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DEVELOPMENT AND CONSTRUCTION OF THE INSTRUMENT FOR GLOBAL ASSESSMENT OF PREGNANT WOMEN IN PRIMARY HEALTH CARE: VALIDATION STUDY

DESENVOLVIMENTO E CONSTRUÇÃO DO INSTRUMENTO DE AVALIAÇÃO GLOBAL DA GESTANTE NA ATENÇÃO PRIMÁRIA À SAÚDE: ESTUDO DE VALIDAÇÃO

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ABSTRACT: Objective: Construct and validate the content of the Instrument for Global Assessment of Pregnant Women in Primary Care (IAGGAP) by experts. **Methodology:** This is a methodological study of the construction and content validation of IAGGAP, which aims to dimensionally investigate the reality of pregnant women treated in primary care. IAGGAP addressed topics ranging from Social Determinants of Health to oral health. The research was conducted with experts in the field between January and June 2022, using the COSMIN checklist guidelines. The instrument was evaluated in Objectivity, Completeness, Pragmatics, and Coherence. For analysis, the Content Validity Index (CVI) was adopted. **Results**: The evaluation of the nine participating judges resulted in a satisfactory CVI for the domains of Objectivity, Completeness, and Pragmatism. The overall CVI was 94.0%. **Conclusion:** The experts considered the aspects of Objectivity, Completeness, and Pragmatism adequate, proposing few feasible adjustments. The instrument proved to be valid for application to the target audience.
KEYWORDS: Primary Health Care. Social Determinants of Health. Validation Study. Pregnant Women. Oral Health.

RESUMO: Objetivo: Construir e validar o conteúdo do Instrumento de Avaliação Global da Gestante na Atenção Primária (IAGGAP) por especialistas. **Metodologia:** Trata-se de estudo metodológico de construção e validação de conteúdo do IAGGAP, o qual visa investigar dimensionalmente a realidade de gestantes atendidas na AP. O IAGGAP abordou desde os Determinantes Sociais da Saúde à saúde bucal. A pesquisa foi conduzida com especialistas na área, entre janeiro e junho de 2022, sendo empregadas as diretrizes do *checklist* COSMIN. A avaliação do instrumento envolveu os domínios Objetividade, Completude, Pragmatismo e Coerência. Para análise, adotou-se o Índice de Validação de Conteúdo (IVC). **Resultados:** A avaliação dos nove juízes participantes resultou em IVC satisfatório para os domínios Objetividade, Completude e Pragmatismo. O IVC global foi de 94,0%. **Conclusão:** Os especialistas julgaram adequados os aspectos de Objetividade, Completude e Pragmatismo, propondo poucos e factíveis ajustes. O instrumento mostrou-se válido a ser aplicado ao público-alvo.
PALAVRAS-CHAVE: Atenção Primária à Saúde. Determinantes Sociais da Saúde. Estudo de Validação. Gestantes. Saúde Bucal.

INTRODUCTION

Pregnancy is a period of great changes and deep meaning for the life of the woman and family that, because it encompasses expectations, discoveries and biological, psychological and social transformations, requires a series of adaptations. [1] Its course and clinical outcome are influenced by Social Determinants of Health (SDH), [1] which comprise individual characteristics and social, economic, environmental, and health aspects. [2]

In the context of the SDH, knowledge of them becomes essential for prenatal care, which stands out among the activities carried out by Primary Health Care (PHC). [3] Through preventive and health promotion actions, prenatal care aims to ensure adequate gestational development, inducing favorable outcomes in labor, birth and postpartum. [4]

In this sense, understanding the SDH and aspects related to pregnancy and prenatal care can provide greater preparation for the care provided to the future mother and the baby, especially in adverse situations, such as the Coronavirus Disease 2019 (COVID-19) pandemic. Added to this context is the influence of oral health on adverse outcomes for pregnant women and newborns, such as preeclampsia, premature delivery and low birth weight, making it relevant to know the reality of this type of health in pregnancy.

