



EDUCATIONAL BOOKLET FOR THE PROMOTION OF IMMUNIZATION AGAINST COVID-19: CONSTRUCTION AND VALIDATION

CARTILHA EDUCATIVA PARA PROMOÇÃO DA IMUNIZAÇÃO CONTRA A COVID-19: CONSTRUÇÃO E VALIDAÇÃO

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How to cite: Santos IS, Silva RAR, Camacho ACLF, Holanda JRR, Ferreira TT, Juraci SDLS, et al. Educational booklet for the promotion of immunization against COVID-19: construction and validation. Online Braz J Nurs. 2025;24:e20256809. <https://doi.org/10.17665/1676-4285.20256809>

RESUMO

Objetivo: descrever o processo de construção e validação de uma cartilha educativa, destinada para a população em geral, sobre as vacinas contra a COVID-19 disponíveis no Brasil. **Método:** estudo metodológico, realizado entre agosto de 2022 a julho de 2023, operacionalizado em três etapas, sendo essas: (1) revisão de literatura, (2) construção de cartilha educativa e (3) validação de conteúdo por juízes especialistas através da técnica Delphi online em duas rodadas. Participaram 56 profissionais de saúde, recrutados por meio da Plataforma Lattes e pela técnica de bola de neve. Consideraram-se como validados os itens com Índice de Validade de Conteúdo $\geq 0,80$ e Índice Kappa $\geq 0,70$. Aplicaram-se os Testes de Mann-Whitney e Alpha de Cronbach. **Resultados:** a verificação da validação da cartilha na rodada Delphi 1 teve como média global o valor de 0,88 e Kappa de 0,91. Houve sugestões de melhorias na primeira versão que foram acatadas e, a cartilha foi novamente submetida para a Delphi 2, tendo índices no valor de 1. O Teste de Mann-Whitney revelou diferença significativa e Alpha de Cronbach demonstrou alta confiabilidade. **Conclusão:** a cartilha “Vacinação contra a COVID-19: o que você precisa saber?” possui validade de conteúdo adequada para a promoção da imunização contra a COVID-19.

Descritores: Vacinas contra COVID-19; Educação em Saúde; Estudo de Validação; Pesquisa Metodológica em Enfermagem; Movimento contra Vacinação.

ABSTRACT

Objective: To describe the process of building and validating an educational booklet, aimed at the general population, about COVID-19 vaccines available in Brazil. **Method:** Methodological study, conducted between August 2022 and July 2023, operationalized in three stages, namely: (1) literature review, (2) construction of educational booklet and (3) content validation by expert judges through the online Delphi technique in two rounds. The participants were 56 health professionals, recruited through the Lattes Platform and the snowball technique. Items with Content Validity Index ≥ 0.80 and Kappa Index ≥ 0.70 were considered validated. Mann-Whitney and Cronbach Alpha tests were applied. **Results:** Verification of the validation of the primer in the Delphi 1 round had a global average of 0.88 and Kappa of 0.91. There were suggestions for improvements in the first version that were accepted and, the booklet was resubmitted to Delphi 2, having indexes in the value of 1. The Mann-Whitney test revealed significant difference and Cronbach's Alpha showed high reliability. **Conclusion:** The booklet “Vaccination against COVID-19: What do you need to know?” It has adequate content validity for the promotion of immunization against COVID-19.

Descriptors: COVID-19 Vaccines; Health Education; Validation Study; Methodological Research in Nursing; Movement Against Vaccination.

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INTRODUCTION

After classifying the new coronavirus outbreak as an international public health emergency, the World Health Organization (WHO) recommended several measures to combat and control the pandemic, among them, the acceleration of vaccines, therapeutic measures and diagnoses were proposed⁽¹⁾.

The humanitarian and economic impact caused by coronavirus disease 2019 (COVID-19) has boosted the use of new vaccine technology platforms to accelerate research. Through the engagement and investment of developed countries, pharmaceutical industries and non-governmental organizations, several vaccine development projects were registered with WHO. In this perspective, in mid-March 2020, the first vaccine candidate started clinical trials in humans⁽²⁾.

