff throughout the organization.
- Study materials to be distributed to patients and/or staff (flyers, information and consent form). Ensure the RA leaves extra copies at the nursing station.

Step 2: **Recruiting and Assessing for Participant Eligibility**

Eligibility criteria will depend on the research questions you are undertaking. For example, if you are doing a study on adults with Type 2 Diabetes, then the following may be your patient eligibility criteria:

- Adult (18 years or older)
- Diagnosed with Type 2 Diabetes
- Received education on diabetes self-care within the last year.
- Are mentally competent and able to give informed consent (a patient's medical status may need to be considered here, in order to ensure that they are capable of providing informed consent).

Unit staff should be informed of the study and eligibility criteria so they can provide study information to potential participants and notify the RA of eligible, interested participants. In some cases, the RA may not approach potential participants to explain the study in more detail until unit staff have obtained a written "permission to call/contact" from an interested participant (see Step 3 below). Depending on study procedures, the RA may collaborate with the Unit/Ward Clerk to secure a list of potential patient participants. Unit/Ward clerks typically have access to patient information on the unit because they are responsible for the logistics of the unit (patient admission to the unit, room placement, movement of patients from unit to appointment and vice versa, etc.). A recruitment approach involving the Unit/Ward Clark may be more appropriate and/or useful when trying to do a "sweep" across a unit or organization involving the recruitment of all (or large numbers of) patients over a short period of time.

If a participant is eligible and if you need to use a permission to call/ contact, go to Step 3. Otherwise, proceed to Step 4.

Step 3: Providing Eligible Potential Participants with Study Information (Flyer, Information Sheet & Consent Form) and Obtaining Permission to Call/Contact– Unit Staff and RA

Prior to the RA discussing the study in more detail with an eligible participant, in accordance with ethical procedures, potential participants should be approached by unit staff first, who will briefly describe the study and/or hand out flyers and ascertain whether an eligible participant is interested in learning more about the study.

If eligible potential participants indicate an interest, then the unit staff will obtain "permission to call/contact" for the RA to further explain the study. The potential participant signs the ***Request for Permission to Call/Contact*** form.

When permission to call is obtained, unit staff will notify the RA and leave the completed **Permission to Call/Contact** form at the nursing station or in the appropriate designated place. In a home care setting, this may involve faxing the completed "permission to call/contact" form to the RA.

Step 4: RA Meeting with Potential Participant to Provide Detailed Explanation of Study and Seek Informed Consent

When you have identified a potential participant for your study, you will need to meet with him or her to discuss and ascertain the following:

- Verify that the potential participant meets eligibility criteria.
- If the potential participant is identified as not eligible, explain this to him/her, thank him/her for his/her time and interest, and end the meeting. Ensure reasons why the potential participant was ineligible get recorded on the Master Sheet (Step 5). This is important information for the study investigators and should be tracked.

- If the potential participant is eligible, explain the study and review materials. Ensure the potential participant has had time to read through the materials.
- Ask potential participant if he/she has any questions and answer them.
- Request signed consent for all parts of the study. Ideally, you would like consent for all study tasks. However, ethically the potential participant does not have to consent to all tasks within a research protocol.
- Have both the participant and the RA sign both copies of the Information Sheet & Consent Form. Leave one copy with the participant.

If the potential participant is not eligible or refuses consent, no further contact should be made with the potential participant. Refusal to participate is also important information to track for study investigators. Ensure this gets recorded on a Master Sheet (see Step 5).

Step 5: Recording Participant Information on the Master Sheet

A Master Sheet allows the RA to track recruitment and data collection. Add pertinent participant information to the Master Sheet for all participants approached (whether identified as eligible or not, and whether consented or not). The following should also be recorded on the Master Sheet:

- Assigned ID Code to participant. ***This assigned ID code will be recorded on all data collection forms.*** None of the data collected should have the participant's name on it. For tracking purposes, only the Master Sheet should link the assigned ID code to the participant. The Master Sheet may include

the patient's hospital chart number or patient ID number (assigned by the hospital at intake), depending on whether the data collection will involve a chart audit/review and retrieval of the patient's health record at a later date from medical records. All data collection forms should be tracked using the assigned ID code.

