

Construction and validation of an educational tool on insulin therapy for adults with diabetes mellitus

Luiz Henrique Diniz Miranda (<https://orcid.org/0000-0003-1795-3062>)¹

Janice Sepúlveda Reis (<https://orcid.org/0000-0002-2465-862X>)¹

Suelen Rosa de Oliveira (<https://orcid.org/0000-0002-7330-6102>)²

Abstract *The insulin therapy used to treat Diabetes Mellitus (DM) lacks educational tools to assist self-care. Thus, we aimed to develop and validate an educational tool for the relationship between glycemic variation and insulin therapy for adults with type 1 and 2 DM. The study was developed in three stages: i) elaboration of the educational tool; ii) validation of content and display by a panel of judges; iii) pre-test with a target audience. Ten judges participated in the second stage, and 12 insulin-dependent adults with type 1 or 2 DM participated in the third stage. The Content Validity Index (CVI) was used to evaluate the adequacy of the material by the judges. The percentages of the agreement by item were calculated for validation by the target audience. The My Treatment Diary (MTD) educational tool was then developed. It obtained a mean CVI of 99.6% and a percentage of agreement of 99%. The results demonstrated that the content and display of the MTD tool were validated and culturally appropriate for the population of adults with type 1 and 2 DM.*

Key words *Self-care, Diabetes Mellitus, Validation Study, Insulin, Health Education*

¹ Faculdade Santa Casa de Belo Horizonte. Av. dos Andradas 2688, Santa Efigênia Belo. 30110-005 Horizonte MG Brasil. sufmg@yahoo.com.br

² Escola de Enfermagem, Universidade Federal de Minas Gerais. Belo Horizonte MG Brasil.

Introduction

Diabetes Mellitus (DM) is a heterogeneous group of metabolic disorders that share elevated glycemic levels, which may result from a totally or partially insufficient insulin secretion or defects in the peripheral action of this hormone or even as a result of both of the previous conditions¹.

Especially in Type 1 Diabetes Mellitus (DM1) and Type 2 Diabetes Mellitus (DM2) advanced cases, the therapeutic approach requires changes in the self-care behavior of patients in this condition², involving insulin therapy, glycemic monitoring, and carb counting, combined with follow-up of a food plan.

The proposed model for insulin therapy seeks to reproduce the endocrine physiology of pancreatic beta cells, employing two types of insulin with different objectives: i) basal and ii) food bolus². In turn, carb counting is a technique that aims to achieve postprandial glycemic targets based on the balance between the amount, in grams, of ingested carbohydrates and the dose of rapid or ultra-rapid insulin administered in food boluses³.

Given the complexity of this treatment, which includes the need to adhere to specific aspects related to insulin therapy and carb counting, the interdisciplinary team has to invest in educational self-care supporting strategies that promote the autonomy of people with DM⁴ and help reduce broad glycemic variation episodes associated with endothelial and microvascular disease⁵.

Considering the multidisciplinary nature of the skills necessary for health self-care, we highlight the benefits of working with educational tools that combine low production cost and simple application⁶⁻⁸, which can help develop the behavioral, cognitive, and clinical potential of people with DM^{9,10}. From this perspective, the literature has shown the development of educational strategies aimed at self-care in insulin therapy, such as booklets¹¹, serial albums¹², and digital programs¹³. However, validated educational tools designed to show the relationship between insulin therapy and glycemic variation still need to be filled.

Therefore, this study aimed to develop and validate an educational tool to promote understanding of the relationship between glycemic variation and insulin therapy in adults with DM1 and DM2.

Methods

Study design, period, and location

This methodological study¹⁴ is reported per the recommendations of the Revised Standards for Quality Improvement Reporting Excellence (SQUIRE 2.0) tool of the EQUATOR¹⁵ network. It was performed from July 2018 to May 2020 in a public outpatient clinic that is a reference for caring for people with DM in Belo Horizonte, Minas Gerais, and developed per the steps shown in Figure 1.

Sample and inclusion and exclusion criteria

As the literature recommends, the validation process should include six to twenty experts to compose the judging committee¹⁶. We searched on the Lattes Platform of the National Council for Scientific and Technological Development (CNPq) to select the judges, and applied the following inclusion criteria: i) health professionals (Medicine, Nursing, Pharmacy, and Nutrition); ii) minimum experience of two years in caring for people with DM; iii) post-graduation at the specialization level, master's or doctorate, and preferably with experience in validating educational materials. We invited by e-mail ten professionals, providing guidance on the evaluation process. All invited judges agreed to participate in the research, and the evaluations occurred from November 2018 to January 2019. The Google Drive platform was adopted to send the online questionnaire link for content validation by the judges. The educational tool was made available in print, in person, by post, and in digital format (e-mail).

A convenience sample consisting of 12 people with DM, regular patients at the reference outpatient clinic setting of this study, was selected for the validation of the educational tool by the target audience. The sample was characterized by adult individuals (18-59 years) of both sexes and on insulin therapy. The sample number was based on recommendations extracted from qualitative research studies and on the concept of saturation, that is, on the data collection point from which new interviews^{17,18} add no relevant information. The following were excluded: i) sensory impairment cases, such as those with severe decrease or loss of visual function; ii) people with intellectual or cognitive impairments that would compromise the use of the proposed tool.