In view of this, the development of instruments addressing these points and their validation can be useful for the promotion, prevention and monitoring of various health conditions of pregnant women and their children. [5] Nevertheless, the development of Brazilian research instruments that analyze the health reality of pregnant women assisted in PHC, from a dimensional and integral perspective, are still scarce and specific to certain contexts. [5] This situation is aggravated when evaluating the number of instruments validated by experts aimed at measuring the construct to be assessed, which can compromise the accuracy of the analysis and the relevance of the results.

Therefore, the construction and content validation of the Instrument for Global Assessment of Pregnant Women in Primary Care (IAGGAP, in Portuguese) aim to address health issues, from aspects related to SDH, pregnancy, and prenatal care to factors associated with oral health and pandemic situations, such as COVID-19. Thus, its adoption by clinicians and researchers will be relevant for the mitigation and prevention of potential risk scenarios for the mother-child dyad, even reducing the allocation of public and private resources, such as financial and human.

Based on the above, this study aimed to construct and validate the content of the IAGGAP by experts.

METHODOLOGY

TYPE OF STUDY

This is a methodological study of construction and content validation of the IAGGAP, developed between January and June 2022, according to the following 6 steps: establishment of the conceptual framework; definition of objectives and population; construction of items; structuring of the instrument; experts' opinion; and adaptation, according to the judges' recommendations. [6] For its description, the guidelines of the COSMIN checklist were used. [7]

ESTABLISHMENT OF THE CONCEPTUAL FRAMEWORK

The conceptual structure stage was built through a narrative review, which directed the aspects that should be portrayed in the instrument's questions and that influence the healthy progression of pregnancy.

DEFINITION OF OBJECTIVES AND POPULATION

The stage of defining the objectives and population began with the conceptualization of the IAGGAP with the purpose of investigating the reality of women assisted in PHC during pregnancy, within the scope of aspects related to SDH, pregnancy, and prenatal care, and factors associated with oral health and pandemic situations, such as COVID-19. In particular, this instrument is intended for all health professionals working in PHC, as well as other professionals whose interest is to comprehensively investigate the issues that can influence the progression of a pregnancy.

After construction, the content validation of the instrument was carried out by a committee of judges from the Nursing and Odontology fields, with experience in PHC. The sample size was defined by applying the formula $n = Z\alpha^2 \cdot P \cdot (1 – P)/d^2$, which considers the final proportion of subjects in relation to a given dichotomous variable and the maximum acceptable difference in this proportion. For Zα, referring to the confidence level adopted, a value of 95% was assigned, a quantity also used for P, the minimum proportion of individuals who agree with the relevance of the instrument's components; as for **d**, taken as the difference in proportion considered acceptable, a value of 15% was admitted. [8] Thus, the final calculation ($n = 1.96^2 \cdot 0.95 \cdot 0.05/0.15^2$) resulted in a sample of 9 judges, of whom 5 were nurses and 4 were dentists.

The search for the judges (academic experts) was carried out on the Lattes Platform at the portal of the National Council for Scientific and Technological Development (CNPq) and the Thesis Database of the Coordination for the Improvement of Higher Education Personnel (CAPES), using the keywords "Thesis", "Dissertation", "Oral Health", "Primary Health Care" and "Pregnancy". Judges who obtained three points were included, based on the criteria adapted from Jasper. [9] Judges who did not respond to the invitation to participate in the research were excluded.

CONSTRUCTION AND STRUCTURING OF ITEMS

Regarding the construction stage, it was conducted based on the narrative review (data not shown), which resulted in the production of 77 questions, of which 26 were subjective and 51 multiple-choice. Subsequently, the instrument was structured, based on the organization and logical presentation of the questions and sections. Thus, the following topics and number of questions were obtained: aspects related to SDH (28 questions); aspects related to pregnancy and prenatal care (14 questions); aspects related to the COVID-19 pandemic (15 questions); and aspects associated with oral health (20 questions).

OPINION AND ADAPTATION ACCORDING TO JUDGES' RECOMMENDATIONS

Regarding the experts' opinion stage, they were contacted individually, through e-mail, at which time an invitation letter and a brief explanation of the study were sent. When the participation was accepted, experts received, also through e-mail, the instrument to be validated by content and a link to

access a form, prepared via Google Forms, containing the Free and Informed Consent Form (FICF) and questions regarding the expert judge's characterization (sociodemographic, academic, and professional aspects) and evaluation of the instrument.

