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Construction and validation of a clinical form for usual-risk prenatal follow-up*

Construção e validação de uma ficha clínica para acompanhamento de pré-natal de risco habitual*

Construcción y validación de una ficha clínica para el monitoreo del riesgo prenatal habitual *

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Abstract: Objective: to build and validate a clinical form record for usual-risk prenatal follow-up. **Method:** methodological research with employment of Delphi Technique to validate the instrument as the relevance/representativeness, by applying the calculation of the content validity coefficient, whose minimum value adopted was ≥ 80 %. The criteria for the selection of participants consisted of being a nurse, professor at government institution with the degree of PhD and specialist in Obstetrics. The first panel was composed of 15 judges and the second, of 13. The study was conducted between February and June 2016. **Results:** the calculation of the Content Validity Coefficient measured the Relevance/Representativeness of each item of the clinical form through the analysis of two panels, which reached the coefficient set. **Conclusion:** the validated clinical form is suitable for application in usual-risk prenatal consultations.
Descriptors: Prenatal care; Clinical form; Pregnancy; Technology; Nursing Care

Resumo: Objetivo: construir e validar uma ficha clínica para acompanhamento do pré-natal de risco habitual. **Método:** pesquisa metodológica com emprego de Técnica *Delphi* para validar o instrumento quanto a pertinência/representatividade, aplicando-se o cálculo do coeficiente de validade de conteúdo, cujo valor mínimo adotado foi ≥ 80 %. Os critérios de seleção dos participantes consistiram em ser enfermeiro, docente de instituição pública com título de Doutor e especialista em Obstetrícia. O primeiro painel foi constituído por 15 juízes e o segundo por 13. O estudo foi realizado entre fevereiro e junho de 2016. **Resultados:** o cálculo do Coeficiente de Validação de Conteúdo mensurou a Pertinência/Representatividade de cada item da ficha clínica mediante a análise de dois painéis, os quais alcançaram o coeficiente estabelecido. **Conclusão**: a ficha clínica validada está apta para aplicação em consultas de pré-natal de risco habitual.
Descritores: Cuidado pré-natal; Ficha clínica; Gravidez; Tecnologia; Assistência de Enfermagem

Resumen: Objetivo: construir y validar una ficha clínica para el monitoreo del riesgo prenatal habitual. **Método:** investigación metodológica con el empleo de la Técnica Delphi para validar el instrumento de acuerdo con la

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pertinencia/representatividad, aplicando el cálculo del coeficiente de validación de contenido, cuyo valor mínimo aprobado era ≥ 80 %. Los criterios para la selección de los participantes consistían en ser un(a) enfermero(a), profesor(a) de institución pública con el título de Doctor(a) y especialista en Obstetricia. El primer panel estuvo integrado por 15 jueces y el segundo, por 13. El estudio se realizó entre febrero y junio de 2016. **Resultados:** el cálculo del Coeficiente de Validación de Contenido midió la pertinencia/representación de cada elemento de la forma clínica a través del análisis de dos paneles, que alcanzaron el coeficiente establecido. **Conclusión:** la ficha clínica validada es adecuada para su aplicación en las consultas prenatales de riesgo habitual.
Descriptores: Forma clínica; Atención prenatal; Embarazo; Tecnología; Cuidados de enfermería

Introduction

The prenatal aims to assist the evolution of pregnancy, intervening in situations of risk that may affect the mother-baby binomial, with a follow-up that encompasses actions of health promotion, prevention and psychosocial support. The early prenatal care within weeks of gestation is an indicator of care quality. [1]

The care provided to the gestational phase aims to reduce maternal and neonatal morbidity and mortality, since the mortality rate is an important indicator of women's health, referring to disparities in a region/country, mainly in developing countries, where 99% of deaths occur. The high rates are a challenge to public health, because a significant number of deaths results from direct identifiable and treatable obstetric causes during the prenatal and postnatal in the primary health care level. [2-3]

