

# Development and validation by the target audience of an educational booklet for people with diabetes mellitus\*

Desenvolvimento e validação pelo público-alvo de cartilha educativa para pessoas com diabetes mellitus

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#### **ABSTRACT**

**Objective:** to develop and validate the content and appearance by the target audience of an educational booklet for promoting health among people with diabetes mellitus. Methods: methodological study involving individuals diagnosed with type 2 diabetes mellitus. Instruments with psychometric properties were used to verify content and appearance, ensuring the reliability and interpretability of the results. The Content Validity Index and Appearance Validity Index were used to mediate data analysis. Results: in the content and appearance validation stage, there was a positive agreement of over 95%. In the content analysis, modifications were recommended for items related to the objective and structure, while in the appearance evaluation, suggestions focused on adjustments to the illustrations and layout. Conclusion: the educational booklet, which focused on promoting health and quality of life, was validated by the target audience in terms of both content and appearance. Contributions to practice: the validated version of the educational material is relevant for the therapeutic management of people with diabetes, and it also represents a potential resource for strengthening health promotion actions. Descriptors: Diabetes Mellitus; Health Promotion; Educational Technology; Validation Study.

#### RESUMO

Objetivo: desenvolver e validar o conteúdo e a aparência pelo público-alvo de cartilha educativa para promoção à saúde de pessoas com diabetes mellitus. Métodos: estudo metodológico envolvendo indivíduos diagnosticados com diabetes mellitus tipo 2. Utilizaram-se instrumentos com propriedades psicométricas para verificar conteúdo e aparência garantindo confiabilidade e interpretabilidade dos resultados. A análise dos dados foi mediada pelo Índice de Validade de Conteúdo e Índice de Validade de Aparência. Resultados: na etapa de validação de conteúdo e de aparência, verificou-se concordância positiva superior a 95%. Na análise de conteúdo, foram recomendadas modificações nos itens referentes ao objetivo e à estrutura, enquanto, na avaliação da aparência, as sugestões concentraram-se em ajustes nas ilustrações e no layout. Conclusão: a cartilha educacional com foco na promoção da saúde e qualidade de vida foi validada quanto ao conteúdo e à aparência junto ao público-alvo. Contribuições para a prática: a versão validada do material educativo mostra-se relevante para o manejo terapêutico da pessoa com diabetes, além de representar um recurso potencial para fortalecer ações de promoção da saúde.

**Descritores:** Diabetes Mellitus; Promoção da Saúde; Tecnologia Educacional; Estudo de Validação.

## Introduction

Diabetes Mellitus (DM) represents a global public health challenge, given its high prevalence. In 2021, it was found that 536.6 million people live with diabetes (diagnosed or undiagnosed), and it is estimated that this number will increase by 46%, reaching 783.2 million by 2045. Brazil ranks fifth worldwide in the incidence of this condition, affecting approximately 16.8 million adults aged 20 to 79 years<sup>(1-2)</sup>.

DM is a multifactorial disease, characterized by its pathophysiological hallmark of hyperglycemia, which results from either absolute or relative insulin deficiency. The state of hyperglycemia leads to an increase in the release of pro-inflammatory chemical mediators, which contribute to a worse prognosis in infections. Thus, this disease was considered a predisposing factor for a worse prognosis of the disease caused by the new coronavirus (COVID-19), specifically Severe Acute Respiratory Syndrome Coronavirus 2 (SARS-CoV-2), in which high rates of hospital admissions and mortality were observed in this population<sup>(3)</sup>.

Although the World Health Organization (WHO) has formally declared the end of the COVID-19 pandemic, the virus continues to circulate in Brazil, and this should be a cause for concern for these individuals. In addition, the lifestyle changes brought about by the pandemic's advent, which significantly contributed to the onset of a sedentary lifestyle, may still have lasting repercussions, causing damage to the health of this group<sup>(4)</sup>. In this context, it is essential to adopt healthy practices that can contribute to the prevention of SARS-CoV-2 infection, as well as maintain stable glycemic levels.