- An example of a unique assigned ID code (that you have created for the study and assigned to the participant) can be made up in the following manner:

XXX	X-XX	X to XXX
Organization	Unit	Patient recruitment number

- The assigned ID code can consist of letters or numbers, and fewer than three digits can be used. For example,
  - The Organization code could be 100
  - The Unit code could be A
  - The participant recruitment number can start at one and increase incrementally by one in consecutive order e.g. (1 would be assigned to the first participant recruited, and 129 to the 129th participant recruited). The unique assigned ID code would look like this: **100A129**

- Store the signed participant consent in a locked cabinet in designated area.
- Always store the Master Sheet in a separate locked cabinet. The Master Sheet should never be stored with the data collection forms.
- Once all data collection is completed, the RA will forward the completed data collection forms to the researcher. The Master Sheet is typically stored for one year after study completion, after which point it should be destroyed by the RA following established procedures at the healthcare organization.
- The researcher will require the RA to summarize recruitment and data collection information from the Master Sheet (e.g. number of interested participants approached by the RA who were eligible versus not eligible; number who consented versus did not consent; number for whom data collection was not completed and possible reasons why; etc). Ethically the RA should not provide the researcher with information that can identify a participant.

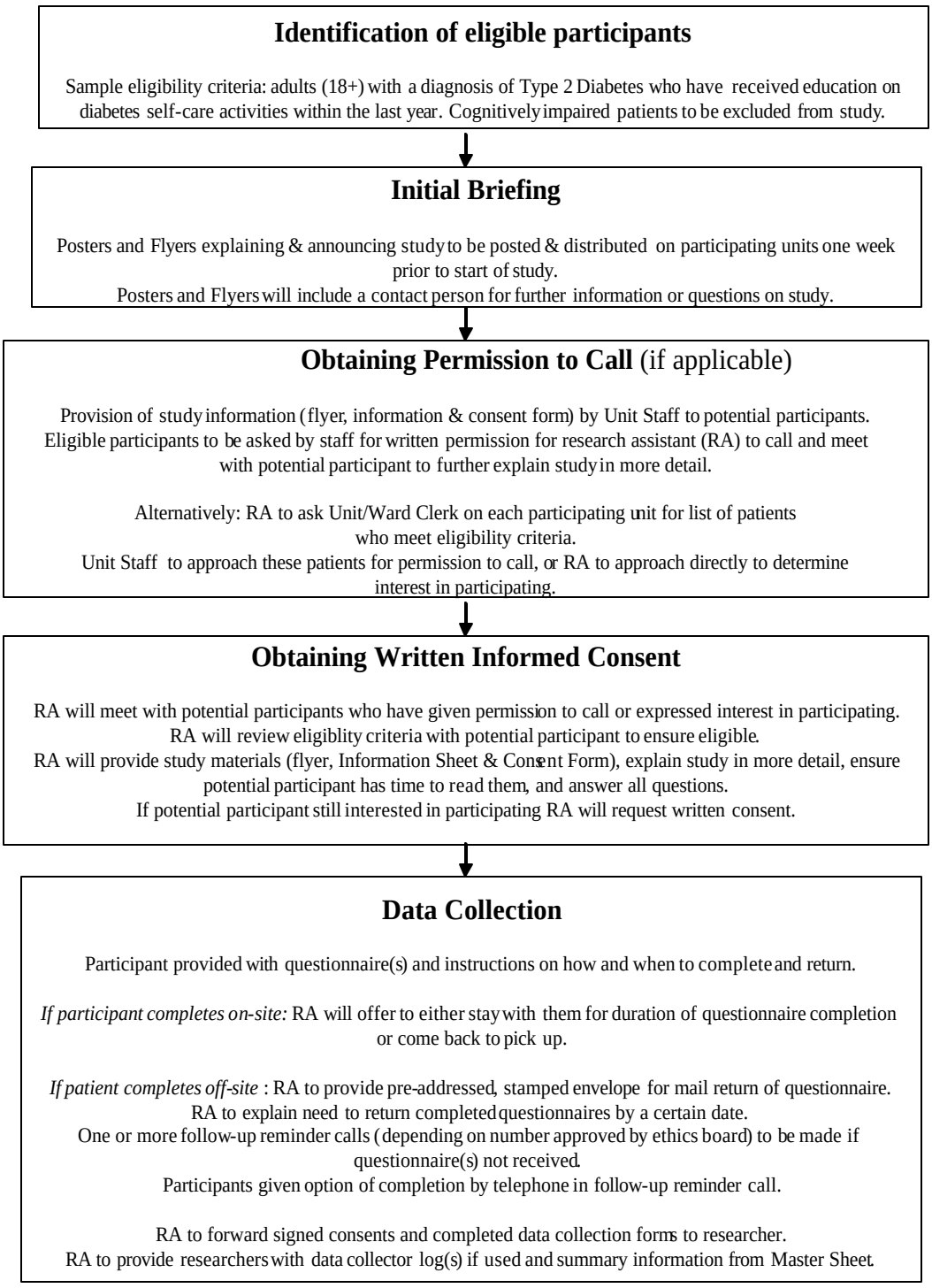
NOTE: Some research projects need to have several sessions with the same participant. Despite the fact that they may participate in more than one session, only ONE unique ID code is assigned to the participant.

