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Original article

Validation of educational-therapeutic technology applied to children with Type 1 Diabetes *Mellitus*: institutional standard protocol*

Validação de tecnologia educativo-terapêutica aplicada à criança com Diabetes *Mellitus* Tipo 1: protocolo institucional padrão

Validación de tecnología educativo-terapéutica aplicada a niños con Diabetes *Mellitus* Tipo 1: protocolo institucional estándar

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Abstract

Objective: developing, validating, and implementing educational-therapeutic technology in the format of an institutional standard protocol aimed at the care of children with type 1 diabetes mellitus. **Method:** a methodological study was carried out in a public hospital in the Federal District of Brazil with the participation of seven nurses in the validation stage and five children and their family members in the implementation stage between August/2021 and October/2022. The validation was carried out online using a *Likert* scale instrument, and an analysis using the Content Validity Index and the Intraclass Correlation Coefficient was performed. During the health education session, in-person interviews were conducted, and notes were taken in the field diary. **Results:** The developed technology raised topics related to the daily care of children and diabetes *mellitus* disease. Validation achieved an agreement rate of 0.78% and a correlation coefficient of 0.525. The implementation stage identified potentialities and weaknesses regarding health care. **Conclusion:** the protocol was considered comprehensive, thus promoting adherence to treatment and supporting quality and safe care.

Descriptors: Pediatric Nursing; Validation Study; Health Education; Diabetes Mellitus, Type 1; Educational Technology



Resumo

Objetivo: desenvolver, validar e implementar tecnologia educativo-terapêutica, no formato de protocolo institucional padrão, destinada ao cuidado da criança com diabetes *mellitus* tipo 1. **Método:** estudo metodológico, realizado em hospital público no Distrito Federal, participaram sete enfermeiros na validação, cinco crianças e familiares, na implementação, entre agosto/2021 e outubro/2022. Realizou-se validação de maneira *on-line*, utilizado instrumento de escala do tipo *Likert* e análise pelo Índice de Validade de Conteúdo e Coeficiente de Correlação Intraclasse. Na sessão educação em saúde, de maneira presencial, foram realizadas entrevistas e anotações no diário de campo. **Resultados:** tecnologia elaborada apresentou assuntos relacionados aos cuidados diários de crianças e à doença diabetes *mellitus*. A validação alcançou um índice de concordância de 0,78%, coeficiente de correlação de 0,525. A implementação identificou potencialidades e fragilidades relacionadas no cuidado da saúde. **Conclusão:** considerou-se o protocolo abrangente, promovedor na adesão ao tratamento subsidiando cuidado com qualidade e segurança.

Descritores: Enfermagem Pediátrica; Estudo de validação; Educação em Saúde; Diabetes Mellitus Tipo 1; Tecnologia Educacional

Resumen

Objetivo: desarrollar, validar e implementar tecnología educativo-terapéutica, en formato de protocolo institucional estándar, destinada a la atención de niños con diabetes *mellitus* tipo 1. **Método**: estudio metodológico, realizado en un hospital público del Distrito Federal, En la validación participaron siete enfermeros, cinco niños y familiares, durante la implementación, entre agosto/2021 y octubre/2022. La validación se realizó en línea, mediante un instrumento de escala tipo Likert y el análisis mediante el Índice de Validez de Contenido y Coeficiente de Correlación Intraclase. En la sesión de educación en salud se entrevistas de forma presencial y se tomaron notas en el diario de campo. **Resultados:** la tecnología elaborada presentó temas relacionados con el cuidado diario de los niños y la enfermedad diabetes *mellitus*. La validación logró una tasa de acuerdo del 0,78% y un coeficiente de correlación de 0,525. La implementación identificó las potencialidades y debilidades relacionadas en la atención de salud. **Conclusión:** el protocolo se consideró integral, eficaz en la promoción de la adherencia al tratamiento, y en el ofrecimiento de una atención segura y de calidad.

Descriptores: Enfermería Pediátrica; Estudio de validación; Educación en Salud; Diabetes Mellitus Tipo 1; Tecnología Educacional

Introduction

Chronic health diseases involve biological, psychological or cognitive conditions, which may lead to dependence on certain medications and the use of devices for continuous care focused on the health and life quality of children and their family members. Diabetes *Mellitus* represents a growing public health problem and is related to several aspects such as rapid urbanization, sedentary lifestyle, disease awareness, and clinical management by health professionals.¹

Diabetes *Mellitus* (DM1) has an increasing incidence, which is triggered by a variety of socioeconomic, demographic, environmental, and genetic factors. It is estimated that 1.1 million children and adolescents live with DM1.² Studies have shown that Brazil has the highest number of cases in the age group between zero and 14 years old and that health education is one of the main measures used to control the disease.^{1,3}

The access to relevant information, from the moment of receiving the diagnosis of DM1 to its treatment process, encourages these individuals to get involved in their health conditions. The complexity of this condition in everyday life entails the promotion of health education. In this sense, there are technological resources that can facilitate the promotion of health education for people with DM1, both in terms of understanding the disease and during their treatment, thus strengthening their self-care. Due to the complexity of this situation, an educational-therapeutic technology (ETT) was chosen in the format of an institutional standard protocol (ISP) to support educational actions by health professionals focused on caring for hospitalized children with DM1.⁴ The use of ETT consists of a practical and effective way of providing information on important aspects for the efficiency of a given treatment and its follow up, in addition to promoting health in the daily lives of people with diabetes.⁵⁻⁶

Health education encourages individual and family responsibility while managing the promotion and treatment of DM1. Communication is the main empowering vehicle of any individual. Therefore, the professional must opt for a person-centered approach, as scientific literature demonstrates that individualized care is effective in encouraging change and helping patients achieve good metabolic control.¹

In the context of the pediatric population, educators of children with DM1, regardless of their level of care, are encouraged to develop educational technologies that facilitate their work process, reinforcing it with a playful resource. This resource allows professionals to use their technical-scientific expertise to share knowledge, thus improving the quality of care they provide.⁷⁻⁸

The relevance of this study includes the use of the ETT as an instrument that assists management and care, thus providing users with new meanings and experiences that will contribute to the development of protective factors for their health. Several ETTs have been developed and validated with the aim of contributing to the care of children with DM1.⁶⁻⁹

The objective of this study was to develop, validate, and implement an ETT in the ISP

format aimed at caring for children with DM1.