According to the World Health Organization (WHO), Brazil has managed to reduce 56% of mortality from 1990 to 2015, decreasing from 140 per 100 thousand live births to 62 per 100 thousand live births. In the world, this drop was 45%, from 380 per 100 thousand live births to 210 per 100 thousand live births. The WHO report reveals that mortality in developing countries is 14 times greater than in developed countries. Between 2016 and 2030, the global mortality is expected to be below 70 deaths per 100 thousand live births, comprising one of the goals of sustainable development that can be reduced through early prenatal care and integral follow-up until the puerperium.2-3

The pre-natal consists of an essential follow-up for guiding behaviors through a clinical evaluation obtained in the consultations able to contribute to reducing the maternal and perinatal mortality rates. However, the country shows discrepancies between what is recommended in policies and their actual implementation, because there is non-compliance regarding the access to prenatal care, number of consultations and full execution of the stages of physical and obstetrical examination, availability of laboratory and imaging tests, which affect the quality and effectiveness of care.[4-5]

Some obstacles to the pre-natal adherence include the financial situation, low schooling, being unmarried and multigravida (which doubles the risk). Furthermore, health status or the distance from the residence to the Primary Care may require spending on transport and hinder the presence at the consultations.[6] The dissatisfaction with the healthcare team, the consultation length, the influence of cultural factors, the absence or difficulty in supply of medications and tests in the health service may reflect the user's perspectives of the assistance available to the pregnancy cycle. [7]

In this way, the usual-risk prenatal consultation is defined as an assistance to pregnant women without previous or current comorbidities that constitute risk of instability that can lead to undesirable outcomes to the binomial, which require medical supervision. Nevertheless, the pre-natal care for pregnant women without complications can be done by the nurse and interspersed with the doctor. In the Primary Health Care context, the nurse will request tests and will prescribe medications according to the protocol adopted by the city, will be responsible for prescribing vaccines, identifying signs of risks and relevant referrals to secondary and/or tertiary care.[8]

The nursing consultation has been approved by the Federal Nursing Council (COFEN) through Resolution n. 159/1993, for being a Science with scientific knowledge that gives autonomy to the professionals to implement the actions present in the law of professional

exercise and make the decision before the events of health and disease.[9] It is an opportunity to build a user history with a high number of information, once the bond established facilitates dialog and directs the treatment plan.[10]

Investment in researches in the nursing area focused on the technological introduction and development constitutes a challenge to the advancement in care modes, constituting one of the priorities of the National Agenda for Health Research Priorities, with an emphasis on regional and national studies.[11] Adherence to clinical forms to record the behaviors and information acquired in the consultations is fundamental to systematize the stages of pre-natal care, including pregnancy, delivery, newborn and puerperium. Nonetheless, the instruments need to contemplate items that will ensure a broad service able to alert the professional regarding the presence of risks, which favors the interventions and can contribute to reducing maternal and perinatal mortality.[12]

Given the above, there arose the interest in developing this research by considering that the specific instrument for nursing consultation in the usual-risk pre-natal may be a technology capable of contributing to the nurse's care in the assistance to pregnant women in Primary Health Care, effectively, based on standards recommended by the Pan American Health Organization and Ministry of Health for the consultations to pregnant women in the usual-risk pre-natal. The use of technologies in the health area increases the care quality and facilitates the processes, from the technical activities that comprise the assistance to the management of health spaces.

The role of nursing in all stages is linked to the use of technologies, which can be classified as soft, translated as the act of caring for people and the interpersonal relationships established between the client and the professional; soft-hard, referring to the creation of care models from scientific bases; and hard, being represented by technological devices.[13]

In this context, the adaptation and validation of an instrument for nursing consultation in the pre-natal falls in the classification of soft-hard technology, as it is able to foster a broad research that facilitates the dialog between the nurse and the user, aiming to identify risk factors relevant to the gestational development. In addition to enabling the achievement of referrals in a timely manner, health education, clarification of doubts and the trust of the pregnant woman.

In this sense, the object of this research consists of adapting a clinical form for the nursing consultation in usual-risk pre-natal in Primary Health Care. The objective is to construct and validate a clinical form for the usual-risk prenatal follow-up.