In Brazil, the vaccines distributed for the National Immunization Campaign were: The COVID-19 (inactivated) Coronavac adsorbed vaccine - by the manufacturer Sinovac in partnership with the Butantan Institute; the COVID-19 (recombinant) Oxford/AstraZeneca vaccine - manufactured in Brazil in partnership with the Oswaldo Cruz Foundation (Fiocruz) and the pharmaceutical AstraZeneca; the COVID-19 (mRNA) Pfizer vaccine - from the manufacturer Pfizer/Wyeth, and finally the COVID-19 (recombinant) Janssen vaccine - from the manufacturer Janssen. All obtained authorization from the National Health Surveillance Agency (ANVISA), the national regulatory body, which approved the use in the Brazilian population, after attesting its safety and efficacy⁽³⁾.

In this scenario, due to the unprecedented acceleration in the production and testing of vaccine effectiveness, several false information began circulating in several communication channels, even before approval for large-scale use in the population. This distorted information is fostered by anti-vaccine and negationist movements of the pandemic, represented by ordinary people, the press and even political authorities⁽⁴⁻⁵⁾.

In view of this scenario, the dissemination of clear, consistent and scientific evidence-based information is fundamental to the population's awareness of immunization against COVID-19⁽⁶⁾. In this context, the present study was justified by the need to create a health education booklet that would enable the understanding and adherence of the population to recommendations for prevention and combat this disease. The relevance of the study focuses on the importance of using validated educational technology, as a safe and appropriate way of obtaining information, as well as its potential to disseminate scientific knowledge through a popularly accessible language.

Therefore, the objective of this study is to describe the process of construction and validation of an educational booklet, aimed at the adult population, on vaccines against COVID-19.

METHOD

Ethical aspects

This research was conducted respecting the ethical standards required, and was approved by the Ethics Committee in Research with Human Beings, receiving the opinion 4.908.881.

Type of study

It is a methodological study, operationalized in three stages, namely: (1) literature review, (2) construction of an educational booklet and (3) content validation by expert judges⁽⁷⁻⁹⁾. The Revised Standards for Quality Improvement Reporting Excellence (SQUIRE 2.0) guide was followed. The study was conducted between December 2023 and April 2024.

Study protocol

In the first stage, the electronic bases consulted were: Virtual Health Library (VHL), Web of Science and Cumulative Index to Nursing and Allied Health Literature (CINAHL), National Library of Medicine (PUBMED); and Scopus; they were accessed by CAPES (Coordination for the Improvement of Higher Education Personnel) through CAFE access (Federated Academic Community). In addition, the gray literature was consulted through manuals, such as the National Plan for the Operationalization of Vaccination in Brazil and the Operational Technical Report Vaccination against COVID-19, also the Vaccine Bullets, published by the Ministry of Health and ANVISA in their electronic sites, in order to identify the risks of vaccination. as well as WHO guidelines.

To elaborate the guiding question was used the PICO strategy (P: Population); I: Intervention [health education/information with scientific evidence to promote immunization against COVID-19]; C: Context [relationship between immunization and COVID-19]; O: Outcome [educational technology/educational booklet]). So the question was: What information with scientific evidence should be listed in an educational booklet to promote immunization against COVID-19, intended for the general population?

Inclusion criteria were used: articles that address the characteristics of vaccines available for use in the population and evidence of their effectiveness, articles that dealt with fake news involving vaccines, and that were available in full in the aforementioned bases. Those who did not answer the guiding questions or who did not meet the objectives were excluded.

For the search, the descriptors indexed in the Medical Subject Heading (MeSH) were used, through the Boolean AND OR operators, as follows: "COVID-19 Vaccines" AND "Efficacy" AND "Anti-Vaccination Movement" OR "Anti-Vaccination Movement". After the application of the filters, and reading the titles and abstracts of the studies, the full reading of the previously selected publications was performed, and identified those that composed the final sample to subsidize the construction of the booklet.