Step 6: Collecting Questionnaire Data from Consenting Participants

- Ensure the participant has provided written informed consent before proceeding (see Step 4).

- Provide the participant with all the appropriate questionnaires and materials. Including a writing pen/pencil, if resources allow, with the package will facilitate both the ease to complete the requested documents as well as provide a token of appreciation for their participation.
- Explain the procedure to him/her (i.e. when he/she is to fill in the questionnaire(s) answering all items to the best of his/her ability, how and when he/she is to return them). If he/she is to fill the questionnaire(s) out immediately, inform him/her the amount of time he/she will have to complete them (how long it is expected to take).
- Provide him/her with the option of you staying in case your help is needed to complete the questionnaire(s), or tell them that you will be back to pick up the questionnaire(s) after the allotted time frame has passed. Reassure him/her that more time can be provided if required, or if he/she finishes early how you can be reached.
- Ensure the participant Assigned ID Code is recorded on all pages of the questionnaire(s) (see Step 5).and not the participant's name. This will ensure that if the pages should get separated, you will still have the data needed for data entry and analysis.
- Provide the participant with an envelope in which they can seal their completed questionnaire responses. This provides the participant with assurance that his/her responses are confidential and to be seen only by the researcher.
- If the participant is to return the questionnaire(s) by mail ensure he/she has had this explained and a pre-addressed, stamped envelope has been provided.
- Ensure the participant is aware of how long he/she has to complete the questionnaire(s), after which time if it has not been received you will call him/her with a reminder to complete and mail back the questionnaire(s) (the participant will have consented to this in the information sheet and consent form).
- In the follow-up reminder call to the participant give the option of completing the questionnaire(s) over the telephone at a convenient time. The frequency and number of follow-up reminder calls to the participant will depend upon the requirements of your study and what is allowed by the site's research ethics board.
- After you have completed all required and/or allowable follow-up reminders and the participant still has not completed and/or returned the questionnaire(s) or you have been unable to reach the participant, you will have to mark their data as missing. Record this information on the Master Sheet. Do <u>not</u> contact the participant again.

Flow Chart of Research Process: Self-Report Questionnaire)



Appendix C: SPSS Data Entry Guidelines

This document provides a guideline for data entry. The recommendations are made assuming SPSS as data entry spreadsheet/software. The methodology explained below considers various types of variables;

1. **Defining variables:**

a. Keep the question number as variable name (e.g., 1 as q1, 1.1 as q1.1, 1.1a as q1.1a etc.
b. Clarify details of the name under "label" for ex. q1 labelled as "marital status".

2. **Universal/Generic Code:** missing=999 for all the variables.

3. **Scale/Continuous data:**

a. SPSS by default keeps two decimal places for the values of numeric variable viz. 1 as 1.00. Thus, 1="very dissatisfied" will appear as 1.00, 2="dissatisfied" as 2.00, 3="satisfied" as 3.00, and 4="very satisfied" as 4.00, etc.
b. Missing=999.

4. **Categorical/Nominal data:**

a. The example might be gender, education, yes/no etc.
b. Follow the same code sequence as given in the questionnaire.
c. Guideline for open ended question:
    i) Gender: male=1, female=2, missing=999
    ii) Yes/No: yes=1, no=2, missing-999
    iii) Education: grade 1=1, grade 2=2, grade 3=3, missing=999.

5. **String and other (date/time etc.) variables:**

a. Specify the length as 250 not the SPSS default as 8.
b. Date: keep the very first date type provided by the system which is dd-mmm-yyyy for ex. May 31 2004 as 31-MAY-2004. You don't need to key exactly the same letters to get this format for ex. if "31 5 4" is keyed it will be displayed by the system as "31-MAY-2004".
c. Time: keep the type as hh:mm:ss for ex. 5 hrs 10 minute 1 sec as 05:10:01. Again it's enough to key "5 10 1" to get the format of "05:10:01".