One way to encourage these individuals to adopt practices is using printed or digital educational materials. Viable strategies promote the socialization of knowledge and stimulate the development of self-care skills, which consequently contributes to lifestyle improvement<sup>(5-6)</sup>.

Several studies indicate that booklets are a viable educational strategy for disseminating informa-

tion, promoting health, preventing diseases, raising individuals' awareness of new forms of care, and serving as a guide in situations of doubt, supporting the decision-making process<sup>(7-8)</sup>. However, the proper use of the booklet requires the completion of preparation and validation stages that integrate methodological procedures of high scientific robustness<sup>(9-10)</sup>.

The need to improve care for people with DM during and after the COVID-19 pandemic justifies the validation of a technology aimed at this group as a means of reinforcing health promotion strategies. Compliance with the guidelines contained therein can improve quality of life and increase autonomy in self-care. In this sense, this study contributes to the circulation of knowledge among the academic community, health services, and people with DM themselves.

The provision of an educational booklet on DM constitutes an effective strategy to enhance care, as it facilitates the understanding of health promotion practices, fosters autonomy, and encourages prevention among individuals with this condition. Considering this, the booklet "Diabetes Mellitus: Care During and after the COVID-19 Pandemic" was developed with the aim of encouraging health promotion practices and was validated by experts in the subject<sup>(11-12)</sup>. Thus, the research question of this study is, did the booklet "Diabetes Mellitus: Care During and after the COVID-19 Pandemic" have evidence of adequate content and appearance validity, according to the perception of people with DM?

It should be noted that two investigations were carried out in previous stages. The first was an integrative literature review. Its objective was to conceptualize the booklet based on the mapping of scientific evidence on health promotion measures aimed at improving the quality of life of people with diabetes mellitus during the COVID-19 pandemic<sup>(11)</sup>. Next, a validation study of the booklet was conducted with experts in the field of diabetes, who evaluated its content and appearance<sup>(12)</sup>. The focus of this study was to validate the booklet, considering its content and appearance, based on the evaluation of people living with DM. Thus, the objective was to develop and

validate the content and appearance by the target audience of an educational booklet for promoting health among people with diabetes mellitus.

## **Methods**

## Type of study

The methodological study focused on the development and validation of an educational booklet developed with the participation of the target audience. The validation of content and appearance was carried out by the target audience, developed in two cities in the state of Paraíba, Brazil, from July 2022 to January 2023, with Primary Health Care (PHC) as the setting. The choice of locations for the study was because they are public higher education institutions with a high prevalence of people with DM.

#### Population and sample

The population investigated in this study consisted of people with DM. For the sample calculation, data from municipal health departments were used and identified from the individual registration report extracted from the Electronic Information System of the Brazilian Unified Health System (e-SUS) and the e-SUS Electronic Citizen Record. A confidence level of 95%, a sampling error of 10%, and a minimum expected proportion of 50% were adopted. The calculation was performed using the public domain software OpenEpi, version 3.01.

In the municipality of Cuité/PB, the population of individuals diagnosed with type 2 DM totaled 708 users, resulting in a sample of 85 participants. In João Pessoa/PB, specifically in Health District III, a population of 4,331 people with the disease was identified, from which a sample of 94 individuals was derived.

#### Inclusion and exclusion criteria

Individuals diagnosed with type 2 diabetes mellitus for more than two years with a minimum of

five years of schooling and a score of ≥26 on the Mini Mental State Examination (MMSE)<sup>(13)</sup> cognitive screening test were considered eligible. They also had 15 to 20 minutes available to participate in the material evaluation activity. By involving individuals with this level of education in the validation process, it is possible to ensure that the language, illustrations, and format of the material are accessible, understandable, and appealing to a general audience, including those with less education. Participants under 18 years of age were excluded.