Method

This is a methodological study about the development and validation of an ETT in the ISP format, focused on providing health education sessions for children with DM1, carried out between August 2021 and October 2022.⁹ This whole process was developed through four stages: I. bibliographic research; II. development of the ETT; III. content validation; and IV. implementation, in which the activity, a health education session, was carried out with an educational-therapeutic approach.

The study was developed in a public hospital in Brasília, a reference in maternal-child care in the Center-West region of Brazil, linked to the State Department of Health of the Federal District (SDH-FD) and belonging to the South Regional Health Coordination. This is a teaching hospital that, in addition to providing health care to the population, develops human resources training activities, being, above all, a reference unit in procedures with greater technological density. It is a training, teaching, and performance center for relevant areas of expertise involving children's health.

Stage I: bibliographical research for developing the ETT

From September to November 2021, non-systematized research was used to obtain technical references on the topic, which led to the following materials: Guideline of the Brazilian Diabetes Society 2019-2020,¹ Basic Care Booklet for the care of people with chronic Diabetes *Mellitus*, No. 16,¹⁰ clinical protocol and therapeutic guidelines for type 2 Diabetes *Mellitus*,¹¹ in addition to instruction manuals supplied by the manufacturers of the materials used for glycemic monitoring and insulin therapy. In this sense, the topics that would compose the ISP content have been determined, which included self-care, resources, glycemic monitoring, waste disposal, and updated recommendations on the care of people with DM1. The choice of content is linked to the autonomy of the person or family member regarding the self-care of the patient with DM1 once the child is discharged from the hospital.

Stage II: development of the ETT

The technological content, in the ISP format, developed by a team of researchers between December 2021 and February 2022, includes title; action to be carried out; sector where it would be used; name of the head researcher; responsible professional; material to be used; procedural guidelines; description of the steps to be carried out before, during and after; expected results; references.

The necessary resources for implementing the ISP were listed as follows: glucometer, blood glucose test strips, lancing device and lancets; fabric doll with polymer material, instructional therapeutic toy (ITT) made with Ethylene-vinyl acetate (EVA); insulin syringes vial of Neutral Protamine Hagedorn (NPH) and Regular insulin, insulin refill, permanent and disposable insulin pen; alcohol swab or cotton balls moistened in 70% alcohol solution; procedure gloves; patient's printed insulin prescription; printed blood glucose diary template.

The ITT used in the health education session is made of virgin silicone fiber 100% polyester (filling foam) and non-woven fabric (TNT); it can be fully disinfected with 70% alcohol, and its disinfection is recommended at each session. It can be pierced with both lancets and needles under the supervision of a responsible adult to avoid accidents and contamination by children; hair and outfits are removable, which makes it possible to change colors for greater resemblance to each child (Figure 1).



Figure 1- Representation of the therapeutic toy used in the health education session.

Stage III: ISP validation

From March to July 2022, this ISP was validated by expert judges. For the selection process, an adaptation of the Fehring criteria¹² were used as a reference. To be considered an *expert*, a minimum score of five points was stipulated.

The selection of eligible experts was carried out through searches made on the Lattes Platform. The "search curriculum" option was selected, and the "subject" filter was used, along with the following keywords: "diabetes *mellitus*," "validation studies," "health education," and "educational technology"; the options "doctors" and "other researchers" were also selected. Once a professional who fulfilled the referred prerequisites was identified, he/she would be asked to recommend others who also met the criteria, thus featuring a snowball sampling.

The criteria for selection included professionals with a master's or doctorate degree and/or professional experience in caring for children with diabetes and/or any scientific production in the field of instrument validation. It must be noted that an odd number of experts was essential to avoid eventual ties regarding the opinions given during the validation stage.

To prepare the survey in the *Likert* format, we chose to use a validated instrument,¹³ containing 22 questions, the answers to which would vary between "I agree," "I partially agree," and "I disagree," with the first answer being considered appropriate for technology validation purposes, as it added information about the judges' sociodemographic profile. This instrument was tested among researchers on the research team and adapted for use in the ISP validation stage. Below each topic, some space was left for the evaluators' comments.

The material was sent to the judges by electronic mail (e-mail), and the attachments included a Free and Clarified Consent Term (FCCT) and an invitation letter with two links, one to be filled with their sociodemographic characteristics such as level of education, length of professional experience, and a survey, with information on the technology's validation.

For data analysis, the Excel program, included in the *Microsoft Office Professional Plus*, version 2013, and the International Business Machines (IBM) *Statistical Package for the Social Sciences* (SPSS) software, version 23.0, have been used. The Content Validity Index (CVI) and the Intraclass Correlation Coefficient (ICC)¹⁴⁻¹⁵ have been calculated. The IVC of 0.78 has been established as the minimum acceptable value for validation, reinforcing that an ICC close to 1 indicates high agreement between the values of the same group and, if low, that is, close to zero, it indicates that the values are not similar. The ICC measures the agreement between more than two evaluators. Currently, it is also a value used to determine the validity of an instrument based on the agreement between the judges.