Method

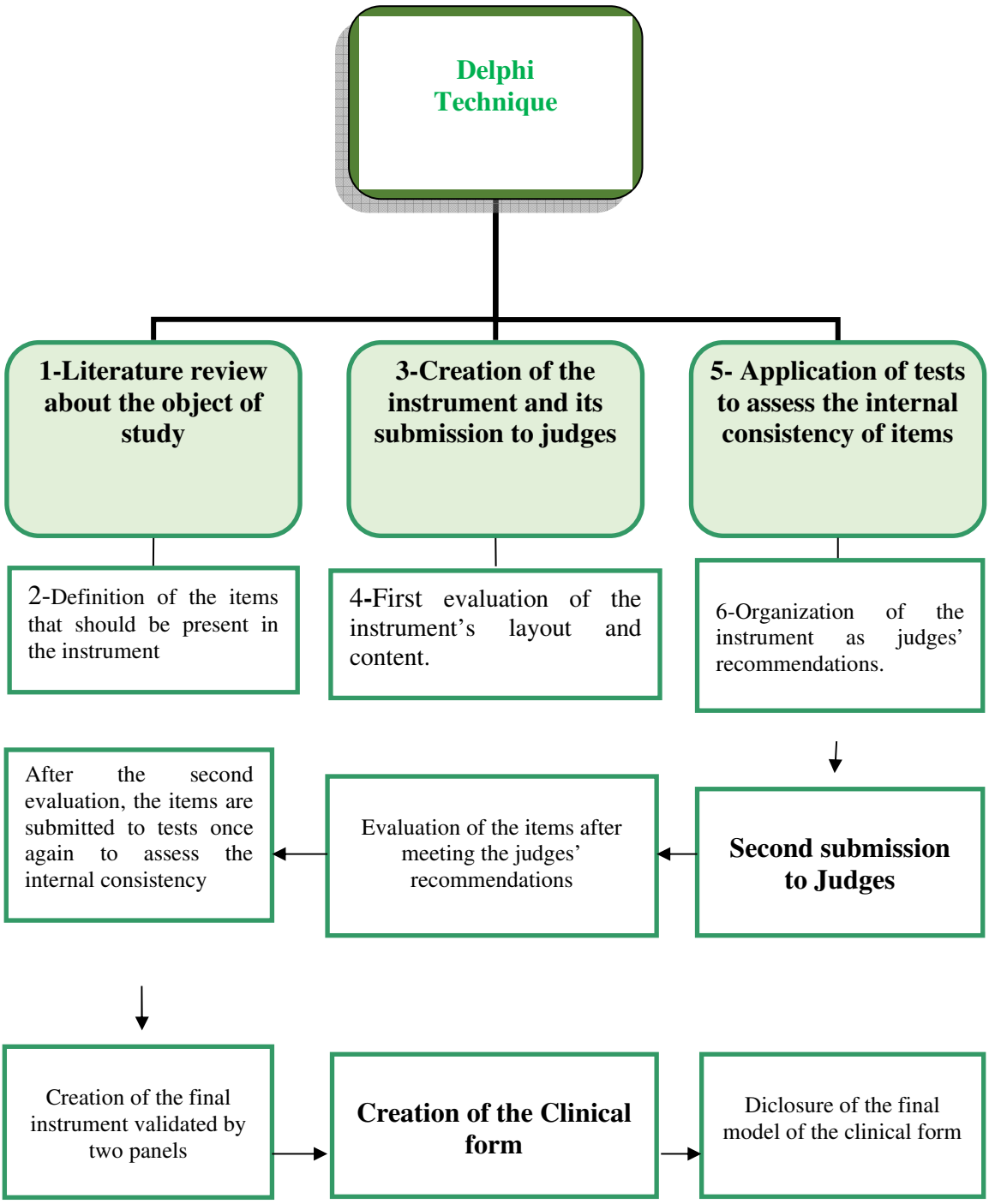
Methodological research with employment of the Delphi Technique to validate an instrument for nursing consultation in usual-risk pre-natal. The methodological study favors exploring methods that aim to select and organize data through the elaboration of instruments that should be submitted to the validation steps. The Delphi technique consists of a systemized method to consolidate information from the consensus of specialists, who may be called judges, experts, specialists, respondents, panelists or experts.[14]