Concerning the analysis of the instrument by the judges, the questions involved the domains of Objectivity (how objective the questionnaire was in achieving what it proposed), Completeness (how complete the questionnaire was in achieving what it proposed), Pragmatism (how correctly the questionnaire addressed what it proposed), and Coherence (how much the questionnaire represented the literature to which it referred). [10] Regarding the answer options, they followed the pattern of the Likert scale, being expressed as: 1 - Strongly agree; 2 - Agree; 3 - Neither agree nor disagree; 4 - Disagree; and 5 - Strongly disagree.[10] After each question, there was a space for the inclusion of possible suggestions.

Regarding data evaluation, data were organized using Microsoft Excel for Windows, version 2013, and analyzed using the Epi Info software, version 7.2.1.0. The results were presented in terms of relative and absolute frequency, as well as measures of central tendency (arithmetic mean and median) and dispersion (standard deviation). The P value was calculated using the statistics software Statistical Package for the Social Sciences (SPSS) for Windows, version 23.0, developed by IBM Corporation in Armonk, NY, USA.

As for the statistical analysis of the content validation results, the Content Validity Index (CVI) was calculated using the R software. This index was determined by adding up the agreements obtained in each domain and dividing the result by the total number of responses attributed to that domain. The overall CVI, in turn, represents the average of the CVI for all domains. It was established, as a validity criterion, that an item would be considered valid if the agreement among the judges was equal to or greater than 0.80. [6] This evaluation was conducted using the binomial test, adopting a significance level of 95%.

After the evaluators sent their answers, the instrument was analyzed and adjusted according to the recommendations of each expert.

The study was approved by the Research Ethics Committee of the University for International Integration of the Afro-Brazilian Lusophony (UNILAB), according to Decision n. 5,547,691. [11]

RESULTS

Nine judges participated in the content validation stage, with a mean age of 38.6 (± 5.6) years, of which 55.5% (n = 5) were male. Regarding education, 77.8% (n = 7) of the participants stated that they had completed their undergraduate studies in public institutions and, in terms of occupation, 55.5% (n = 5) were currently working in educational institutions. Concerning years of experience in Primary Health Care Units (PHCUs), 77.8% (n = 7) of the judges had at least five years of experience in the area.

All participants stated that they had a *lato sensu* postgraduate degree and a master's degree, and 66.7% (n = 6) reported not having a doctorate. Regarding involvement in research, 66.7% (n = 6) of the judges were part of research groups, of which 50.0% (n = 3) were researchers in the Collective Health field, and 88.9% (n = 8) had publications in the area of Primary Care.

Concerning the validation of the instrument's content, the Objectivity, Completeness, and Pragmatism domains showed satisfactory/acceptable CVI. The overall CVI obtained was of 94.0% agreement among the judges (Table 1).

Table 1 – Content Validity Index of the instrument by domain and overall

Domains	CVI*	CI95%**	p-value
Objectivity	1	0.66-1	1.000
Completeness	1	0.66-1	1.000
Pragmatism	1	0.66-1	1.000
Coherence	0.77	0.39- 0.97	0.540
Overall CVI			0.94

*CVI: Content Validity Index; **CI: 95% confidence interval, based on the binomial test.

As for the judges' suggestions, according to each domain, for Objectivity, they recommended specifying the title of the instrument; verification of items related to the SDH and adoption of a technical reference; and removal of similar items. All observations were accepted (Table 2).

Table 2 – Judges' suggestions for each domain contained in the instrument undergoing validation

Domains	Suggestion
Objectivity	
Make the title less broad	Accepted
Review items related to SDH* and adopt a technical reference	Accepted
Remove similar items	Accepted
Completeness	
Include "desired pregnancy" variable	Accepted
Include variable on referral for dental evaluation	Accepted
Include variable on the importance of dental monitoring	Accepted
Include variable on the fulfillment of dental monitoring	Accepted
Include variable on which professionals performed prenatal care	Accepted
Add number of prenatal appointments	Accepted
Change disease in the oral cavity to oral disease	Accepted
Add stratifications to marital status, according to IBGE	Not accepted
Add a "how" item after asking about the influence of pregnancy on overall health	Not accepted
Pragmatism	
Add variables about the vaccination schedule and laboratory tests during pregnancy	Not accepted
Coherence	
Search for a validated instrument that has the same theme	Not accepted

*SDH – Social Determinants of Health.