Once the validation stage was completed, the ISP was adjusted in accordance with the validated data and the judges' suggestions, and a pilot test was arranged, which was carried out in two meetings with the participation of the research team. The following topics were addressed: initial information about the relevance of patient care, management of the guiding

question, group relaxation, and further relevant aspects to be addressed. In the pilot test, the ISP was implemented concomitantly with the ITT, with the presence of a nurse, a child, and their respective family member. It is noteworthy that these individuals did not participate in the implementation stage. The pilot test reinforced the fact that the protocol was suitable for being implemented in educational and health sessions with children and their family caregivers.

Stage IV: ETT implementation

This stage was carried out between August and September 2022. Participants were chosen for convenience and approached during hospitalization based on the child's clinical condition. Here are the inclusion criteria during the development of this stage: children hospitalized with DM1 and their respective family caregivers; in turn, these were the exclusion criteria: children who did not feel clinically suitable to participate and those with behavioral disorders, as well as family caregivers with cognitive difficulties. The term "family caregiver" was chosen to represent a family member who did not have any training in the healthcare area but who had acquired some experience, a definition adopted by the Brazilian Ministry of Health and by this study.¹⁶ To ensure their anonymity, participants were designated by the term Family followed by a sequential number from 1 to 5.

The session was personalized, with the collection of data on sociodemographic and clinical profiling of the participants, which included age, sex, the family caregiver, the person primarily responsible for accompanying the child, the type of diabetes, the time since diagnosis, medications in use, whether or not any type of training was performed, how it was performed and which devices were used for glycemic monitoring; as well as some data on the family members: main caregiver who will be responsible for handling care and their level of schooling, and information on how waste was disposed of and what was its final destination.

Before starting the educational session, the researcher came forward, informing their name and occupation, providing information on the research, its objective, the average duration of the semi-structured interview, the material to be filled out, in addition to presenting the FCCT and requesting the signature of the family caregiver, they also requested the child to sign the Agreement Term, and so the bond between the researcher and the dyad began. During the session, the doll was used to illustrate the situation. Each participant named the doll and referred to their own health condition.

The session was arranged to last approximately 60 minutes. The location was chosen by the child in accordance with its physical space possibilities. Based on the interview carried out, the strengths and weaknesses of the dyad in relation to the context of diabetes were identified and analyzed in light of the daily life of the child with DM1 during the ISP implementation. The field diary and field observations were used, constituting important tools that made it possible for researchers to document their reflections in order to analyze the narratives and determine the profiling of the children and their family caregivers, as well as to report the interaction with the EVA doll. The narratives were associated with theoretical references,^{1,10-11} manufacturers' instruction manuals. After the initial contact, the steps listed in the ISP were duly followed, and at each completion, additional information was included in parentheses as field diary notes.

The project was submitted and approved by the SES-DF Research Ethics Committee. The entire research was based on Resolution No. 466/2012 of the National Health Council of the Ministry of Health, which ensures the transparency of the process and the privacy of its participants. It was approved by protocol No. 5.192.420 of January 4, 2022. This research ensures the privacy and confidentiality of those involved, and they are guaranteed the right to withdraw consent to participate at any time without causing any damage to them.

Results

Stage I: bibliographical research for developing the ETT

The research carried out based on the referred framework^{1,10-11} aimed to collect information to produce the ETT. The matrix provided by the Permanent Commission of Health Care Protocols of the SES-DF was used as a basis, followed by the choices on the type of font and font size, in which case, the Times New Roman font and font size 10 with left-aligned text. It is recommended that the ISP is introduced to the child in the presence of the family caregiver who is accompanying them during the health educational session, as the presence of the family member is essential for the success of the session and for the child's comfort. Stage II: development of the ETT

The technology developed was entitled "Institutional Standard Protocol for children and their family in the therapeutic management of DM1", consisting of six pages that covered the following topics: guidelines, necessary materials, description of the steps (glycemic monitoring, glucometer, reagent strips, lancing pen and capillary blood glucose testing), insulin therapy (conservation and validity of sealed insulin in use, transport of unopened packaging, flask, refill, disposable and permanent pen, insulin syringes, recommended sites for injection, rotation technique, as well as preparation and injection technique), waste disposal and its final destination, procedure after session and expected results.

The illustrations were used with the aim of portraying the idea of each topic covered by the technology. To this end, they were arranged on each page according to the topic presented (Figure 2). Regarding the written form, it was decided to use topics with explanatory content.



Figure 2 - Example of a figure presented in the ISP about the recommended sites for insulin injection. Source: Brazilian Society of Diabetes, 2020¹

Stage III: ETT content validation

Following the ISP development process, content validation was carried out, with the feedback of seven judges. The group of judges was made up of nurses with master's degrees (71.4%) and doctors' degrees (28.6%).

Table 1 shows the judges' responses for each domain included in the instrument, as well as its content assessment. The best-rated items with 100% agreement involved domains 5, 8, 12, 13, 14, 15, and 20. The items in which the "I partially agree" score was higher than the "I agree" score were "layout assessment" and "guidelines," both with a 57.1% agreement rate.

Items that had a mean lower than the CVI established in the study were reviewed and

modified. Considering the appropriate responses as "I agree" and "I partially agree", a total CVI of 1.0 was achieved. In this study, the ICC was 0.525 (95% I.C. –0.103 – 0.899), which represents moderate agreement between participants.