The construction of the clinical form occurred after thorough literature review and observation of the instruments recommended by the Latin American Center for Perinatology, Women's Health and Reproductive Health of the Pan American Health Organization/World Health Organization and the Ministry of Health of Brazil. Thus, there was the establishment of relevant information and contents that passed through the validation process, i.e., participants verified whether the instrument is able to provide reliable and accurate responses within the studied topic.[14-15]

The selection criteria to participate in the research was a non-random sample of nurses, professors and specialists in Obstetrical Nursing, with PhD degree, working in government universities in the country, in order to obtain representatives from all regions, as a requirement to validate the instrument and ensure constructs that are compatible with the regional variances. The participants considered were nurses, specialists with at least two years of teaching in the area of women's health, identified from the curriculum available on the Lattes Platform and through the snowball technique. This technique recruits new participants from the indication of a previous one and so on, until achieving the proposed goal.[16]

Figure 1 presents the steps that comprise the Delphi Technique:

Figure 1 - Delphi Technique



Source: Created by the authors.

The validation step of the first panel occurred between February 15 and March 25, 2016. After curricular analysis, 63 professionals were considered eligible, but 33 e-mails sent were not answered, 12 professionals refused to participate in the study, three dropped and 15 agreed to participate in the sample of judges in the first panel of validation of the research. The second panel occurred between May and June 2016 by sending the link to the 15 participants in the first step, of whom 13 professors answered the questionnaire until the end of the validation phases.

The evaluation of empirical indicators by specialists occurred through a platform built on forms of the Google Docs, on the internet. Thus, each participant received an invitation with a link to access the platform. By clicking on the link, the specialist was automatically directed to the platform and, after agreeing to participate in the study, clicked on the link of acquiescence of the Informed Consent Form (ICF), on the first page. After agreeing, the participant had access to the content of the instrument for the evaluation of each item. The instrument was submitted to layout and content validation by the specialists through the Delphi Technique. The degree of relevance of each item of the instrument was evaluated considering the concepts of clarity and relevance/representativeness.

The concordance was evaluated from the frequency of repetition of answers in each unit. The reliability was assessed from the homogeneity of responses, stability and equivalence. The Content Validity Coefficient (CVC) was used to evaluate the Relevance/Representativeness of each item of the instrument as a whole. The judges used a 4-point scale to assess the adequacy of the Relevance/Representativeness, being 1 = irrelevant, 2 = little relevant, 3 = relevant and 4 = very relevant. The items should present CVC ≥ 0.80.[17-18]

The CVC was calculated through the following equations:

1) Mx = Σx/J, where Mx represents the mean value for each item, Σx corresponds to the sum of the values obtained in the Likert scale and J is the number of judges;

2) CVCi = Mx / Vmax, where CVCi is the CVC of each item and Vmax is the highest value of each item on the 4-point Likert scale;

3) CVCt = Mcvci, where CVCt is the total CVC of the questionnaire and Mcvci represents the mean content validity coefficient of the items of the questionnaire.

The error due to possible biases of the judges was $2{,}284x10^{-18}$ and was not considered in the calculation of the CVC, since it was close to zero. To evaluate the clarity of language, the percentage of concordance was used. The judges used a 2-point scale to assess the adequacy of the clarity of language of items, being 1 = Adequate and 2 = Inadequate. The concordance for each item was calculated with the number of judges who considered the item adequate divided by the total number of judges, multiplied by 100.[18]

The project was submitted for analysis and opinion of the Research Ethics Committee of the Federal University of Juiz de Fora, and after approval through opinion 1.324.662, on November 16, 2015, the validation step of the instrument began with the professors who agreed to participate as judges, considering the suggestions provided as confidential and respecting the Resolution 466/2012 of the National Health Council of the Ministry of Health, which regulates researches carried out with human beings.