Regarding the judges' suggestions on the Completeness domain, the following observations were made: inclusion of variables (desired pregnancy; referral, importance, and fulfillment of dental monitoring; and identification of professionals who performed prenatal care); add the number of prenatal appointments; and change of the expression "disease in the oral cavity" to "oral disease".

For the suggestions that were not accepted for this domain, the proposal to add stratifications to marital status, according to the terminology of the Brazilian Institute of Geography and Statistics (IBGE), would make it impossible to dichotomize the variable, changing the application of the statistical analysis proposed for the evaluation of the instrument's data. In addition, the recommendation to include a "how" item, after asking about the influence of pregnancy on overall health, would lead to the addition of a non-quantitative variable to the instrument.

Concerning the Pragmatism domain, the judges suggested the addition of variables related to the vaccination schedule and laboratory tests during pregnancy. Specifically, the suggestion was disregarded in view of the extension of the instrument.

Regarding the Coherence domain, the indication to use an instrument validated in the literature that addressed the theme of this research was not carried out. This action was justified since, even though there are previously constructed instruments of similar designs, the set of variables portrayed in this instrument, associated with the reality to which its application is directed, were considered as determining points in the decision of its construction and validation.

DISCUSSION

The process of constructing the Instrument for Global Assessment of Pregnant Women in Primary Care (IAGGAP, in Portuguese) addressed here may contribute to its dissemination and use among students, professors, and researchers in the fields of Nursing, Odontology and related areas, with reliability and applicability in different studies. [6] Its relevance is also based on the fact that it addresses different factors that directly or indirectly interfere in the reality of pregnant women, which may guide actions to promote, prevent and reestablish the overall and oral health of pregnant women by managers, health professionals, and the society, with repercussions in different spheres, such as the family, social, economic, and political.

As for the findings of this study, regarding the age of the judges, the average of 38.6 years recorded was lower than that found among research productivity (PQ, in Portuguese) scholarship holders in the area of Health Sciences at CNPq in 2021, whose predominant age group was 50 to 59 years. [6] Regarding the composition of the judges consisting mainly of men, this data may come from the lower presence of women in the sciences and, consequently, in scientific production. This data may also have resulted from the criteria established for the selection of experts, which disregarded gender. In addition, male experts were the most agile when replying to the evaluation of the instrument and, therefore, in their inclusion in the research.

Concerning the fact that most of the judges graduated from public institutions, it is opposed to the fact that Brazilian higher education is essentially private. [12] For the predominance of participants who held occupations in public institutions, this result can be justified by the stability provided by public selections and their admission. [13]

Regarding the years of experience, the fact that most of the judges had at least 5 years of experience in the PHC field can be understood due to their age and current occupation, as well as the participants' postgraduate qualifications, situations that involve time and the choice for a specific area of activity. Concerning the fact that all participants had a master's degree and a *lato sensu* postgraduate degree, this finding corroborates the growth of postgraduate programs in Brazil, accompanied by a greater distribution of scholarships among graduate students. [14] This finding may also explain the fact that a significant number of judges were linked to research groups.

About the area of activity, the emphasis on Collective Health and publications in PHC may be linked to the judge selection process used in this study and to the themes of the instrument to be validated. In particular, the concentration of participants in Collective Health may have contributed to a more appropriate content validation process, since it aims to analyze the determinants of the social production of disease, health, and care, and the same is true when the centralization of publications in PHC is considered.

Regarding the content validation process, the positive evaluation, by the judges, for the Objectivity, Completeness, and Pragmatism domains indicates the importance of the applicability of the construct.

Specifically, the instrument proposed here obtained a considerable CVI, including the Overall CVI, making its content valid and its application reliable and consistent with the target population (pregnant women), [6] representing what was proposed. It is worth noting that CVI is widely used, as it enables the analysis of each domain, each component, each item, and of the instrument in its entirety [6]. In this scenario, we highlight the need to create valid and reliable instruments that can contribute to qualified actions and interventions in the Health field.