Table 1 - Descriptive analysis of the survey answered by judges participating in the validationstudy of educational technology for children with type 1 diabetes *mellitus*, Brasília, 2022

Logardially agree	-		
i partially agree	3	42.8	
l agree	4	57.1	
I partially agree	4	57.1	
l agree	3	42.8	
I partially agree	2	28.6	
l agree	5	71.4	
I partially agree	4	57.1	
l agree	3	42.8	
I partially agree	2	28.6	
l agree	5	71.4	
I partially agree	4	57.1	
l agree	3	42.8	
l agree	7	100	
I partially agree	1	14.3	
l agree	6	85.7	
I partially agree	2	28.6	
l agree	5	71.4	
l agree	7	100	
I partially agree	1	14.2	
l agree	6	85.7	
I partially agree	1	14.3	
l agree	6	85.7	
I partially agree	2	28.6	
l agree	5	71.4	
lagree	7	100	
lagree	7	100	
l agree	7	100	
lagree	7	100	
I partially agree	1	14.3	
lagree	6	85.7	
I partially agree	2	28.6	
lagree	5	71.4	
I partially agree	1	14.2	
lagree	6	85.7	
I partially agree	3	42.8	
l agree	4	57.1	
l agree	7	100	
	l partially agree l agree l agree	I partially agree3I agree4I partially agree4I agree3I partially agree2I agree5I partially agree4I agree3I partially agree2I agree5I partially agree4I agree3I partially agree4I agree7I partially agree1I agree6I partially agree1I agree7I agree7I agree7I agree7I agree7I agree7I agree1I agree6I partially agree1I agree5I agree5I agree6I partially agree1I agree5I partially agree1I agree6I partially agree3 <td>I partially agree 3 42.8 I agree 4 57.1 I partially agree 4 57.1 I agree 3 42.8 I partially agree 2 28.6 I agree 5 71.4 I partially agree 4 57.1 I agree 3 42.8 I partially agree 4 57.1 I agree 3 42.8 I partially agree 2 28.6 I agree 5 71.4 I partially agree 4 57.1 I agree 5 71.4 I partially agree 1 14.3 I agree 6 85.7 I partially agree 1 14.2 I agree 6 85.7 I partially agree 1 14.3 I agree 6 85.7 I partially agree 1 14.3 I agree 7 100 I agree 7 100 I agree 7 100 I agree</td>	I partially agree 3 42.8 I agree 4 57.1 I partially agree 4 57.1 I agree 3 42.8 I partially agree 2 28.6 I agree 5 71.4 I partially agree 4 57.1 I agree 3 42.8 I partially agree 4 57.1 I agree 3 42.8 I partially agree 2 28.6 I agree 5 71.4 I partially agree 4 57.1 I agree 5 71.4 I partially agree 1 14.3 I agree 6 85.7 I partially agree 1 14.2 I agree 6 85.7 I partially agree 1 14.3 I agree 6 85.7 I partially agree 1 14.3 I agree 7 100 I agree 7 100 I agree 7 100 I agree

Items Domain 21: procedure after implementing the	I partially agree	1	14.3
therapeutic toy	l agree	6	85.7
Items Domain 22: expected results	I partially agree	1	14.3
items Domain 22. expected results	l agree	6	85.7
Overall assessment of the instrument (check that all	I partially agree	3	42.8
dimensions were included). Is the instrument comprehensive?	lagree	4	57.1
Total		7	100

Adequacy of the ETT after validation by the expert judges

After each item was validated, the judge presented suggestions, a relevant moment for obtaining constructive criticism, thus enabling improvements in the educational material.

In the content validation related to the ETT title, three judges validated it as partially adequate. For consisting of a specific population, experts suggested the inclusion of the term "family," which was accepted in its final version. Regarding the layout of the instrument, an expert suggested more playfulness, with the inclusion of photos, especially in the domain relating to the rotation of injection sites. Therefore, illustrations were added to this topic.

In the initial version of the ISP, a 40-minute duration was stipulated for the health educational session. However, one of the judges, claiming that this duration was insufficient, suggested the extension of this time range to encompass every topic of the instrument. The suggestion was accepted, and the respective amendment was made to the final version, with the session duration being extended to 60 minutes.

Another judge suggested changing the ISP presentation order, inserting the "guidelines" above the "required materials," and proposed changes regarding spelling and accentuation. Referring to domain 1, "required materials," three judges responded that they partially agreed. It was suggested that there be a separation between the topics "glucometer" and "battery," the inclusion of the insulin pen, specifying which type would be used, and finally, the inclusion of a figure of a storage box for transporting and storing insulin. Regarding domain 2, "guidelines," four judges responded that they partially agreed and justified their answers. The second evaluator of this topic suggested a standardization of terms. The third, in turn, suggested the addition of the phrase "allow the child and accompanying adult to carry out the procedure in the ITT, under supervision, to avoid accidents and correct possible errors." Another evaluator suggested replacing the term "doll" with "simulator"; this observation was appreciated; however,

it did not interfere with the improvement of the educational material and was therefore disregarded.

In relation to domains 3, 4, and 5, referring to "description of the steps," "glycemic monitoring," and "reagent strips", respectively, suggestions were made regarding the rearranging of the sequence of the steps, the addition of symptoms of hypoglycemia and hyperglycemia and the spelling correction of some words. In relation to domains 6 to 10 on insulin therapy, the following suggestions were made: inclusion of images, exclusion of technical terms that are irrelevant to the healthcare professional, rewriting of guidelines with greater detail in order to highlight certain information, correction of formatting errors, and inclusion of topics.

Regarding domains 11 to 22, which address topics related to transportation and conservation of insulin, insulin therapy devices, injection sites, preparation and rotation technique, waste disposal and its final destination, expected procedures after implementation, and expected results, the experts suggested adding explanations for technical terms, including images, producing standardized nomenclature, replacing terms and separating topics, all aiming to simplify the understanding.

The judges carried out the overall validation of the instrument, which was considered comprehensive by its evaluators. Suggestions from each professional for improving the material were analyzed and accepted as shown in the final version, available at:

https://drive.google.com/file/d/1hyTrM4H6GNOZ_EboFzyKahLE_eHLTA/view?usp=drivesdk.