6. **Multiple response questions:**

Key only Yes (= 1) or No (= 2) for the following type of questions unless specified otherwise;

Were any of the following noted as predisposing factors to Diabetes complications: *(please check all that apply)*;

- Eye Disease
- Nerve Damage
- Heart disease
- Kidney disease
- Other, please specify _____

Appendix D: Sample Variable Lists and SPSS Scoring Program

Sample SPSS variable names and labels

Variable Name	Variable Label
Q1.1	Preparing a dose of insulin by myself
Q1.2	Giving myself an insulin injection
Q1.3	Safely disposing of used needles or syringes
Q1.4	Doing a blood sugar test with a meter
Q1.5	Testing blood sugar as often as recommended by the nurse/doctor
Q1.6	Knowing what to do if blood sugar is high
Q1.7	Knowing what to do if blood sugar is low
Q1.8	Monitoring blood sugar more often when having a bad cold or flu
Q1.9	Following instruction from the nurse/doctor
Q1.10	Preventing low blood sugar
Q1.11	Recognizing when blood sugar is low
Q1.12	Knowing when to contact doctor or health care team for assistance
Q1.13	Making healthy food choices when eating in familiar places
Q1.14	Making healthy food choices when eating in unfamiliar places
Q1.15	Making healthy food choices with people who don't know I have diabetes
Q1.16	Choosing from recommended snack foods
Q1.17	Choosing foods from different food groups
Q1.18	Spacing meals apart as recommended
Q1.19	Reducing fat content as recommended
Q1.20	Reducing sweets
Q1.21	Eating the recommended amount of starchy foods

For each of the variable or item, the values are 0=not applicable, 1= not at all confident, 2=not very confident 3=moderately confident, 4=very confident, 5=extremely confident.

Sample SPSS scoring

```
*************************************************************************************************.
* Objective 1) To obtain percent missing data for self-efficacy items.

* For Insulin Administration Scale.
FREQUENCIES
  VARIABLES=Q1.1 Q1.2 Q1.3 Q1.4 Q1.5 Q1.6 Q1.7 Q1.8 Q1.9 Q1.10 Q1.11 Q1.12
  /STATISTICS=STDDEV MEAN
  /ORDER=  ANALYSIS .

* For Diet Management Scale.
FREQUENCIES
  VARIABLES= Q1.13 Q1.14 Q1.15 Q1.16 Q1.17 Q1.18 Q1.19 Q1.20 Q1.21
  /STATISTICS=STDDEV MEAN
  /ORDER=  ANALYSIS .

* Objective 2) To recode 0 or 99 as missing.

RECODE
Q1.1 Q1.2 Q1.3 Q1.4 Q1.5  Q1.6 Q1.7 Q1.8 Q1.9 Q1.10
Q1.11 Q1.12 Q1.13 Q1.14 Q1.15 Q1.16 Q1.17 Q1.18 Q1.19 Q1.20 Q1.21
  (0=SYSMIS) (99=sysmis) (ELSE=Copy) INTO  Q1.1R  Q1.2R  Q1.3R  Q1.4R  Q1.5R
Q1.6R Q1.7R Q1.8R Q1.9R Q1.10R Q1.11R Q1.12R Q1.13R Q1.14R Q1.15R
Q1.16R Q1.17R Q1.18R Q1.19R Q1.20R Q1.21R.
EXECUTE .

* Objective 3) To obtain total scores and scale scores for the self efficacy scale.

COMPUTE ses_a = (Q1.1R+ Q1.2R+ Q1.3R+ Q1.4R+ Q1.5R+ Q1.6R+ Q1.7R+ Q1.8R+
Q1.9R+ Q1.10R+ Q1.11R+ Q1.12R) /12.
VARIABLE LABELS ses_a 'Self-Efficacy Scale Score: Insulin Admin' .
Formats ses_a (f8.2).
EXECUTE .

Compute ses_b = (Q1.13R+ Q1.14R+ Q1.15R+ Q1.16R+ Q1.17R+ Q1.18R+ Q1.19R+
Q1.20R+ Q1.21R)/9.
Variable labels ses_b 'Self-Efficacy Scale Score: Diet'.
Formats ses_b (f8.2).
Execute.

Compute ses_tot= (ses_a+ ses_b)/2.
Variable labels ses_tot 'Self-Efficacy Total Score'.
Formats ses_tot (f8.2).
Execute.

DESCRIPTIVES
  VARIABLES=ses_a ses_b ses_tot
  /STATISTICS=MEAN SUM STDDEV MIN MAX KURTOSIS SKEWNESS .
*************************************************************************************************.
```

Appendix E: Resources

For information on the Registered Nurses' Association of Ontario (RNAO) Best Practice Guidelines Project, consult the website of the RNAO. The nursing BPGs can be downloaded for free. Hard copies are available for purchase.
http://www.rnao.org/bestpractices

For further information on developing, implementing and evaluating nursing practice guidelines, consult the RNAO *"**Toolkit: Implementation of clinical practice guidelines.**"* The RNAO Toolkit can also be downloaded for free and hard copies are available for purchase through the RNAO website.