Regarding the publications of official portals of the Ministry of Health, ANVISA and WHO, the most current publications pertinent to the subject were selected, which contained statistical data on the effectiveness of vaccines and guidelines for the general population. Outdated or rectified by a later publication were discarded.

In the second stage, the construction of the booklet took place from the meeting of the main information inherent to the COVID-19 vaccination campaign in Brazil. The illustration and layout of the contents of the booklet was carried out by the main researcher on the platform facilitating graphic design Canva, which provides ready-to-use illustra-

tions, in addition to varied graphic resources, to make the contents of the booklet more playful.

In the third stage, the content of the booklet was validated by experts, through the Delphi technique in two online rounds. The content was organized in an instrument through a structured form available online on the Google Forms tool page, and resulted in the final version of the booklet, after considering and incorporating the suggestions for improvement presented by the judges.

As a strategy for the selection of expert judges for the second stage, the website of the Lattes Platform of the National Council for Scientific and Technological Development (CNPq) was used as the site of the study. Therefore, the sample size was defined from the formula $n_0 = (Z1 - \alpha/2 \cdot S/e)$. $Z1 - \alpha/2$ is configured as the confidence level ($95 = \% 1.96$ 0.17), the S is equivalent to the standard deviation, being considered in this calculation the value of 5, and finally, the variable “and” means the sample error, being used the value of 5% ⁽¹⁰⁾. The ideal sample size was 45 judges.

At this stage, the sample was composed of specialists, based on the following inclusion criteria: Masters and doctors with published articles, on teaching and assistance in the areas of Health Education and/or Popular Education in Health, focusing on infectious diseases and/or immunization.

After the selection of the judges, an invitation letter was sent, the Free and Informed Consent Form (TCLE) and the form in the Google Forms tool with the material to be validated, via email. Considering the difficulty selecting the judges and obtaining the results in a timely manner, after the first submission, the “snowball technique” was also used to contact other judges who work in the study area and fit the inclusion criteria. The deadline of 30 days for evaluation of the booklet and filling the instrument was stipulated.

The instrument submitted to the experts was composed of three parts. The first part had questions to characterize the judges. The second part was composed of variables of the booklet, evaluated through the Likert scale with a score of 1 to 5, namely: 1) totally inadequate; 2) inadequate; 3) neither adequate nor inadequate; 4) adequate and 5) totally adequate; where items 4 and 5 were considered concordant⁽¹¹⁾.

After each topic evaluated using the Likert scale, an open space was made available to apply the suggestions of the judges⁽¹²⁾.

Finally, the third stage was composed of the final opinion of the booklet, with the general evaluation based on the following criteria: practical relevance, clarity of language, objectives, presentation, content, update, theoretical relevance, sequence of topics and global grade assigned to the booklet. All items were arranged for evaluation on a scale from 1 to 10, using the Delphi technique⁽¹³⁾.

Data analysis

To assess relevance/representativeness, the answers may include: 1 = not relevant or non-representative, 2 = item needs major revision to be representative, 3 = item needs minor revision to be representative, 4 or 5 = relevant or representative item.

The index score is calculated by means of the sum of agreement of the items that were marked with 4 or 5 by the experts. Those who receive score 1, 2 or 3 would be reviewed or eliminated. Thus, the Content Validity Index (IVC) has also been defined as the proportion of items that receive a

score of 4 or 5 by experts. After the analysis of the first Delphi round, the items that did not obtain IVC values within the parameters established as acceptable according to the suggestions of the judges were changed, then the instrument was again submitted to the experts (Delphi round 2).

For content validation, the judges' evaluations were inserted in a spreadsheet, where the scores assigned to each item were verified to determine the level of agreement between them, and the IVC was calculated for each item, the I-CVI (content validity of the individual items), and the IVC was calculated for each item, the I-CVI (content validity of the individual items). and for the total set of booklet items (IVC Global).