## Study protocol

Participants were recruited at Family Health Units from Monday to Friday. Individuals who agreed to participate were assessed using the MMSE, with a minimum score of 26 points established as the eligibility criterion.

The team responsible for data collection was properly trained. At the time of data collection, all participants had been vaccinated against COVID-19, wore masks and disposable gowns, and followed biosafety recommendations.

The instrument used in content validation covered 18 items, organized into the following aspects: objectives (purposes, goals, or aims); structure/presentation (organization, structure, strategy, coherence, and sufficiency); and relevance (significance, impact, motivation, and interest)<sup>(14)</sup>.

The appearance validation included 10 questions related to the quality of the illustration and the organization of the layout<sup>(15)</sup>. For content and appearance validation, a three-point ordinal scale was applied, where 0 corresponded to "disagree," 1 to "partially agree," and 2 to "totally agree."

The degree of agreement for each item, both in the content and appearance validation instruments, was calculated using the Content Validity Index (CVI) and the Appearance Validity Index (AVI), with values above 0.95 being considered adequate. Items with lower indices were reviewed and adjusted according to suggestions from the target audience.

#### **Ethical aspects**

The research was conducted in accordance with Resolution No. 466/2012 of the National Health Council and the guidelines of the National Research Ethics Commission. Each participant formalized their agreement by signing the Free and Informed Consent Form. The study was approved by the Research Ethics Committee of the Federal University of Campina Grande, under Certificate of Presentation for Ethical Review No. 37369120.5.0000.5182, through opinion No. 4,329,230/2020.

#### Results

Of the 179 individuals with type 2 diabetes mellitus included in the sample, only 87 had a minimum score of 26 on the MMSE and were considered eligible to validate the second version of the booklet.

The sociodemographic data for the 87 participants are described in Table 1, highlighting ages between 25 and 87 years (mean: 59.1; ±10.0) and schooling between 5 and 21 years (mean: 10.2; ±4.2).

**Table 1** – Sociodemographic characteristics of study participants. João Pessoa, Cuité, PB, Brazil, 2022–2023

Variables	n (%)
Gender	
Female	60 (69.0)
Male	27 (31.0)
Self-reported skin color	
Brown	46 (52.9)
White	33 (37.9)
Black	7 (8.0)
Yellow	1 (1.1)
Marital status	
Married	39 (44.8)
Single	20 (23.0)
Widowed	13 (14.9)
Divorced	9 (10.3)
Consensual union	5 (5.7)
Separated	1 (1.1)
Living arrangement	
Lives alone	74 (85.1)
Lives with someone	13 (14.9)

(the Table 1 continue...)

Variables	n (%)
Religion	
Catholic	52 (59.8)
Evangelical	22 (25.3)
Spiritist	7 (8.0)
Other	6 (6.8)
Level of education	
Completed high school	27 (31.0)
Complete primary education	18 (20.7)
Higher education complete	15 (17.2)
High school incomplete	5 (5.7)
Incomplete higher education	1 (1.1)
Income (minimum wage)	
> 1	42 (48.3)
1	27 (31.0)
< 1	18 (20.7)
Occupation	
Retired	32 (36.8)
Civil servant	14 (16.1)
Self-employed	12 (13.8)
Unemployed	9 (10.3)
Farmer	3 (3.4)
Other	17 (19.5)

Clinical and behavioral data revealed a diagnosis time ranging from 2 to 38 years (mean: 8.93; ±6.9). It was observed that 55 participants (63.2%) used exclusively the public health system; hypertension was the most frequent associated condition (56; 64.4%). Regarding self-care, 33 (37.9%) followed a hypoglycemic diet and 33 (37.9%) practiced physical exercises. Regarding drug treatment, 79 (90.8%) used oral antidiabetic drugs and 18 (20.7%) used insulin. Among the participants, 6 (6.9%) were smokers, 5 (5.7%) were alcoholics, 26 (29.9%) had already been affected by COVID-19, and 65 (74.7%) had completed the vaccination schedule with two doses and two booster doses.