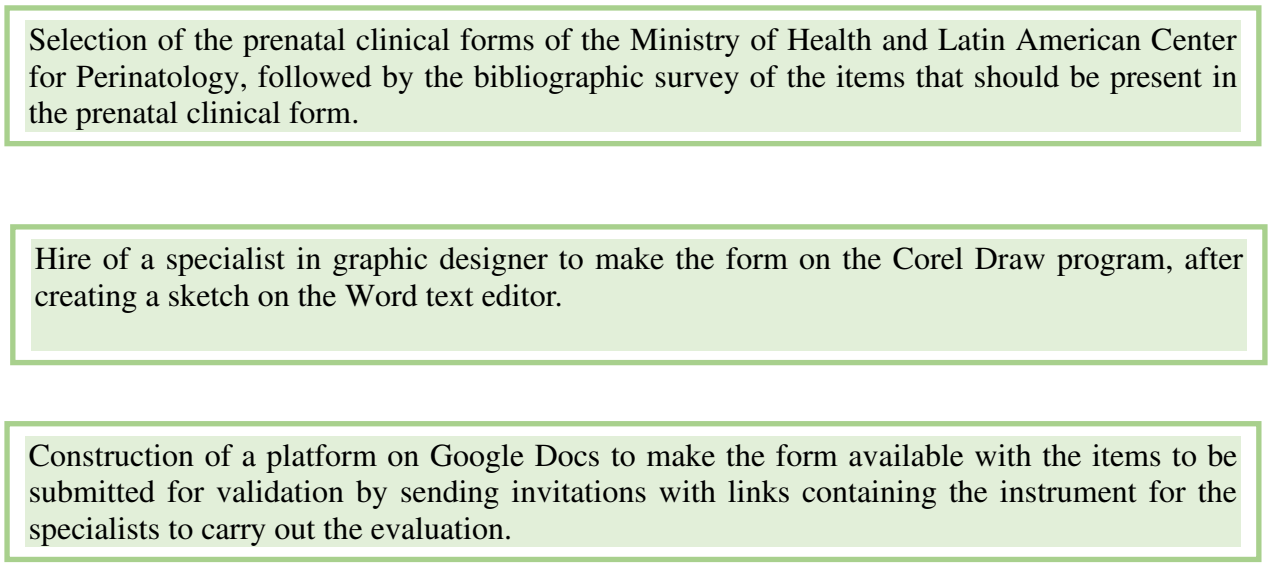
Results

The instrument was developed through a survey on clinical forms recommended by the Ministry of Health and the Latin American Center for Perinatology, Women's Health and Reproductive Health of the Pan American Health Organization/World Health Organization. This decision considered the need to adapt a comprehensive material, so that the professional has safety to follow-up the usual-risk pre-natal with quality in Primary Care. The documents of the Ministry of Health consulted were the pre-natal forms in the Prenatal and Birth Handbook,

2014 and 2015 Pregnant Woman's Booklet, 2015 and 2016Women's Health Care Protocol, 2014 Delivery and Birth Humanization Book.

The construction of the instrument followed the steps presented in Figure 2.

Figure 2 - Construction of the instrument



The final elaboration of the clinical form validated in the first panel occurred after the creation of an outline in Word, which was delivered to a designer prepare the model, being this step performed twice in order to improve the distribution of spaces between the items and add information suggested by specialists.

The first round of the validation occurred in February 2016 through the Delphi technique, being constituted by 15 nurses, professors of government universities in Brazil, specialists in Obstetrical Nursing, of whom 10 were PhD and 5, Postdoc. The minimum experience in the education area was nine years, and the maximum, 38 years, with a mean of 22 years; the minimum working time in the area of Women's Health was 14 years, the maximum, 38 years, with a mean of 24 years; the performance in the pre-natal had a minimum period of 5 years, a maximum of 38 years and mean of 20 years.

Among the obstacles, there was the difficulty in selecting the sample, since it required make a wide search in curricula on the Lattes platform to look for the e-mails. Concerning the benefits, there was the opportunity to carry out a study with professionals from all Brazilian regions with freedom to issue opinions and viable suggestions to improve the work even though they are distant from the researchers. The final sample of specialists reached all regions of the country: North (Acre): 1; Midwest (Brasília, Mato Grosso do Sul): 3; Northeast (Maranhão): 1; Southeast (São Paulo, Rio de Janeiro): 6; South (Rio Grande do Sul): 4.