The Kappa index is used to measure the reliability of judges' opinion and evaluates the proportion of agreement between them, ranging from “minus 1” to “plus 1”. The maximum limit of κ is 1, which represents the perfect agreement between judges, so the closer to 1, the better the level of agreement between participants. As an acceptance criterion, agreement ≥ 0.70 was established among judges, considered as a good level⁽¹⁴⁾.

The evaluation standard was considered: IVCi equal to 1.00 – perfect, IVCi between 0.81 and 0.99 – great, IVCi between 0.61 and 0.80 – good, and IVCi 0.41 to 0.60 – regular. IVCi less than or equal to 0.60 were eliminated, or modified the items in the booklet. In the absence of acceptable agreement among experts for a sufficient number of items foreseen for the final version of the instrument, the repetition of the evaluation process by the experts would be performed (Delphi Round 2), as recommended, until this level of agreement was reached. Items with CVI greater than or equal to 0.80 ⁽¹⁵⁾ were considered validated.

The Mann-Whitney Test was applied to verify the significance between Delphi rounds 1 and 2. Finally, for the verification of the internal reliability of the experts' evaluations, Cronbach's Alpha coefficient was calculated for each dimension, considered acceptable values of $\alpha \geq 0.70$ and high reliability $\alpha \geq 0.80$ ⁽¹⁶⁾.

RESULTS

After searching the articles in the aforementioned databases, 337 studies were found. By applying the filters of articles published in the last three years, in Portuguese, English and Spanish, and which were available in full, a total of 222 articles were obtained. From these, it was performed the reading of titles and abstracts, and the disposal of duplicate articles that did not fit the inclusion criteria.

At the end of this stage, a total of 37 articles were obtained for full reading. Subsequently, with the complete reading of the works, six articles were selected to compose the construction of the review, as shown in Figure 1.

In the construction stage of the booklet, the textual elaboration was carried out from the gathered content, followed by the application of the appropriate illustrations and layout of the content. The final version of the booklet, entitled “Vaccination against COVID-19: What do you need to know?”, totaled 25 pages composed of cover; back cover/catalographic sheet; introduction that addresses how vaccines work and the importance of vaccinating; which vaccines are available for use in Brazil; mechanisms of action, posology, efficacy, age group authorized and adverse effects of each vaccine; questions and answers that fight fake news and finally, a list of references. Figure 2 shows the cover and

summary of the booklet validated as a final product, with the following link, its full version: https://www.canva.com/design/DAEmLIiNko/Q-3uUzT3kFDc67WbERELAw/edit?utm_content=DAEmLIiNko&utm_campaign=designshare&utm_medium=link2&utm_source=sharebutton

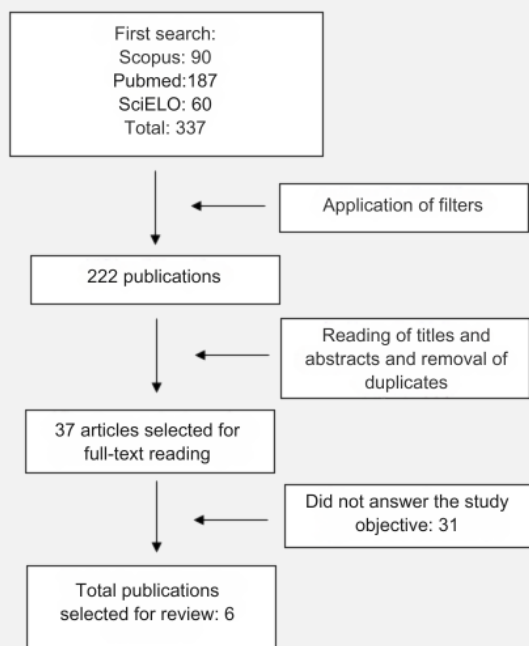


Figure 1 – Flowchart of search in databases and selection of studies. Natal, RN, Brazil, 2024