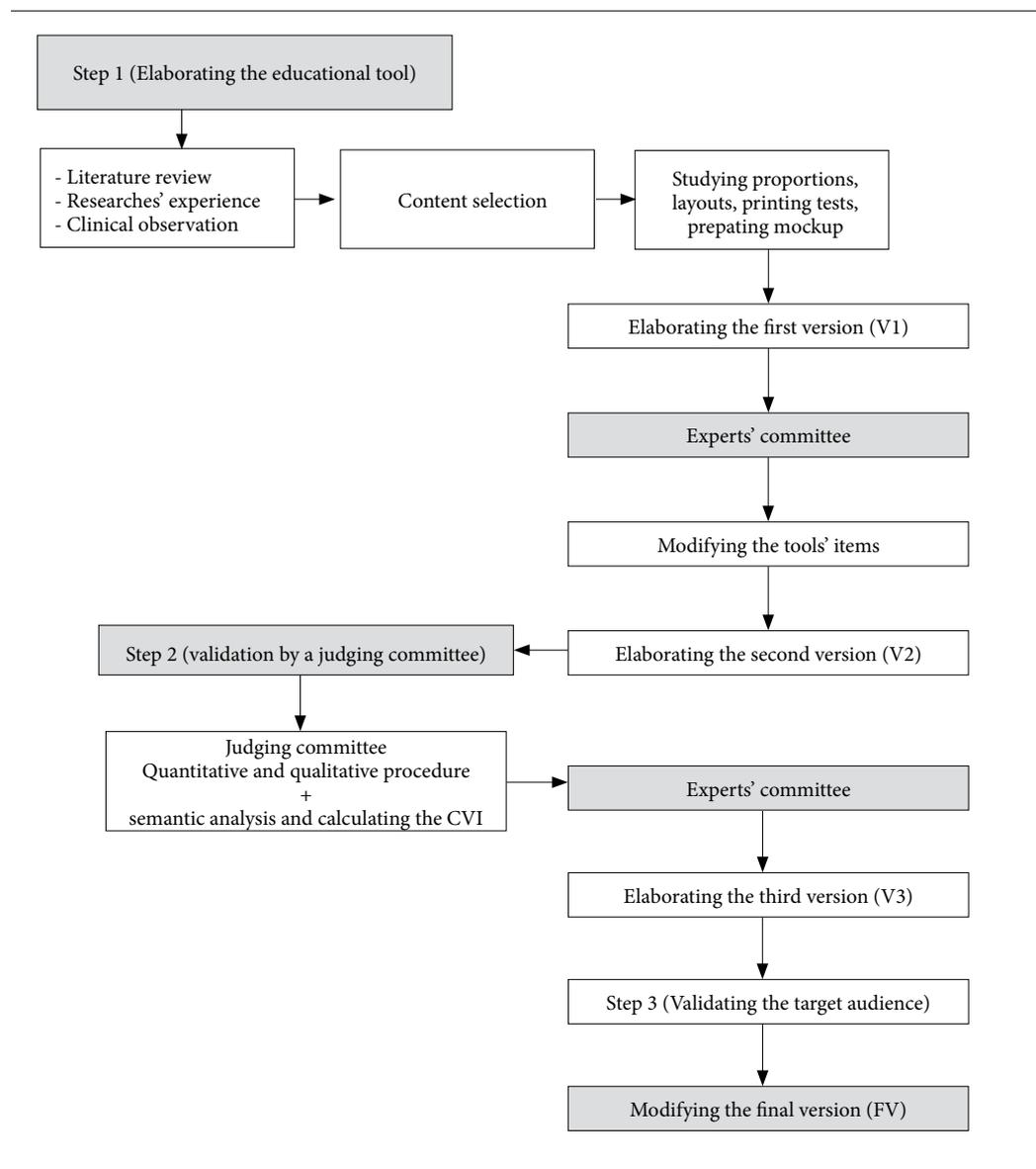


Figure 1. Flowchart of the study steps. Belo Horizonte, Minas Gerais, Brazil, 2020.

Source: Authors (2020).

Study protocol

Step 1 consisted of creating the educational tool and started with a literature review to define the content. We searched PubMed and the Virtual Health Library (BVS) electronic databases, besides the manuals of the American Diabetes Association (ADA)¹ and the Brazilian Diabetes Society (SBD)¹⁹.

Thus, we produced the first version of the (V1) named My Treatment Diary (MTD) edu-

cational tool, consisting of three components, namely: i) virtual manual (booklet with detailed explanation and presentation of the educational tool); ii) educational tool My Treatment Diary (printed leaflet with scales and subscales for completion and interpretation); and iii) sheet of self-adhesive labels (to be detached and used to complete the scales). Thus, the authors refer to the three components presented above when the My Treatment Diary (MTD) tool is mentioned throughout the text.

An expert committee composed of an endocrinologist, three nurses and a nutritionist, professors, and researchers in DM was organized at the end of V1 to assist in discussions on the content and initial layout of the tool and point out adjustment needs, producing the second version (V2), which was submitted to Step 2, featuring validation by the judging committee.

With the physical tool, the sheet of stickers, and its manual in virtual format, the judges evaluated the V2 of the MTD tool for clarity and relevance, using a Likert scale, assigning a score from one to four stars, meaning: 1 star - requires complete redesign; 2 stars - requires partial redesign with many changes; 3 stars - requires partial redesign with optional changes to improve content; 4 stars - no need to redesign.