In particular, for the judges' suggestions regarding the Objectivity domain, the request to make the title of the instrument more specific was accepted to facilitate its dissemination and understanding, [15] as well as the suggestion to remove similar items. This attitude ensured greater objectivity to the instrument.

Regarding the proposal to reassess the items related to the SDH, through a technical reference, this reflection was important considering that the existing nomenclature and classifications for these determinants brought greater reliability to the instrument and clarity in the interpretation of its results. [16]

Thus, it is presumed that, when undertaking the validation of an instrument, the researcher takes on responsibility for the implications of the decisions made about care, treatment, and/or health interventions. Also, the approximation with standardized terminologies is essential and brings formality to the construct. [17]

Concerning the Completeness domain, this was the one that had the most recommendations by the judges, which corresponded especially to the addition of variables. For the request to include a desired pregnancy variable, this addition was important when admitting that the desire for a child may exceed the need for planning, despite having repercussions on the life of the woman and her family, involving social and cultural aspects that influence and determine the evolution and management of the pregnancy. [18]

As for the odontological issue during pregnancy, the judges' proposal to include variables on the referral, importance, and fulfillment of dental prenatal care were of great relevance to the idea of the construct. In fact, the literature points to different gaps in the dental monitoring of pregnant women, which may imply a decrease in the quality of health care provided and the occurrence of avoidable risks, such as premature birth and low weight at birth. [19] Thus, understanding the dental reality during the gestational period is of paramount importance for knowledge and decision-making regarding the public investigated in this study, via the instrument.

The suggestion to incorporate the health professionals who assisted the pregnant women during prenatal care can be justified by the increase in the quality of care provided to the mother-to-be when carried out by a multiprofessional team. [20] As an example of this need, the study conducted by Marques et al. [21] indicated a higher prevalence of guidance given by health professionals to pregnant women when prenatal care was conducted by nurses and doctors, compared to care mostly provided by one professional.

Regarding the opinion to incorporate the number of prenatal appointments, this attitude may have been based on the recommendation by the Ministry of Health, [22] which advises at least six appointments during the gestational period, a number that is justified by the decrease in the occurrence of negative maternal and infant outcomes. In addition, knowledge of this variable also enables better understanding of the logistics of service in relation to pregnant women.

Concerning the suggestion to exchange the term "oral cavity disease" for "oral disease", despite the similarity in writing, the former seems to be a less common phrasing in the general context and in the context of health services. It is known that, in general, knowledge about oral health in the population

is reduced, especially in pregnant women, in which there are even falsehoods. [23] Thus, bringing a more habitual nomenclature optimizes the application of the instrument and the reliability of its results.

In particular, the IAGGAP has the potential to contribute as a tool in the field of health research, especially in the context of women's health, with regard to systematized, broad, and validated data collection. In addition, considering the lack of instruments that address the variables proposed in the IAGGAP, it can optimize decision-making and health actions and services offered to pregnant women, based on data collection and interpretation of the results obtained.

Regarding the limitations of this study, we highlight the judges' lack of availability to respond in a timely manner and their interest in participating in the research, as well as the feedback regarding the evaluation of the instrument. As for the process of obtaining evidence related to validity, the limitation consisted especially in the lack of other instruments to support reliability, feasibility, sensitivity, and responsiveness in realities similar to that of this study.

CONCLUSION

Based on the data obtained, it can be concluded that, in the process of content validation of the IAGGAP by judges qualified both in the context of graduate training and in the area of professional and scientific activity, the focus of the study, they judged the aspects of objectivity, completeness, and pragmatism of the instrument to be adequate, proposing few and feasible adjustments. In addition, the instrument proved to be adequate in its content and format.

The development of this instrument is paramount for carrying out complete data collection, allowing the results to point to a holistic care for pregnant women. In addition, the multiprofessional participation of experts in the validation of this instrument was essential for the gathering of questions pertinent to the overall care of pregnant women by the different professionals who assist them.

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