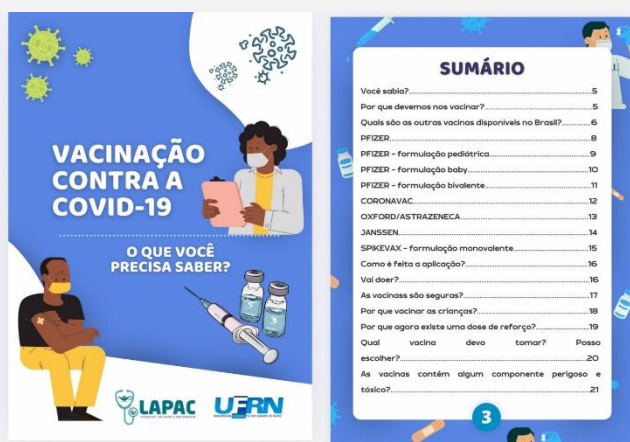


Figure 2 – Representation of the cover and summary Final version of the booklet. Natal, RN, Brazil, 2024

In the first round of validation of the booklet, 56 specialists participated, 48 (85.7%) of which were female, in the age group between 30 and 39 years, 47 (84%) nurses; six (10.7%) were doctors; and three (5.3%) were dentists. The sample of the second version of the booklet was composed of 45 participants, 39 (86.7%) of the female gender aged between 30 and 39 years and 40 (88.9%) nurses.

The validation verification in the first version of the booklet was carried out by the calculation of the IVC, with the overall mean of the IVC the value of 0.88, considered optimal by the criteria previously stipulated, where the individual values of I-CVI varied from 0.68 to 0.95, and with an optimal Kappa index (0.91). The global IVC corresponding to the second version of the booklet obtained the value of 1,

considered perfect. All I-CVI values were satisfactory, there was unanimity in the validation, and the Kappa index 1, considered the perfect agreement among the judges. Through the Mann-Whitney test, for a significance level of 5%, evidence of statistical difference of Delphi 1 with Delphi 2 was identified in the items analyzed, with better evaluation in the second round, as shown in Table 1.

Through Cronbach's Alpha, the data reliability was verified. It can be observed that all the criteria evaluated by the experts obtained an alpha above 0.80. From the point of view of these criteria, phase 2 presented better results compared to phase 1, but in both the reliability was quite satisfactory, as presented in Table 2.

Although the global IVC in the first round was considered optimal (0.88), according to the previously established criteria, there were pertinent suggestions that contributed to the improvement of the educational material and allowed to achieve a more satisfactory global IVC. In this perspective, the material was submitted again for evaluation.

In the Delphi 1 round, there were suggestions for changes and improvements in some items of the booklet, which subsidized the construction of the second version. On the cover it was suggested to insert the question mark at the end of the phrase “What you need to know”, and also the translation of the word Vaccine in the illustration of the vaccine vial. In the introductory item, it was suggested by most judges to reduce the text, for a more direct and succinct introduction. It was also proposed the removal of the term “herd immunity” highlighted in red, because, according to the expert, this way draws attention and is a term widely used by vaccine negationists.

Regarding the presentation of the vaccines available in Brazil for use in the population, it was suggested to update the information about the authorized age group of Coronavac vaccine, which had already been authorized for use in children under 18 years of age, given the dynamics of the vaccination campaign during the period of construction and validation of the booklet. In addition, it was suggested to replace the font color of the name of the laboratories, to improve the layout and visualization of the terms.

Through the Mann-Whitney test, evidence of statistical difference was obtained from the Delphi phase 1 to the 2 in the dimensions of practical relevance, language clarity, objectives, presentation, content, update, theoretical relevance, sequence of topics and global grade attributed to the booklet, was according to Table 2, which compares the means between the two versions of the booklet, where a better evaluation was observed in the Delphi phase 2 in the respective variables, revealed in Table 3.

In 2023, the Brazilian Ministry of Health decided to withdraw the AstraZeneca vaccine from the National Immunization Program. The decision was motivated by the strategy of prioritizing vaccines more effectively against emerging variants of SARS-CoV-2, such as bivalent vaccines and the introduction of new immunizers such as Spikevax from the Moderna manufacturer. In addition, the availability of vaccines with messenger RNA technology (mRNA), which have demonstrated greater adaptability and response to new variants, influenced the change in the composition of NBP. Thus, this information was included in the final version of the booklet along with the latest updates of the NBP vaccination scheme.