At the end of the quantitative evaluation, in the online questionnaire, the judges made qualitative considerations about the clarity, relevance, and display of the MTD tool and its manual in a space intended for this purpose.

Once the judges gathered the validation stage considerations, the expert committee met again to produce a pre-final consensual version (V3), where the necessary adjustments were made, involving the redesign of the design project, new proportion studies, and print tests.

We then proceeded to Step 3, which consisted of validation by the target audience. At this stage, a researcher approached the participants individually and showed them only the printed leaflet of the educational tool (V3) and the sheet of self-adhesive labels, asking them to assess their relevance and understanding. The interviews were conducted with a questionnaire prepared by the researchers themselves, which addressed: i) sample identification, containing sociodemographic and clinical data; ii) evaluation of the general understanding of the tool, containing two open-ended questions and seven closed-ended questions, with four Likert response options, where four stars indicated no need for redesign and one star indicated the need for complete redesign; and iii) assessment of the relevance and indication of the MTD, containing two closed-ended questions, also Likert-type, ranging from one to four stars. The respondent could make suggestions in a specific space at the end of the questionnaire.

The target audience recognizing the communication code²⁰ adopted in the MTD and people with DM relating it to the metabolic and pharmacological reflex that involves insulin therapy were considered tool adequacy indicators, consisting of icons and symbolic elements designed to rep-

resent: i) the types of insulin used in their treatment; ii) the bioavailability and half-life of these drugs; and iii) the glycemic variation after the ingestion of carbohydrates – the communicational code only reaches its objective when identified by users.

Analysis of results and statistics

We calculated the Content Validity Index (CVI), which measures the percentage of judges per the aspects of the educational tool and its items, to analyze the validation data from the judging committee. As previously mentioned, the three components of the educational tool are contained in its virtual manual that presents and explains in detail the MTD tool. Therefore, the educational tool was validated by evaluating the judges on each page of the referred manual.

The CVI was calculated with a four-point Likert-type scale. In possession of the physical tool (printed leaflet and sticker sheet) and the manual in virtual format, the judges chose the following answers to assess the relevance of the tool from each page of its manual: 1 point for “not relevant or not representative”; 2 points for “item requires significant revision to be representative”; 3 points for “item requires minor revision to be representative”; and 4 points for “representative item”. The educational tool’s content clarity was also evaluated with the same scale, from each page of its manual, with different response options: 1 point for “unclear”; 2 points for “somewhat unclear”; 3 points for “fairly clear”; and 4 points for “very clear”. The data obtained were analyzed from the sum of responses 3 and 4 from each judge in each MTD item, dividing the sum by the total number of responses^{21,22}.

Content validity consists of the level of representativeness of the concept that the tool intends to measure and provides for evaluating items by clarity and relevance. Clarity assesses whether the textual construction of the MTD items allows proper reading and favors the understanding of the assessed content. At the same time, relevance refers to the content’s meaning level and ability to generate impact and generate interest. We adopted a minimum CVI value of 0.90^{21,22}.

The agreement percentage values were calculated per evaluated item to analyze the target audience’s validation data. A minimum of 75% agreement of positive answers (considered as three- and four-stars evaluations) was adopted for each item of the questionnaire²² to be considered adequate.

Ethical aspects

The Research Ethics Committee of the Santa Casa de Misericórdia de Belo Horizonte evaluated and approved this research under Resolution No. 466/2012 of the National Health Council, which approves the guidelines and regulatory standards for human research²³. All research participants signed the Informed Consent Form (TCLE).

Results

Preparing the My Treatment Diary (MTD) educational tool

The first version (V1) of the MTD educational tool was formulated from the consulted bibliography (Figure 2). The virtual MTD manual was designed with 27 pages in Portable Document Format (PDF) with instructions for professional MTD applicators distributed in four subheadings: 1 - About the MTD; 2 - Complete the MTD; 3 - Main scales; 4 - Chromatic modules. In subtitle 1, the tool, its purpose, and the proposed use are presented to the reader. Subtitle 2 contains a step-wise explanation of how to complete the MTD. An example of data completed by a fictitious patient is presented to facilitate understanding. In subheadings 3 and 4, each scale (basal insulin, insulin for food boluses, and meals with carbs) is explained in detail, besides the meaning of the color variations in each one. The example of a fictitious patient filling in data is preserved.

The printed leaflet of the My Treatment Diary educational tool was designed in A3 format (42 X 29.7cm) printed on 300g matte coated paper, in CMYK color scale (C (cyan), M (magenta), Y (yellow), and K (black)) 4 x 4 colors (front and back). The illustration on the leaflet includes three scales composed of 24 cells each, each of which represents one hour of the day of the therapeutic plan for people with DM. The scales should be completed per the individualized times of meals with carbs and insulin application, both basal and for food boluses, schematically showing the glycemic variation and the half-life of the different types of insulin. The filling is performed by applying the stickers designed per the size of the scales in the leaflet design and obeying the existing color correspondence between the scale and the sticker.