Table 2 shows the CVI of the material, as assessed by the target audience, in terms of objectivity, structure, and relevance. In the validation of the objectives, four items did not meet the established criterion (CVI > 0.95): "the booklet covers the proposed topic" (CVI = 0.95), "the booklet is appropriate for the teaching and learning process" (CVI = 0.95), "clarification

of doubts about the topic addressed" (CVI = 0.91), and "reflect on DM and COVID-19 care" (CVI = 0.94).

Regarding structural content, three items had lower than desired values: "language that is easy to understand for people with diabetes" (CVI = 0.94), "language that is easy to understand for the general

population" (CVI = 0.90), and "appropriate text size" (CVI = 0.92). In the evaluation process, it was found that only the "objectives" aspect was below the reference value, with an CVI of 0.94. The "relevance" aspect had the highest scores among the three evalua-

**Table 2** – Content validation of the educational booklet for people living with Type 2 Diabetes Mellitus (n=87). João Pessoa, Cuité, PB, Brazil, 2022-2023

Aspects/Items		$\textbf{CVI-} \textbf{A}^{\dagger}$
Objectives		
1. Does the booklet cover the proposed topic?	0.95	
2. Is the booklet suitable for the teaching-learning process?	0.95	
3. Does the booklet clear up any doubts about the subject?	0.91	0.94
4. Does this booklet make you think about diabetes care during the COVID-19 pandemic?	0.94	
5. Does this booklet encourage you to change your lifestyle habits to better control your diabetes?	0.97	
Structure		
6. Do you think the language of this booklet is easy to understand for people with diabetes?	0.94	
7. Do you think the language of this booklet is easy to understand for the general population?	0.90	
8. Do you think this booklet has interactive language and allows people to get involved in the educational process?	0.95	
9. Is the information in this booklet correct?	0.97	
10. Is the information in this booklet objective?	1.0	0.96
11. Is the information in this booklet clear?	1.0	
12. Do you think the information in this booklet is necessary?	0.99	
13. Does the booklet present a logical sequence of ideas?	0.97	
14. Do you think the topic covered in the booklet is topical?	0.97	
15. Do you think the size of the texts is appropriate?	0.92	
Relevance		
16. Do you see potential in this booklet to learn more about the topic?	0.98	
17. Does this booklet contribute to your knowledge of COVID-19 and diabetes?	0.98	0.98
18. Does this booklet motivate you to want to learn more about the subject?	0.99	

<sup>\*</sup>CVI-I: Content Validity Index of the Item; †CVI-A: Content Validity Index of the Aspects

The appearance validation covered the aspects of illustration and layout. The booklet was evaluated positively by people with type 2 DM; however, in the "illustration" dimension, the items "handling of the booklet" and "number of illustrations" had an AVI of 0.92, which was lower than the established value.

Regarding "layout," the items "text formatting" (CVI = 0.95) and "choice of colors" (CVI = 0.94) also did not reach the reference value. After adjustments, the domains "illustration" and "layout" achieved an overall CVI of 0.96 (Table 3).

**Table 3** – Validation of the appearance of the educational booklet by people living with Type 2 Diabetes Mellitus (n=87). João Pessoa, Cuité, PB, Brazil, 2022-2023

Aspects/Items	AVI-I*	AVI-A†
Illustration		
1. Are the illustrations necessary for understanding the topic?	1.0	
2. Do the illustrations motivate you to handle the booklet?	0.92	
3. Do the illustrations clarify the content?	0.98	0.96
4. Is the number of illustrations adequate for the content?	0.92	
5. Are the features and/or resolution of the illustrations appropriate for the target audience?	0.98	
Layout		
6. Is the formatting of the text (font and font size) appropriate?	0.95	
7. Is the visual composition attractive and organized?	0.99	
8. Is the choice of colors appropriate?	0.94	0.96
9. Are the pages the right size?	0.97	
10. Is the number of pages appropriate?	0.97	

<sup>\*</sup>AVI-I: Appearance Validity Index of the Item; †AVI-A: Appearance Validity Index of the Aspects

The items' objective, structure, and relevance that did not exceed 0.95 in the VAT and CVI were ree-

valuated and adjusted according to the suggestions of the target audience (Figure 1).