Table 1 – Agreement of judges on the variables of the booklet in its first and second versions. Natal, RN, Brazil, 2024 (n=56)

Items	Delphi 1			Delphi 2			p value ‡
	N	(%)*	I-CVI †	N	(%)*	I-CVI †	
1. Cover – page 1	56	89	0.89	45	100	1	0.012
2. Introduction – page 3	56	88	0.88	45	100	1	0.026
3. Vaccines available in Brazil – page 4	56	89	0.89	45	100	1	0.012
4. Pfizer Vaccine – page 5	56	86	0.86	45	100	1	0.034
5. Pfizer vaccine (Pediatric formulation) – page 6	56	95	0.95	45	100	1	0.001
6. Pfizer vaccine (baby formulation) – page 7	56	90	0.90	45	100	1	0.020
7. Pfizer vaccine (Bivalent formulation) – page 8	56	87	0.87	45	100	1	0.015
8. Coronavac Vaccine – page 9	56	85	0.85	45	100	1	0.042
9. Oxford/AstraZeneca Vaccine – page 10	56	95	0.95	45	100	1	0.001
10. Janssen Vaccine – page 11	56	93	0.93	45	100	1	0.006
11. Vaccine application – page 12	56	84	0.84	45	100	1	0.013
12. Vaccines safety – page 13	56	95	0.95	45	100	1	0.001
13. Why vaccinating the children? – page 14	56	90	0.90	45	100	1	0.020
14. Why is there a booster dose? – page 15	56	90	0.90	45	100	1	0.020
15. Which vaccine should I take? – page 16	56	89	0.89	45	100	1	0.032
16. Do vaccines contain any toxic components? – page 17	56	85	0.85	45	100	1	0.042
17. Vaccination in pregnant women – page 18	56	91	0.91	45	100	1	0.007
18. Important Note – page 19	56	89	0.89	45	100	1	0.032
19. Post infection vaccination – page 20	56	84	0.84	45	100	1	0.013
20. Maintenance of preventive measures – page 21	56	82	0.82	45	100	1	0.046
Global IVC			0.88			1	
Kappa Index			0.91			1	

*Percentage of agreement; †Item-Level Content Validity Index; ‡ p Value for the Mann Whitney test

Table 2 - Data reliability in relation to the Global Assessment items of the first and second version of the booklet. Natal, RN, Brazil, 2024 (n=56)

Evaluation requirements	Delphi 1*	Delphi 2*
Practical relevance	0.848	0.948
Clarity of language	0.836	0.936
Objectives	0.840	0.940
Presentation	0.843	0.943
Content	0.841	0.971
Update	0.866	0.966
Theoretical relevance	0.850	0.950
Sequence of topics	0.900	0.980
Global grade assigned to the booklet	0.878	0.980

* Cronbach's Alpha

Table 3 - Data reliability in relation to the Global Assessment items of the first and second version of the booklet. Natal, RN, Brazil, 2024 (n=56)

Dimensions	Delphi 1*		Delphi 2*		Value – p
	Average	Standard deviation	Average	Standard deviation	
Practical relevance	9.41	0.73	9.89	0.31	0.001
Clarity of language	9.28	0.75	9.84	0.37	0.018
Objectives	9.22	0.64	9.85	0.49	0.023
Presentation	9.11	0.83	9.89	0.56	0.001
Content	9.32	1.02	9.89	0.79	0.001
Update	9.21	1.07	9.88	0.35	0.002
Theoretical relevance	9.11	0.88	9.89	0.23	0.041
Sequence of topics	9.08	0.79	9.88	0.29	0.019
Global grade assigned to the booklet	9.02	0.75	9.89	0.41	0.001

DISCUSSION

Brazil is a country that has already had a high immunization rate compared to the immunobiologicals available to the population. However, it faces a context of ideological and political conflicts, with the presence of anti-vaccine movements. Although few, these movements can affect the success of the COVID-19 vaccination campaign by creating and

disseminating fake news related to new immunobiologicals⁽¹⁷⁻¹⁸⁾.