The leaflet scales have three colors that refer to the following components of the therapeutic plan: i) yellow scale = basal insulin (NPH or

long-acting insulin); ii) red scale = meals; and iii) blue scale = food bolus insulin (rapid or ultra-rapid insulin). In orange, below each scale, a subscale indicating the hours was inserted corresponding to the cells of the scale in question, allowing the selection of times regarding the feeding and medication (insulin therapy) routine foreseen in the therapeutic plan by ink recording.

Essential information was inserted under the heading “Five Steps to Understanding My Treatment Diary” on the back of the tool to reinforce the guidelines received by people with DM during the visit: 1 - Recognize the colors: this step contains information about the meaning of each color in the MTD tool (yellow = basal insulin; blue = insulin for food boluses; and red = meal with carb intake), besides space to record the name of each type of insulin used by patients and the carbs most commonly ingested by them; 2 - Recognize the drawings: the symbols used for basal insulin, rapid or ultra-rapid insulin, and meals are presented in this step. In Steps 3, 4, and 5 (3 - Understand how much basal insulin your body has; 4 - Understand how much rapid or ultra-rapid insulin your body has, and 5 - Understand how much carb your body has), the meanings of tone variation of the stickers to be used for completing and interpreting the MTD are explained. Thus, stickers with lighter tones indicate lower insulin bioavailability (for the yellow and blue colors) or lower blood glucose values (for the red scale); and darker shades of stickers indicate greater insulin bioavailability or higher glycemic value.

The two sheets of self-adhesive labels printed on adhesive paper, measuring 24 X 37.5 cm, have 168 labels measuring 3.1 X 1.5 cm each, produced using the same digital printing technique as the leaflet.

The developed tool can be used during individual visits with health team professionals and group activities. It is suggested that patients and health professionals, with the MTD leaflet and the self-adhesive labels in hand, complete the scales of the tool together per the types of insulin used and the reported food consumption during individual or collective educational stages, respecting the color tonality variation to represent more higher or lower availability of insulin and glucose in the body.

Judging committee MTD validation

The multidisciplinary judging committee was composed of ten health professionals. Nine

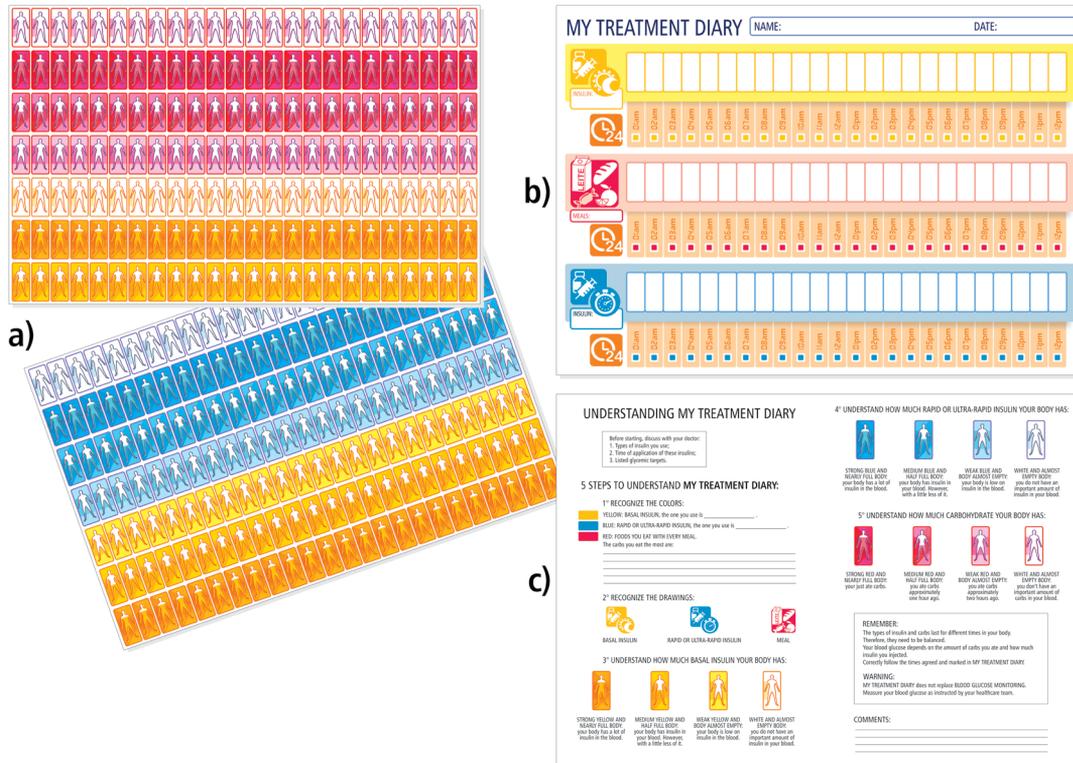


Figure 2. Self-adhesive labels and MTD physical tool. Belo Horizonte, Minas Gerais, Brazil, 2020.

Note: a) Self-adhesive labels; b) Front of the MTD tool, and c) Back of the MTD tool.

Source: Authors (2020).

(90%) were aged 21-44 years, nine (90%) were female, with three (30%) nurses, three (30%) nutritionists, two (20%) endocrinologists, and two (20%) pharmacists. Four (40%) had a doctorate, four (40%) had a master's degree, and two (20%) had a specialization.

The validation of the second version (V2) of the MTD and its virtual manual performed by the judges obtained a mean CVI of 0.996, which indicates a high level of agreement among the judges (Chart 1).