Stage IV: implementation of the ETT

The session took place at the bedside, and strengths and weaknesses in the care process were identified. In each session, subsidized by the ITT, the child, their family caregiver, and the resident nurse from the SES-DF Multidisciplinary Child Health Program were present.

Five children aged between four and nine years old participated, as well as their respective family members, two of whom resided in the Federal District of Brazil and three in the state of Goiás. Of the participating children, three were female, and two were male. According to the sociodemographic data of the family members, all of them were the children's mothers; two had completed higher education, one had incomplete higher education, and two

had completed high school.

Regarding the children's clinical data, the time since DM1 was diagnosed varied between one month and one year, and four received the DM1 diagnosis less than a month ago. All used human and NPH insulin, three also used Regular insulin, and two used ultra-rapid-acting human insulin analogs. Four were waiting to be trained by a specialized team, and one reported having received training from a health professional in another healthcare unit.

In Chart 1, we can verify the participation of each member and their ability to recognize the materials used. During the implementation of this ISP, it was observed that the focus must remain on children under the age of five who showed little participation.

Family	Session date and duration	Participation	Recognition and interaction with the material provided
1	Held on June 10, at 7 pm, with a duration of 46 minutes	Child, 5 y/o, little participation/interest in the process	Maintains good interaction with the doll and shows the ability to associate with it. Unable to recognize the materials needed for their self-care.
2	Held on June 21, at 4:30 pm, with a duration of 44 minutes	Child, 8 y/o, high participation/interest in the process	Maintains good interaction with the doll and shows the ability to associate with it. Able to recognize the materials needed for their self-care.
3	Held on July 10, at 10 am, with a duration of 40 minutes	Child, 4 y/o, little participation/interest in the process	Maintains little interaction with the doll and the interviewer. Unable to recognize the materials needed for their self-care.
4	Held on July 10, at 11 am, with a duration of 55 minutes	Child, 4 y/o, little participation/interest in the process	Maintains little interaction with the doll and the interviewer; the child shows fear, sometimes expressing the desire not to be "pierced". Does not recognize the materials needed for their self-care. Knowledge was reinforced, guided,

Chart 1 - Description of participation of each research member and recognition of the materials used, Brasília, 2022

			and applied in a playful way, only on the doll, as a guiding and driving instrument for efficient practice.
5	Held on July 20th at 5 pm, with a duration of 50 minutes	Child, 9 y/o, high participation/interest in the process	Maintains good interaction with the doll and shows the ability to associate with it. Able to recognize the materials needed for their self-care.

Caption: y/o – years old

Chart 2 provides information on knowledge related to: glycemic monitoring in which the handling of the glucometer and/or sensor was addressed; insulin therapy, including transport, conservation, handling of syringes, and the rotation technique; and, finally, waste disposal and its final destination.

Chart 2 – Participants' narratives regarding glycemic monitoring, insulin therapy, and waste disposal, Brasília, 2022

Family	Glycemic monitoring	Insulin therapy	Waste disposal
1	Devices for following and monitoring blood glucose levels from the own child were used. The mother demonstrated a lack of knowledge and difficulties in handling the device. Information on the injection site rotation for glycemic control, how to take good care of the glucometer, and signs of hypo and hyperglycemia were reinforced	The mother struggled to demonstrate knowledge. Proper care while rotating insulin injection sites was reinforced, as well as knowledge of how to handle the syringe and properly store it	Little knowledge doubts were resolved, and information for adequate practice was provided.
2	Devices for following and monitoring blood glucose levels from the own child were used. The mother and child demonstrated relevant knowledge	Both were confident; however, some aspects that would improve safety were evidenced, such as reinforcing proper care while rotating insulin injection sites	Little knowledge doubts were resolved, and information for safe practices in daily routine was provided.
3	Devices for following and monitoring blood glucose levels from the hospital were used. The mother demonstrated a lack of knowledge and difficulties in handling the device. Details on care and the necessary adjustments for good functioning of the glucometer	The mother showed little knowledge and handling difficulties. Proper care while rotating insulin injection sites was reinforced.	Little knowledge of the need for safely disposing of waste materials resulting from the treatment was emphasized.

	were reinforced.		
4	Devices for following and monitoring blood glucose levels from the own child were used. The mother demonstrated relevant knowledge; the correct functioning of the glucometer was reinforced.	The mother demonstrated insufficient knowledge about insulin injection; safe practices while injecting insulin were reinforced, as well as the risks of possible errors.	Little knowledge necessary information was provided.
5	Devices for following and monitoring blood glucose levels from the own child were used. The mother and child showed some insecurity, and knowledge of glucometer maintenance was reinforced.	The mother and child demonstrated knowledge of handling and injecting insulin; however, they were uncertain about its proper dosage and the administration times for injecting the insulin correction dose. Safe practices while injecting insulin were reinforced, as well as the risks of possible errors.	Little knowledge necessary information was provided.

At the end of each session, the child and their family caregiver were asked about how they felt after the experience, and the narratives were unanimous about the instrument being educational and enlightening, as they were able to count on the presence of a professional, a facilitator that clarified their doubts; in addition, the ITT brought playfulness and lightness to the educational process.