Aspects	Suggestions from the target audience
	The booklet covers the proposed topic: summarizing information on COVID-19 and mask use, in view of the
	new epidemiological scenario.
	The booklet is suitable for the teaching and learning process: explain what Diabetes Mellitus is in the
Objectives: purposes,	presentation.
goals or aims of the	Clarify any doubts about the topic: break down the topic of food further, giving examples of fruit, carbohydrates
booklet	for people with DM, what to eat and how much. Clarify glycemic values.
	Reflect on DM care during the COVID-19 pandemic: insert more information on medication use (number of
	times a day and best time). Talk about diabetic foot care. Give advice on the impact of not taking care of diabetic
	feet and suggest a diet app for people with DM.
Structure/presentation:	Interactive language, allowing active involvement in the educational process: insert a playful/interactive part to
organization, structure,	make the booklet better understood in relation to medication.
strategy, coherence and	Appropriate text size: summarize the information more, as the texts are long and require a lot of time to read.
sufficiency	Reduce the number of pages.
Illustration	Update the virtual consultation figure, as they are out of date; consultations are now held in person. The advice
	to wear a mask and sanitize your hands could only be given when you go to the health service. Insert more
	illustrations about food for people with DM. Remove the telephone consultation, which is already taking place
	in person.
Layout	The formatting of the text in terms of font (type) and font size is appropriate: there are pages with a small size,
	such as the page on vaccines.
	The choice of colors is appropriate: change the color contrast. Light colors under light colors make it difficult
	to see.

**Figure 1** – Summary of suggestions from people with Type 2 Diabetes Mellitus regarding the content and appearance of the educational booklet (n=87). João Pessoa, Cuité, PB, Brazil, 2022-2023

The final version of the booklet contains 28 pages and is available at the *link* https://drive.google.com/file/d/1UN1XZTANeC4dciUNb4pwVDPkm98E 28or/view?usp=sharing. The guidelines are divided into two sections: individual and collective health

promotion measures, with information on the therapeutic management of DM and COVID-19 prevention measures; and government health promotion measures, with information on COVID-19 vaccines. Figure 2 shows some pages from the booklet.



**Figure 2** – Final version of the booklet "Diabetes Mellitus: care during and after the COVID-19 pandemic" after validation with experts and the target audience. João Pessoa, Cuité, PB, Brazil, 2022-2023

#### **Discussion**

The educational booklet was developed with the aim of contributing to the autonomy of individuals with DM in implementing health promotion measures both during the pandemic and post-pandemic periods of COVID-19. It has a predominant focus on the post-pandemic period, considering the current epidemiological context. Its construction followed robust methodological criteria whose purpose was to measure

its applicability by the target audience and to verify whether the educational booklet constructed is accurate in its understanding of ideas, language, and motivation for handling and reading<sup>(16-17)</sup>.

To ensure methodological robustness, the study had a significant sample, characterized by the number of participants and diversity in terms of education. There are validation studies in national and international literature in which the size of the target audience varies greatly<sup>(18-20)</sup>. In another study that developed

and validated a booklet for women with gynecological cancer, the MMSE was also used to test the aptitude of the participants<sup>(21)</sup>. Thus, the methodology employed demonstrated potential to support the construction of an accessible, motivating, and instructive language tool, serving as an example for the development of other educational booklets, both on this topic and in different areas of health.

The diversity of educational levels has the capacity to add various knowledge when evaluating the theme and approach presented in the material. As in other studies, it was feasible to analyze the educational material according to different levels of education<sup>(7,22)</sup>.