For further information on evaluation of nursing best practice guidelines and other evaluation tools, contact the Nursing Best Practice Research Unit. Other monographs include measures on organizational innovation characteristics, organizational stability, organizational culture for change, organizational support for BPG implementation, education and supportive processes, and perceived worth of the BPG, and interviewing nurses and administrators.

http://www.nbpru.ca

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Appendix F: Quick Reference Guide

Name	**Confidence in Administering Insulin and Managing Diet Scale (CAI-MDS)**
Purpose	To assess the patient's or client's self-efficacy when implementing recommendations of the RNAO Best Practice Guideline on the Subcutaneous Administration of Insulin for Adults with Type 2 Diabetes.
Description	The CAI-MDS consists of two subscales: 1) Insulin Administration and Glucose Monitoring subscale with 12 items, and 2) Diet Management subscale with 9 items. Each item uses a 5-point Likert scale from "not at all confident" to "extremely confident".
Type of data	Self-administered questionnaire; can also be administered through an interview (e.g., interviewer reading the questions to the client or patient).
Estimated time to collect data	About 10 to 15 minutes, depending on reading ability and ability to understand English.
Training requirements	Familiarity with administering surveys or self-administered questionnaires. Familiarity with a spreadsheet or statistical software, if administering the scale to a large number (e.g., more than 50). Since this evaluation measure is to be used in conjunction with the RNAO BPG on insulin administration, some training on the specific BPG is recommended.
Cost	Free electronic copies. Hard copies of the user guide can be purchased.
Summary of Procedures	1. Identify who among the staff will be giving out the questionnaires. 2. Identify who are the patients or clients that will be approached to complete the questionnaire. Ensure that the client is able to understand English or has an interpreter available. 3. Check with the patient about the form he or she wants to complete the questionnaire (self-administered or with the help of a staff). 4. Give the questionnaire to the patient or client. 5. Follow-up with clients or patients who have not turned in their questionnaires, considering guidelines by the research ethics board of your organization. 6. When the questionnaires are turned in, immediately check for blank items and ask patients or clients if they have a question or need to have the item clarified. 7. Score and interpret the results.
Scoring & Interpretation	Each item is scored from 0 to 5. NA items are not scored. Add scores for each subscale and divide by number of items (excluding NA items) in the subscale for a mean subscale score. The Insulin Administration & Glucose Monitoring subscale score is the total of the first 12 items, divided by 12. The Diet Management subscale score is the total of items 13 to 21, divided by 9. The Total Confidence score is the total of the two subscale scores.

Name	**Confidence in Administering Insulin and Managing Diet Scale (CAI-MDS)** Higher scores suggest higher levels of confidence in self-administering insulin and managing diet.
Citation	Davies B, Danseco E, Ray K, Zarins B, Skelly J, Santos J, Edwards N, Brez S & Lybanon V. (2006). Nursing Best Practice Guidelines Evaluation User Guide: The Confidence in Administering Insulin and Managing Diet Scale (CAI-MDS). Nursing Best Practice Research Unit, University of Ottawa, Canada. pp. 1-29.
Contact Information	Dr. Barbara Davies, Co-Director Nursing Best Practice Research Unit University of Ottawa School of Nursing 451 Smyth Road Ottawa, ON K1H 8M5 Tel. 613-562-5800 ext. 8436 Barbara.Davies@uottawa.ca

We would like to hear from you about this user guide or the CAI-MDS.

1. We plan to use the "Confidence in Administering Insulin and Managing Diet Scale" in our organization: ☐ Yes ☐ No
2. The approximate number of patients/ clients who will use this tool: _____
3. Health sector/ type of organization:
   - ☐ Long-term care
   - ☐ Complex continuing care
   - ☐ Rehabilitation
   - ☐ Acute care hospital
   - ☐ Community services
   - ☐ Home care
   - ☐ Public health
   - ☐ Hospice/ palliative care
   - ☐ Mental health/ substance abuse/ addictions
   - ☐ Other: (please specify): _____

Please take a few moments to write and tell us about your experiences, suggestions, questions or ideas:

Name (optional) _____

Where can we contact you?
(email or telephone) _____

Fax this form to: Nursing Best Practice Research Unit
ATTN: Dr. Evangeline Danseco
(613) 562-5892

Or email to: edanseco@mail.health.uottawa.ca or
bdavies@uottawa.ca

Nursing Best Practice Guidelines Evaluation User Guide

The Confidence in Administering Insulin and Managing Diet Scale (CAI-MDS)

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L'Association des infirmières et infirmiers autorisés de l'Ontario

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