Discussion

It is inevitable and expected that changes will occur within any family after receiving a disease diagnosis. Family habits and dynamics tend to be rearranged in order to adapt to the new condition following a DM1 diagnosis. Family is the main source of support when it comes to childhood illness, and changes in the routine and structure are demanded to readapt to these new needs. Joint action between professionals and family members facilitates adaptation to this new phase of life. The strategic role of nurses in health education stands out, thus building conditions for improving the quality of life of children with DM1 and their family members.¹⁷

As a product of this research, the ISP was developed, validated, and implemented with

the aim of preparing the child and their family caregiver for the therapeutic management of DM1. In line with this objective, the results demonstrated an IVC of 1.0, indicating that the construct is suitable for use. In this sense, the ISP tool contributes to the care guidelines, in addition to strengthening self-care practices and allowing adequate identification of risks, singularities and vulnerabilities.¹⁷⁻¹⁸

ETT are important guiding resources for professional practice. Therefore, to be properly implemented, they must be validated so that they become a reliable product.¹⁸ Studies show that the development of educational materials and their validation by proficient professionals favor the creation of a resource aligned with the needs of DM1 patients.¹⁹⁻²⁰ Based on this perspective, the creation of healthcare technologies brings numerous benefits due to their welfare practices, such as: promoting autonomy and independence for the individual.²⁰

In the process of developing educational materials in health education, we must emphasize that the ETT do not constitute habit-change tools, given that knowledge alone does not produce any changes. In this aspect, it is essential that professionals put these materials into practice, aiming to encourage their client's autonomy.²¹

The aim of health education is to reduce barriers, empower behaviors, promote favorable management conditions, prevent complications, and provide day-to-day improvements to the well-being of people living with this health condition. An ETT, like the one presented in this study, contributes to pointing the care plan in the right direction, in addition to helping recognize strengths and weaknesses, thus stimulating changes in behavior and encouraging self-care. A direct, effective, and interactive language provides conditions that not only involve the educational process but also influence learning and favor the promotion of appropriate management.^{1,22} The use of health education encourages the implementation of knowledge and practices that help build self-care in addition to producing health. With this practice, it is possible to provide innovation in a context that requires reference patterns and methodologies to reduce potential challenges in the care process.

Overall, it is important to point out that although this ETT was well-validated by the experts, they have listed different observations, one of which refers to readjusting and alternating its language to make it easier to understand by the target audience. Scientific literature encourages the development of a construct that has readability and legibility as its pillars, as this will result in a clearer understanding.²³ And in corroboration of this finding, a

previous study reported that alternate use of the language, that is, switching between verbal and non-verbal, favors health education, as it draws the attention and interest of those involved.²²

We must reinforce that, according to the judges' suggestions, the topic regarding the reuse of needles by the patient has been excluded, as there is no national or global consensus regarding this practice and because there are studies that show possible risks arising from such reuse.¹ Transposing this problem to the reality of Brazil, the orientation of this practice is not safe due to the lack of protocols and also because it is not possible to guarantee that a health professional will be able to monitor whether the injection application is being carried out correctly.

Printed ETT can transform habits if they include the demands of children, parents, and caregivers, show objective content, and provide a follow-up care plan.²⁴ It is worth highlighting that the person-centered approach is essential for encouraging self-care, as through the interaction between professional and patient, it is possible to achieve different nuances, that is, biopsychosocial aspects.¹ ETT can potentially help improve the education of this target group, arising as therapeutic support strategies that, when implemented by healthcare professionals in health-promoting actions, facilitate the mediation of learning content.¹⁸ The educational process must permeate both the primary and tertiary care settings. To corroborate this, a systematic review proved that moving users from one hospital setting to another level of care that provides a follow-up care plan reduces the reintegration rate, as well as the length of hospital stay.²⁵

The promotion of health education can change people's habits, as difficulties in handling the necessary materials for glycemic control can cause problems and affect the glycemic profile of the patient with diabetes. By ensuring safe practices, providing thoughtful handling measures, and the appropriate use of insulin, it is possible to obtain satisfactory measures,²⁶⁻²⁷ since the action of insulin as a hypoglycemic hormone is essential for the quality and maintenance of human vitality. However, errors in its therapeutic application can be a common problem and directly affect the glycemic profile.²⁸ By ensuring safe practices, providing thoughtful handling measures, and the appropriate use of insulin, it is possible to obtain adequate indicators of glycemic control.

Another relevant factor refers to safe waste disposal. In this study, all participants

mentioned that they were unaware of proper disposal procedures and that they stored their waste in inappropriate containers, thus posing potential risks to third parties and the environment. Therefore, proper procedures must be taught right from the beginning and reinforced during hospital stays. Disposing of materials in sufficiently rigid, puncture-proof units is the safest and most appropriate measure to be taken. Maintaining safe conditions for disposing of healthcare waste is as important as any DM1 control or management actions.^{1,26-27}

Increasing evidence of the use of technologies aimed at developing health education actions has been noted. In the context of DM1 care, the development of ETT can significantly contribute to the professional's work process, as they will be able to identify potential handling weaknesses while implementing actions that strengthen and improve care.¹

In the context of the pediatric population, diabetes educators must be dynamic and have a good sense of progression; that is, they must be able to adapt a certain action to the learner's age group. Those responsible must also have a sense of engagement, as this is a vital component for the adequate management of this chronic condition.⁶ Based on its current development stage, there is sufficient evidence that the use of ITT favors the bond between professional and patient, bringing the scientific knowledge closer to the child's universe, which is a fundamental aspect of promoting self-care.²⁸ In this study, the ITT was used as a mediator in health education, as a tool that helps assimilate the process and facilitates communication and interaction with the child.⁴ By using the ITT, children will be able to prepare themselves for the process and understand the procedures around them and their functionality, in addition to properly handling the materials used. This tool must be guided by the referred procedural stages and allows children to connect with the professional, seeing them as a symbol of trust and improvement of their health.²⁸⁻²⁹

The study found its limitation in the validation stage, as it was carried out with the presence of only one professional category, plus it was conducted in a pediatric unit, thus showing the reality of a public hospital in the country. However, it was possible to observe the potential of this instrument in terms of follow-up care and habit changes after the ETT was implemented. Therefore, future reassessments will contribute to further follow-up care, and habit changes through the implementation of this technology. It is reiterated that the ETT improve care, in addition to contributing to comprehensive care, by using an innovative and low-cost instrument for the service. In this sense, it is essential that healthcare services provide

ETT that support nursing actions. This resource can provide standardization of actions and contribute to the quality management of DM1.