In view of this, the creation of a material that encompasses the essential information about available vaccines, when addressing aspects such as their origin, posology and potential side effects, through an accessible and easy-to-understand language, built on scientific evidence and validated by expert judges becomes a health education tool. Such ma-

terial has the potential to benefit not only direct readers, but also the population as a whole⁽¹⁹⁻²⁰⁾.

Because it is a material aimed at the general population, caution should be exercised when developing a simplified and understandable language for citizens of different levels of education. This approach aims to promote the democratization of knowledge, which allows access and understanding to a greater number of people. It is also necessary that the material has attractive aesthetics, objective information and that add useful knowledge to the context of the target audience⁽¹³⁾.

Teaching materials streamline health education activities. In the context of a pandemic, the conflict of information in which the population is inserted requires the provision of useful information and scientific knowledge in the context of the immunization campaign against COVID-19, since it is a context that generates, since the beginning of the pandemic, several speculation and dissemination of false information⁽¹⁹⁾.

Therefore, it is essential that this material goes through a process of validation of content and appearance, by specialists in the subject, to ensure the quality of the material and the effective transmission of the proposed message. In addition, the participation of a multiprofessional team in this process brings together several specialized knowledge on the subject covered by the material, which provides greater credibility⁽²¹⁾.

The Delphi technique allows the realization of successive rounds, until a consensus of opinions is obtained⁽²²⁾. Other authors cite the adaptation of the material from the suggestions of multi-professional experts as an essential step in the process of construction and validation of an educational material, because it allows to rethink, replace, improve and reformulate items, from the perspective of several professionals. Thus, what could escape the perception of some individuals can be observed and analyzed by others⁽¹⁹⁻²³⁾.

In addition, the researchers maintain the commitment to keep the booklet up-to-date, to ensure that the population has access to accurate and up-to-date information, strengthening adherence to the vaccination campaign. Information about the vaccine of the modern manufacturer, which was also included in the vaccination scheme of Brazil, were included in the final version of the booklet. Moderna mRNA-1273 vaccine, similar to Pfizer vaccine, uses messenger

RNA (mRNA) technology to induce an immune response against SARS-CoV-2⁽²⁴⁾.

Studies have shown that the modern vaccine is highly effective in preventing severe cases of COVID-19, including those caused by newer variants. The inclusion of the modern vaccine in the NBP further expands the arsenal of available immunizers, allowing greater flexibility in the administration of doses and vaccine schemes adapted to the needs of the population. Therefore, the need to rectify the information in the educational booklet is evident, since the dynamics of vaccination against COVID-19 continues to evolve⁽²⁴⁻²⁶⁾.

Although only knowledge is not able to produce, alone, the change of behavior and perspective in relation to the presented problem, it can provoke a significant change in the way of thinking and acting, when shared clearly and efficiently⁽²¹⁾. In this sense, the construction and dissemination of the educational booklet becomes a viable and elucidating form of health education, and can play a crucial role in the success of the immunization campaign against COVID-19, as well as in other immunization campaigns directed to the Brazilian population⁽¹⁹⁾.

As limitations of this study, it is worth mentioning the lack of validation by experts in the field of communication and advertising, as well as the limitation of use by groups with visual impairments or illiteracy. Materials in braille and audiovisual format can be more effective in these cases, however, this issue can be explored in future studies.

CONCLUSION

The booklet "Vaccination against COVID-19: what do you need to know?" was considered a valid educational technology in terms of its content to promote immunization against COVID-19. With this, it is expected that the booklet will be used as a resource that promotes knowledge and empowerment of the population, and that it will be available online, digitally and physically, on the Internet, social media, schools and health units.

CONFLICT OF INTERESTS

The authors have declared that there is no conflict of interests.

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