The qualitative considerations of the judging committee originating in the content validation stage were presented at the second meeting of the expert committee, which considered the following suggestions in the MTD manual: i) Replacing the tool's name "My Choice Diary (MCD)"

with "My Treatment Diary (MTD)"; ii) Page 11: changing the term "glycemic index" to read "glycemic variation", since it is a dynamic process that is not restricted to an index obtained in isolated dosage of capillary glycemia; iii) Pages 13 and 14: content and lexical adjustments related to serum insulin level and postprandial glycemic variation, respectively. iv) Page 22: change of title and text of "REPRESENTATION OF THE GLUCOSE CURVE. Note: glycemic elevation within one postprandial hour with a progressive decrease in circulating glucose levels, especially in the second hour after the meal" to read "REPRESENTATION OF THE EXPECTED GLYCEMIC VARIATION. Note: wide glycemic variation within 1 hour after the meal with a progressive drop in circulating glucose levels, especially in

the second hour after the meal". This procedure was followed by correction in the corresponding chromatic module. v) Page 25: adjustment of the content related to the pharmacokinetics of ultra-rapid insulin, which consisted of changing the text from "onset of action occurs 10 to 20 minutes after the injection, with action peak at 3 hours and 3-5 hours action duration" to "onset of action occurs 10 to 20 minutes after injection, with action peak at 1 hour and 3-5 hours action duration", followed by a correction in the corresponding chromatic module.

The expert committee discussed the evaluation data and suggestions made by the judging committee, generating the third version (V3), which was submitted to target audience validation.

Target audience MTD validation

This step was carried out through face-to-face interviews conducted by the study researchers. The studied target population's predominant sociodemographic characteristics were adults, females, living with a companion, and higher education. Regarding clinical data, 58.33% were diagnosed with DM1, 33.34% with DM2, and 8.33% with Wolfram's syndrome. The most prevalent comorbidities and complications were cardiovascular, retinopathy, and severe hypoglycemia episodes (Table 1).

Although the predominant sample had higher education (50%), other levels of education were considered in the research, observing subjects with incomplete primary education or incomplete secondary education. In turn, this condition was not a cognitive impediment to understanding the tool, with a high level of understanding of the MTD even by less-educated strata representatives (Chart 2).

As seen in Chart 2, the understanding and relevance assessment reached the expected levels since only one participant had difficulty understanding the term ultra-rapid, referring to the conceptual meaning item of the blue scale. However, this note was not deemed sufficient to generate changes in the MTD item since the term "ultra-rapid" was taken out of context from the specific user's care routine.

The other suggestions presented by the sample were characterized by: i) subjective observations, such as chromatic predilection; or ii) doubts when completing the fields of the tool (name, date, type of insulin, ingested carbs), which was resolved with the repeated explana-

tion regarding the questioned element. They also did not justify changes in content or layout in the MTD because they are unrelated to the understanding of the educational tool.

The MTD version valid for use in the Brazilian population with DM 1 and 2 was achieved at the end of the described stage.

Discussion

This study aimed to contribute to understanding the relationship between insulin therapy and glycemic variation by adults with DM1 and DM2, investing in the interface between health professionals and patients through an educational tool. Considered a barrier to self-care, the lack of knowledge of DM fundamentals justifies the need for scientific investment in building materials and methods or teaching and learning tools based on a friendly language that facilitates understanding by less-educated people, improving the individual perception of their health and, consequently, the related care^{4,24}.

As the MTD is a tool developed for a conversation about the diet/insulin therapy relationship with people with diabetes, the diabetes educator must, after applying it, interpret the result for the patient, highlighting the need for insulin and carb levels proportionate and adequate to prevent wide glycemic variations. This pertinence is identified in the insulin therapy and meal scales. Thus, when identifying flaws in the scales, adjustments in meal times or greater attention to insulin therapy make more sense for the users.

We could observe the heterogeneous glycemic variability concepts while developing this work: even people with many years of DM could not define insulin therapy, nor did they clearly understand the influence of carb intake on postprandial glycemia. This condition justified the construction of the MTD and led to adopting a methodology sensitive to the sociocultural demands of the population of interest.

Studies^{25,26} show that sociocultural variables influence the self-care behavior of people with chronic conditions. In this sense, by investing in DM as a sociocultural element, the MTD adopts symbolization as a mechanism for articulating the repertoire and language, creating a visual scale that shows educational potential by allowing the target population to understand their condition better. The MTD showed that expressing technical-scientific reasoning through a symbolic system is a valid communication strategy to

Chart 1. Quantitative data from the judging committee regarding the analysis of the MTD. Belo Horizonte. Minas Gerais. Brazil. 2020.