The study, in addition to assessing the protocol, focused on the training of children and their family members in the process of carrying out safe treatment practices and also provided the user with the tool. The use of ETT can help healthcare professionals carry out educational interventions with this target audience since individual education, supported by technology, is effective in terms of promoting behavioral changes.

Based on data analysis, the agreed objective that was previously established was achieved, thus ratifying the importance of using this tool in care practices, aiming at contributing to the promotion of health education within the scope of this material and to the development of a comprehensive care plan. This protocol is intended to guide the knowledge acquired on the referred disease through an innovative instrument in order to train children and their family members to properly manage the disease, in addition to encouraging supported self-care. Being a low-cost technology, this material is easily applicable in the health service, and it also provides a standardization of actions, contributing to the quality management of DM1.

Conclusion

The validated health technology herein presented was considered suitable for use by the evaluators, and upon its implementation in health education activities, it proved to be a quality tool for promoting health, in addition to supporting an effective therapeutic process. The protocol is shown to be a strategy for organizing care, in addition to being a resource that enables quality and safe practices for said target audience.

References

- Sociedade Brasileira de Diabetes. Diretrizes Sociedade Brasileira de Diabetes 2019-2020. São Paulo: Editora Clannad [Internet]; 2020 [cited 2022 Nov 12]. 455p. Available from: http://www.saude.ba.gov.br/wp-content/uploads/2020/02/Diretrizes-Sociedade-Brasileira-de-Diabetes-2019-2020.pdf
- 2. Magliano D, Boyko EJ. IDF diabetes atlas. 10th edition. Brussels: International Diabetes Federation [Internet]; 2021 [cited 2022 Nov 12]. Available from: https://diabetesatlas.org/idfawp/resource-files/2021/07/IDF_Atlas_10th_Edition_2021.pdf
- 3. Patterson CC, Karuranga S, Salpea P, Saeedi P, Dahlquist G, Soltesz G, et al. Worldwide estimates of incidence, prevalence and mortality of type 1 diabetes in children and adolescents: Results from the International Diabetes Federation Diabetes Atlas, 9th edition. Diabetes Res Clin Pract [Internet]. 2019;

[cited 2022 Nov 12];157:107842. Available from: 10.1016/j.diabres.2019.107842

- Freitas KKA, Santos PUA, Melo MC, Moura AS, *Boeckmann LMM, Dutra LMA*. Autorelato da criança e do adolescente no seu cotidiano com a diabete mellitus tipo 1:estudo narrativo. Enferm. Foco [Internet];2020 [cited 2022 Nov 12];11(3):187-94. Available from: https://doi.org/10.21675/2357-707X.2020.v11.n2.2730
- 5. Araújo EF, Ribeiro ALT, Pinho IVOS, Melo MC, Abreu VJ, Nascimento ETS et al. Elaboração de tecnologia educacional sobre educação em saúde para crianças com diabetes mellitus tipo I. Enferm.Foco.2021 [cited 2022 Nov 12];11(6). Available from: https://doi.org/10.21675/2357-707X.2020.v11.n6.3915
- Ribeiro ALT, Araújo ÉF de, Pinho IVOS de, Melo MC, Martins RGG, Lara CCQ. Evaluation of educational technology for children with type I diabetes mellitus: methodological study. Esc Anna Nery [Internet]; 2021 [cited 2022 Nov 12];25(5):e20200282. Available from: https://doi.org/10.1590/2177-9465-EAN-2020-0282
- Brilhante RR da C, Moreira TMM, Oliveira SKP de, Florêncio RS, Pessoa VLM de P, Cestari VRF. Serial album on Continuous Insulin Infusion System as an innovative educational technology in diabetes. Rev Bras Enferm [Internet]; 2022 [cited 2022 Nov 12];75(5):e20210277. Available from: https://doi.org/10.1590/0034-7167-2021-0277pt
- 8. Souza JV de, Ferreira MA, Andrade JIA de, Calixto AVD, Lira RC de. Technologies that promote health education for the community elderly: integrative review. Rev. Latino-Am. Nursing. [Internet]; 2021 [cited 2022 Nov 12];13(5):e7014. Available from: https://doi.org/10.25248/reas.e7014.2021
- 9. Polit DF. Fundamentos de pesquisa em enfermagem. 35 ed. Porto Alegre: Artes Médicas; 1995.
- Brazil. Ministério da Saúde. Secretaria de Atenção à Saúde. Caderno de Atenção Básica Nº16. Brasília: Ministério da Saúde [Internet]; 2006 [cited 2022 Nov 12]. Disponível em: https://bvsms.saude.gov.br/bvs/publicacoes/diabetes_mellitus_cab16.pdf
- Brazil. Ministério da Saúde. Secretaria de Ciência, Tecnologia, Inovação e Insumos Estratégicos em Saúde. Protocolo Clínico e Diretrizes Terapêuticas do Diabete Melito Tipo 2. Brasília. Ministério da Saúde [Internet]; 2020 [cited 2022 Nov 12]. Disponível em: https://bvsms.saude.gov.br/bvs/publicacoes/diabetes_mellitus_cab16.pdf
- 12. Fehring RJ. Methods to validate nursing diagnoses. Heart and Lung: Journal of Critical Care [Internet]; 1987 [cited 2022 Nov 12]; 16(6Ptl):625–629. Available from: https://pubmed.ncbi.nlm.nih.gov/3679856/
- 13. Coluci MZO, Alexandre NMC, Milani D. Construction of measurement instruments in the area of health. Ciênc Saúde Coletiva. [Internet] 2015 [cited 2022 Nov 12];20(3):925–36. Available from: https://doi.org/10.1590/1413-81232015203.04332013
- 14. Mierzejewska E, Honorato-Rzeszewicz T,Świątkowska D, Jurczak-Czaplicka M, Maciejewski T, Fijałkowska A, et al. Evaluation of questionnaire as an instrument to measure the level of nutritional and weight gain knowledge in pregnant women in Poland. A pilot study. PLoS ONE. [Internet]. 2020 [cited 2020 Apr 01]; 15(1): e0227682. Referenced in doi: 10.1371/journal.pone.0227682.
- Yusoff MSB. ABC of content validation and content validity index calculation. Education in Medicine Journal. [Internet]. 2019 [cited 2020 Jan 05];11(2):49–54. Referenced in doi: https://doi.org/10.21315/eimj2019.11.2.6.
- 16. Lopes JMC. Manual de assistência domiciliar na atenção primária à saúde [Internet]. Brasília: Ministério da Saúde.Secretaria de Políticas de Saúde, Porto Alegre: Serviço de Saúde Comunitária do Grupo Hospitalar Conceição [Internet]; 2003 [cited 2022 Nov 12]. Disponível em: http://bvsms.saude.gov.br/bvs/publicacoes/ManualCuidadoresProfissionais. pdf
- 17. Dantas IRO, Neris RR, Zago MMF, Santos MA, Nascimento LC. Explanatory models of families of