The topic addressed is relevant in the context in question. The study that formed the basis for the booklet listed important measures, including healthy eating, regular physical exercise, the use of oral medication/insulin, the importance of adequate sleep, attending routine appointments, and monitoring capillary blood glucose. COVID-19 prevention practices include wearing masks, social distancing, hand hygiene, home care, and vaccines. Together, these measures can promote quality of life for the target audience<sup>(23)</sup>.

Practices for proper DM control are associated with better prognoses in cases of COVID-19, and measures to prevent this disease have a positive impact on containing the spread of SARS-CoV-2<sup>(24)</sup>.

In general, the responses to the content validation items were consistent. The booklet's contents were presented in a coherent manner, demonstrating the feasibility of enhancing the educational process regarding DM and encouraging the reader to reflect. A study that validated an educational booklet on non-pharmacological resources aimed at pain control during childbirth also obtained a higher-than-expected CVI for content; however, a set of elements that differed from those used in this study was employed, including textual presentation, illustrative resources, level of specificity and comprehensiveness, clarity of reading, printing characteristics, and consistency of information<sup>(25)</sup>.

The CVI certified the adequacy of the booklet's

content; however, the target audience proposed improvements, such as summarizing information, restructuring texts, and inserting playful and interactive elements, with the aim of facilitating understanding and making reading more dynamic. These contributions were considered and incorporated to adapt the booklet to the reality of its users, promoting clarity, attractiveness, and accessibility.

In addition, according to the AVI, the booklet was also approved in terms of appearance. This means that the set of graphic elements used to portray the information was considered important for elucidating the theme, as they affect empathy, trust, and willingness to recognize oneself in the material. Suggestions such as changing the font size and color contrast were accepted to make the material even more accurate. When comparing these data with those found in the literature, it can be observed that the other study also obtained satisfactory agreement rates when evaluating the appearance of a booklet. But the items that evaluated this aspect were integrated with the items that evaluated content, and there was no specific instrument for this purpose<sup>(26)</sup>.

## **Study limitations**

It is noteworthy that, although the booklet achieved high CVI values, a considerable number of suggestions for improvement were observed, possibly influenced by the participant's individual perceptions. Although he assigns a satisfactory score to the item, he does not associate it with a gap in the booklet, but identifies potential for improvement, revealing a limitation in the methodological process of this type of study. In addition, the inclusion criteria used may reduce the generality of the findings, limiting the application of the results to other contexts or specific care populations.

## **Contributions to practice**

The booklet, developed and validated by the target audience, has content and appearance relevant

to the therapeutic management of DM. It can be used to guide practices for the prevention of complications from COVID-19 and other infections, as well as complications from DM itself, especially in the PHC context.

This type of production represents an increase in health literacy actions, since the booklet has the potential to contribute to the strengthening of health promotion practices in nursing and other areas of care for people with DM. In addition to supporting educational programs, the material can serve as support for follow-up consultations in PHC. The aim is to widely disseminate it to expand its reach in health services and enable its use by the target audience.

Thus, it is important to evaluate the contribution of the booklet to the teaching-learning process, especially as an educational intervention in comprehensive care and health promotion. Future studies are suggested as clinical trials to test the effectiveness of this technology to make it even more accurate.

## Conclusion

It can be concluded that the booklet "Diabetes *Mellitus: Care During* and after the COVID-19 Pandemic" was considered an effective educational material, validated by the target audience and satisfactory for health professionals and people with diabetes, acting as a tool capable of stimulating health promotion and health literacy.

## Authors' contribution

Conception and design or analysis and interpretation of data; Drafting of the manuscript or critical revision of intellectual content; Final approval of the version to be published; Responsibility for all aspects of the text in ensuring the accuracy and integrity of any part of the manuscript: Santos CLJ, Silva AS, Costa MML, Andrade LL. Writing of the manuscript or critical revision of the intellectual content; Final approval of the version to be published; Responsibility

for all aspects of the text in ensuring the accuracy and integrity of any part of the manuscript: Alves AMPM, Oliveira PS, Oliveira JS.

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