| Page content | Page evaluation parameter | Page | Evaluators | | | | | | | | | | CVI | |
|---------------------------------------------------------------------------------|---------------------------|------|------------|----|----|----|----|----|----|----|----|----|-------|-----|
| | | | 01 | 02 | 03 | 04 | 05 | 06 | 07 | 08 | 09 | 10 | | |
| Cover and authors | Clarity text | 02 | 4 | 4 | 4 | 4 | 4 | 4 | 4 | 4 | 4 | 4 | 4 | 1 |
| | Relevance text | 02 | 3 | 4 | 4 | 4 | 4 | 4 | 4 | 4 | 4 | 4 | 4 | 1 |
| Opening text and guidance to educators | Clarity text | 03 | 4 | 4 | 4 | 4 | 4 | 4 | 4 | 4 | 4 | 4 | 4 | 1 |
| | Relevance text | 03 | 4 | 4 | 4 | 4 | 4 | 4 | 4 | 4 | 4 | 3 | 4 | 1 |
| MTD kit presentation | Clarity text and image | 04 | 4 | 4 | 3 | 4 | 4 | 4 | 4 | 4 | 4 | 4 | 4 | 1 |
| | Relevance text and image | 04 | 4 | 4 | 3 | 4 | 4 | 4 | 4 | 4 | 4 | 4 | 4 | 1 |
| Image of the inner side of the leaflet (scales) | Clarity text and image | 05 | 4 | 4 | 4 | 4 | 3 | 4 | 4 | 4 | 4 | 4 | 4 | 1 |
| | Relevance text and image | 05 | 4 | 4 | 4 | 4 | 4 | 4 | 4 | 4 | 4 | 4 | 4 | 1 |
| Identification of MTD subscales | Clarity text | 06 | 4 | 3 | 4 | 4 | 4 | 4 | 4 | 4 | 4 | 4 | 4 | 1 |
| | Relevance text | 06 | 4 | 4 | 4 | 4 | 4 | 4 | 4 | 4 | 4 | 4 | 4 | 1 |
| Identification of MTD scales | Clarity text | 07 | 4 | 4 | 3 | 4 | 4 | 4 | 4 | 4 | 4 | 4 | 4 | 1 |
| | Relevance text | 07 | 4 | 4 | 4 | 4 | 4 | 4 | 4 | 4 | 4 | 4 | 4 | 1 |
| Illustrative therapeutic plan for the educator | Clarity text and image | 08 | 4 | 4 | 4 | 4 | 4 | 4 | 4 | 4 | 4 | 4 | 4 | 1 |
| | Relevance text and image | 08 | 4 | 4 | 4 | 4 | 4 | 4 | 4 | 4 | 4 | 4 | 4 | 1 |
| Inner side of the leaflet with the completed insulin therapy scales | Clarity text | 09 | 4 | 4 | 4 | 4 | 4 | 4 | 4 | 4 | 4 | 4 | 4 | 1 |
| | Relevance text | 09 | 4 | 4 | 4 | 4 | 4 | 4 | 4 | 4 | 3 | 4 | 4 | 1 |
| Illustrative food plan for educators | Clarity text and image | 10 | 4 | 4 | 3 | 4 | 4 | 4 | 4 | 4 | 4 | 4 | 4 | 1 |
| | Relevance text and image | 10 | 4 | 4 | 4 | 4 | 4 | 4 | 4 | 4 | 4 | 4 | 4 | 1 |
| Inner side of the leaflet with the completed meal scale | Clarity text | 11 | 4 | 4 | 3 | 4 | 4 | 4 | 4 | 4 | 3 | 4 | 4 | 1 |
| | Relevance text | 11 | 4 | 4 | 4 | 4 | 4 | 4 | 4 | 4 | 4 | 4 | 4 | 1 |
| Description of the sticking technique of the MTD scales | Clarity image | 12 | 4 | 3 | 4 | 4 | 4 | 4 | 4 | 4 | 3 | 4 | 4 | 1 |
| | Relevance image | 12 | 4 | 4 | 4 | 4 | 4 | 4 | 4 | 4 | 4 | 4 | 4 | 1 |
| Image of self-adhesive label flyers | Clarity text and image | 13 | 4 | 3 | 3 | 4 | 4 | 4 | 4 | 4 | 4 | 4 | 3 | 1 |
| | Relevance text and image | 13 | 4 | 4 | 4 | 4 | 4 | 4 | 4 | 4 | 4 | 4 | 4 | 1 |
| Criteria for using colors and illustrations of MTD stickers (insulin therapy) | Clarity text and image | 14 | 4 | 4 | 3 | 4 | 4 | 4 | 4 | 4 | 2 | 4 | 3 | 0.9 |
| | Relevance text and image | 14 | 4 | 3 | 4 | 4 | 4 | 4 | 4 | 4 | 3 | 4 | 4 | 1 |
| Criteria for using colors/illustrations on MTD stickers (meals) | Clarity text and image | 15 | 4 | 4 | 4 | 4 | 4 | 4 | 4 | 4 | 4 | 4 | 4 | 1 |
| | Relevance text and image | 15 | 4 | 4 | 4 | 4 | 4 | 4 | 4 | 4 | 3 | 4 | 4 | 1 |
| Basal insulin recording template | Clarity text and image | 16 | 4 | 4 | 3 | 4 | 4 | 4 | 4 | 4 | 3 | 4 | 4 | 1 |
| | Relevance text and image | 16 | 4 | 4 | 4 | 4 | 4 | 4 | 4 | 4 | 4 | 4 | 4 | 1 |
| Meal log template | Clarity text and image | 17 | 4 | 4 | 4 | 4 | 4 | 4 | 4 | 4 | 3 | 4 | 4 | 1 |
| | Relevance text and image | 17 | 4 | 4 | 4 | 4 | 4 | 4 | 4 | 4 | 3 | 4 | 4 | 1 |
| Insulinization log template for food boluses | Clarity text and image | 18 | 4 | 4 | 4 | 4 | 4 | 4 | 4 | 4 | 4 | 4 | 4 | 1 |
| | Relevance text and image | 18 | 4 | 4 | 4 | 4 | 4 | 4 | 4 | 4 | 4 | 4 | 4 | 1 |
| Inner side of the leaflet with the completed scales (insulin therapy and meals) | Clarity text | 19 | 4 | 4 | 3 | 4 | 4 | 4 | 4 | 4 | 4 | 4 | 4 | 1 |
| | Relevance text | 19 | 4 | 4 | 4 | 4 | 4 | 4 | 4 | 4 | 4 | 4 | 3 | 1 |
| Patient tool interpretation guidelines | Clarity text | 20 | 4 | 3 | 4 | 4 | 4 | 4 | 4 | 4 | 4 | 4 | 4 | 1 |
| | Relevance text | 20 | 4 | 3 | 4 | 4 | 4 | 4 | 4 | 4 | 4 | 4 | 4 | 1 |
| Description of the content on the outer side of the leaflet | Clarity text and image | 21 | 4 | 4 | 4 | 4 | 4 | 4 | 4 | 4 | 3 | 3 | 4 | 1 |
| | Relevance text and image | 21 | 4 | 4 | 4 | 4 | 4 | 4 | 4 | 4 | 4 | 3 | 4 | 1 |
| Image of the outer side of the leaflet | Clarity text and image | 22 | 4 | 4 | 4 | 4 | 4 | 4 | 4 | 4 | 3 | 4 | 4 | 1 |
| | Relevance text and image | 22 | 4 | 4 | 4 | 4 | 4 | 4 | 4 | 4 | 4 | 4 | 3 | 1 |
| Chromatic modules for completing the meals' scale | Clarity text and image | 23 | 4 | 4 | 4 | 4 | 4 | 4 | 4 | 4 | 3 | 4 | 4 | 1 |
| | Relevance text and image | 23 | 4 | 4 | 4 | 4 | 4 | 4 | 4 | 4 | 4 | 4 | 4 | 1 |
| Chromatic modules for completing the basal insulin therapy scale | Clarity text and image | 24 | 4 | 4 | 4 | 4 | 4 | 4 | 4 | 4 | 3 | 4 | 4 | 1 |
| | Relevance text and image | 24 | 4 | 4 | 4 | 4 | 4 | 4 | 4 | 4 | 4 | 4 | 4 | 1 |
| Color modules for completing the insulin therapy scale for food boluses | Clarity text and image | 25 | 4 | 4 | 4 | 4 | 4 | 4 | 4 | 4 | 3 | 4 | 4 | 1 |
| | Relevance text and image | 25 | 4 | 4 | 4 | 4 | 4 | 4 | 4 | 4 | 4 | 4 | 2 | 0.9 |
| Mean CVI | Clarity | | | | | | | | | | | | 0.996 | |
| | Relevance | | | | | | | | | | | | 0.996 | |