children with type 1 diabetes mellitus.Rev. Bras.Enferm [Internet];2020 [cited 2022 Nov 12];73(suppl4):e20180975. Available from: https://doi.org/10.1590/0034-7167-2018-0975.

- Rosa BVC da, Girardon-Perlini NMO, Gamboa NSG, Nietsche EA, Beuter M, Dalmolin A. Development and validation of audiovisual educational technology for families and people with colostomy by cancer. Texto Contexto - Enferm [Internet]; 2019 [cited 2022 Nov 12];28:e20180053. Available from: https://doi.org/10.1590/1980-265X-TCE-2018-0053
- Menezes LGC, Guedes MVC, Oliveira SKP de, Rocha RM, Pinheiro AKB, Silva L de F da, et al. Production and validation of the short film Pés que te quero®: educational technology for people with diabetes. Rev Bras Enferm. [Internet] 2022 [cited 2022 Nov 12];75(5):e20210329. <u>https://doi.org/10.1590/0034-7167-2021-0329</u>
- 20. Aguiar Chaves MA, Ferreira dos Santos R, Batista Moura LK, Campêlo Lago E, Jardel Feitosa Sousa KH, et al. Development and Validation of an Educational Guide for the Prevention of Diabetic Foot Complications. Rev Cuid [Internet]. 2021 [cited 2022 Nov 12]; 12(1):e1233. Available from: *http://dx.doi.org/10.15649/cuidarte.1233*
- 21. Rodrigues SC, Schleder Gonçalves L. Educational technology for people using insulin. Ciênc Cuid E Saúde [Internet]. 2020 [cited 2022 Nov 12];19:e50376. Available from: 10.4025/cienccuidsaude.v19i0.50376
- 22. Fernandes C da S, Lima MM de S, Araújo DV de, Galindo Neto NM, Caetano JÁ, Barros LM. Construction and validation of a serial album for companions of patients with stroke. Rev Bras Enferm. [Internet] 2022 [cited 2022 Nov 12];75(4):e20210843. Available from:
- Rodrigues VES, Oliveira FGL, Machado ALG, Beleza CMF, Pereira FGF. Construction and validation of care-educational gerontechnologies: integrative review. Rev Bras Geriatr e Gerontol. [Internet] 2021 [cited 2022 Nov 12];24(4):e210144. Available from: https://doi.org/10.1590/1981-22562021024.210144.pt
- Lima KF, Gomes ALA, Melo ESJ, Vasconcelos FX, Sousa JL de, Martins MC, et al. Content validation of an educational booklet for asthma control and management in children. Rev Bras Enferm. [Internet] 2021 [cited 2022 Nov 12];74(suppl 5):e20200353. Available from: https://doi.org/10.1590/0034-7167-2020-0353
- Gonçalves-Bradley DC, Lannin NA, Clemson L, Cameron ID, Shepperd S. Discharge planning from hospital. Cochrane Effective Practice and Organisation of Care Group, organizador. Cochrane Database Syst Rev [Internet]. 2022 [cited 2022 Nov 12];2022(2). Available from: http://doi.wiley.com/10.1002/14651858.CD000313.pub6
- 26. Vieira ASM, Castro KV, Canatti JR, Oliveira IAVF, Benevides SD, Sá KN.Validation of an educational booklet for people with chronic pain: EducaDor. BrJP [Internet];2019 [cited 2022 Nov 12]; 2(1):39-43. Available from: https://doi.org/10.5935/2595-0118.20190008.
- 27. Banca R, Marroni M, Oliveria M, Sparapani V, Pascali P, Oliveira S et al. Técnicas de aplicação de insulina. Diretriz Oficial da Sociedade Brasileira de Diabetes [Internet];2022[cited 2022 Nov 12]. Disponível em: 10.29327/557753.2022-4.
- Santana GAS, Melo MC. Tecnologia assistencial: emprego do brinquedo terapêutico instrucional para preparar crianças submetidas à punção venosa periférica. Com. Ciências Saúde [Internet]. 2022 [cited 2023 Jun 12];33(2). Disponível em: <u>https://doi.org/10.51723/ccs.v33i02.1088</u>.
- 29. Barroso MC, Santos RS, Santos AE, Nunes MD, Lucas EA. Children's perception of venipuncture through therapeutic toy. Acta Paul Enferm [Internet]. 2020 [cited 2021 Jun 26]; 33:1-8. Disponível em: 10.37689/acta-ape/2020AO0296.

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