Source: Authors (2020).

Table 1. Sociodemographic and clinical data of the target population sample. Belo Horizonte, Minas Gerais, Brazil, 2020.

| Variable | Frequency | % |
|---------------------------------|-----------|-------|
| Age (years) | | |
| 18-20 | 2 | 16.67 |
| 21-44 | 7 | 58.33 |
| 45-59 | 3 | 25.0 |
| Sex | | |
| Male | 5 | 41.67 |
| Female | 7 | 58.33 |
| Marital status | | |
| With a companion | 7 | 58.33 |
| Without a companion | 5 | 41.67 |
| Schooling | | |
| Incomplete Elementary School | 2 | 16.67 |
| Incomplete High School | 2 | 16.67 |
| Incomplete Higher Education | 2 | 16.67 |
| Higher Education | 6 | 50.0 |
| Diabetes Mellitus Type | | |
| DM1 | 7 | 58.33 |
| DM2 | 4 | 33.34 |
| Wolfram's syndrome | 1 | 8.33 |
| Comorbidities and complications | | |
| Cardiovascular complications | 3 | 25 |
| Retinopathy | 3 | 25 |
| Nephropathy | 2 | 16.67 |
| Severe hypoglycemia | 3 | 25 |
| Severe hyperglycemia | 2 | 16.67 |
| Ketoacidosis | 2 | 16.67 |

Source: Authors (2020).

configure the educational and pedagogical message during the tool's testing phase. This conceptual proposal dialogues with health studies that aim to approach resources sensitive to the specificities of vulnerable communities^{27,28}.

Specifically, concerning the symbolic treatment given to insulin pharmacokinetics, MTD resonates with previous pharmaceutical care studies. In 1991, Lefèvre considered the drug's symbolic and psychosocial functions linked to its chemotherapeutic performance in curing or improving symptoms²⁹. More recently, an experience report at a PHC Unit described the benefits of using icons and pictograms to humanize pharmaceutical care³⁰. The same MTD strategy was used to guide the rational use of medications and encourage self-care. By using symbolic visual communication resources in the leaflet, such as i) the representation of the day in scales; ii) the development of icons for insulin types and carb intake; iii) the chromatic gradation to simulate the glycemic variation and the pharmacological bioavailability of insulin, the MTD mediates learning about the terms and their meanings related to DM, which are complex for most of this population.

Developing educational tools that respond to the target population's need for knowledge also involves drawing educators and people with DM closer. Based on this premise, the MTD communication project proposed articulating two language levels: i) technical enough to guide professional practice and ii) accessible enough to

Chart 2. MTD evaluation in the pre-test phase. Belo Horizonte, Minas Gerais, Brazil, 2020.

| MTD items | | Agreement* |
|-------------------------------------------------------------|--------------------|------------|
| Question 1: MTD general aspects | | 1 |
| Questions 2 and 3: Understanding the yellow scale | Conceptual meaning | 1 |
| | Graphic meaning | 1 |
| Questions 4 and 5: Understanding the red scale | Conceptual meaning | 1 |
| | Graphic meaning | 1 |
| Questions 6 and 7: Understanding the blue scale | Conceptual meaning | 0.9 |
| | Graphic meaning | 1 |
| Question 8: MTD relevance assessment | | 1 |
| Question 9: MTD indication assessment | | 1 |
| Total agreement percentage | | 0.99 |

*Agreement based on the frequency of responses rated as 3 and 4 stars. Comprehension assessment scale: 4 points = "user had no difficulty understanding"; 3 points = "user had difficulty understanding"; 2 points = "user requested the explanation to be repeated" and 1 point = "user did not understand". Relevance and indication assessment scale: 4 points = "user believes so"; 3 points = "user believes it can be of some use"; 2 points = "user is unable to give an opinion" and 1 point = "user believes not".

Source: Authors (2020).

represent relevant information as easy repertoire mastery symbols. Initially, these plans are found in different interfaces and later articulated upon educational practice: manual (intended for professional educators) and leaflet (for use by people with DM).

The literature also provides other strategies applied to this context, from advanced technological resources, such as apps and smartphones, to those that remain in light healthcare technologies^{30,31}. The professional educator should identify the one that best fits the intervention environment and the specific demands of the population of interest.

The primary limitations observed in the study were: i) the convenience sampling of the target audience that evaluated the tool, ii) the need for a qualified health educator to work with the MTD, iii) and the financial investment for the production of MTD kits (leaflets and self-adhesive labels).

Considering the sampling limitations, the study fully complied with the defined inclusion and exclusion criteria, although the sample was restricted to outpatient service users. Notably, the group participating in this validation stage had a balanced distribution regarding gender, age, schooling level, and DM type, securing participants with different profiles regarding variables that could interfere with a greater or lesser understanding of the tool. The MTD is a tool used during healthcare and should not be self-administered. Thus, the presence of health professionals during its application can facilitate the resolution of potential user concerns about the tool.

The need for a trained professional to apply the tool is justified by the demand to analyze the insulin therapy/carb intake ratio. The diabetes educator is expected to be a doctor, nurse, nutritionist, or pharmacist – professions that gather the necessary expertise to guide people with DM adequately. Thus, the fact that different health team professionals can use the tool facilitates its use, mitigating the disadvantage characterized by the need for training.

The MTD manual was designed in a virtual format to facilitate access, providing a more flexible medium for consultation on mobile devices and distance training. Its content was written with objective language, built from a practical example that could represent the reality of professional educators and facilitate their understand-

ing. Moreover, the digital format of its manual is also a cost-cutting strategy, and only the brochure and self-adhesive labels should be printed.

The need for financial investments to implement the educational intervention that uses the MTD is indisputable. The support of government agencies is necessary for reproducing, disseminating, and widely distributing this material in health services. On the other hand, it is essential to consider that its reproduction cost (currently calculated at R\$ 3.10/MTD kit, consisting of a leaflet and adhesive labels) is substantially lower than the potential expenses with the necessary investments to treat acute and chronic complications of people with ineffective control of the medication regimen for DM, a situation in which MTD can contribute.

Finally, noteworthy is the challenge of presenting the results of a methodological study with the objectivity and clarity imposed by scientific writing. In this process, using the SQUIRE 2.0 tool contributed to selecting, organizing, and presenting the most relevant information produced by this study. The SQUIRE 2.0 guidelines provide an instrumental framework for reporting new knowledge about interventions to improve health care and can be adapted to the most varied approaches and interventions that share this purpose¹⁵. Its use has been increasing in methodological development studies, including studies on elaborating and validating educational technologies³²⁻³⁵.

Access to the tool for downloading the virtual manual and the printing files for the leaflet and self-adhesive labels is available at: <https://drive.google.com/drive/folders/1XUSX9pWCy-jc0ZzUq6PU8yZ3V3DLWDYMB>, with copyright assigned to Santa Casa Faculty of Belo Horizonte.

Conclusions

The content and display of the My Treatment Diary (MTD) educational tool are deemed validated and culturally appropriate to promote understanding of insulin treatment in adults with type 1 and type 2 DM. We expect that future studies will be conducted to evaluate the effectiveness of MTD as a motivator of adequate self-care behavior that produces clinical benefits from greater control over glycemic variability.

Collaborations

LHD Miranda: study conception and design; data analysis and interpretation; paper writing and approval of the version to be published. JS Reis: study conception and design; data interpretation; article critical review and approval of the version to be published. SR Oliveira: study conception and design; data interpretation; article critical review and approval of the version to be published.

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