The second panel was held in June 2016, with the participation of 13 specialists who responded to the previous round, being composed of items that had not reached the validation in panel 1 or with suggested adjustments. In relation to the clarity and understanding, the Total Content Validity Coefficient was 0.97. All items presented Content Validity Coefficient above the cutoff point established, although some specialists pointed out the need for adjustments. The minimum value observed was 0.85. In relation to the relevance, the Total Content Validity Coefficient was 0.84. The minimum value observed was 0.73.

Discussion

The creation of the final version of the work considered the rigor and accuracy of the suggestions described in the results regarding the layout to offer professionals an organized material, easy to fill and with good visualization of the blocks. In validation surveys with more than five experts, the validity coefficient must be greater than or equal to 80%, which confirms the success of this research.[19-20]

Moreover, the use of a clinical form constructed from a validation work enables a safe assistance to the patient with emphasis on complete records according to the code of professional ethics and in line with the patient safety protocol. Furthermore, the record

constitutes as a document that can be submitted to audits, requested by the justice or by the patient because this document reflects the care quality and patient safety.[21]

The improvement of the form encompassed the prenatal follow-up of the partner chosen by the pregnant woman, regardless of being the father, once the diversity of genders and new conformations of families were respected. Thus, the partner selected by the pregnant woman to be inserted in the prenatal consultations can extend the care with his/her health and understand the changes his/her partner will experience during pregnancy, increasing the couple's complicity.[22]

In this way, all the adjustments made in the instrument until the preparation of the final version of the clinical form were anchored in scientific evidence, and in a practical designer to optimize the working process of the Primary Care professional, divided into: Pregnant Woman's Identification; Personal history; Family history; Obstetric history; Gynecological History; Breastfeeding history; Nutritional history; Physical Activity; Current pregnancy; Oral health; Breasts; Obstetric conditions; Examinations; Prenatal consultation; Chart for the prenatal consultations; Graphs for gestational age monitoring; Prenatal care of the partner; Examinations of the partner; Delivery/Abortion; Newborn; Maternal discharge from the place of delivery; Newborn's discharge.

A graphical representation of the clinical form occurred in A4 sheet occupying five pages, but, for the clinical practice, it should be arranged in an A3 sheet to reduce the volume of papers in the records. The final model may be consulted in the dissertation entitled "Validation of a clinical record for the prenatal consultation for usual-risk pregnant women: A proposal for nurses" available from http://www.ufjf.br/pgenfermagem/files/2010/05/Disserta%C3%A7%C3%A3o-Daniela-Aparecida-Almeida-Duque.pdf.

The development of materials to qualify health care consists of a strategy to highlight the Nurses' consultations in Primary Care and corroborates the new COFEN Resolution 606 of 2019, which regulates the practice of nursing in works as offices and private clinics. The assistance in offices and clinics should base on the nursing care systematization and be engaged with the records in conventional or electronic records.[23]

This work met all the steps proposed by the method, as occurred in other studies that helped understanding the steps during the validation path. In addition, its layout and content are organized in order to guide and standardize the prenatal consultations.

Final thoughts

This research revealed that the clinical form validated is a soft-hard technology that can be used by nurses and by other professional categories that perform prenatal consultations in Primary Health Care, constituting as an instrument for the prenatal consultation to the usual-risk pregnant women in the perspective of a quality assistance, able to contribute to reducing maternal and fetal morbidity and mortality in Brazil.

During the form validation, the specialists showed to be involved, satisfied and engaged when collaborating to the research and expectations in relation to the contribution of the result for the professionals who work in the Unified Health System. Moreover, the study evidenced the importance of the clinical form as a technology in the training of nursing students who will be able to use it in prenatal care in practical lessons.

A limitation of the study was the lack of time to apply the clinical record to a sample of professionals to measure the work dimensions in the routine of Primary Health Care.

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2 – Betânia Maria Fernandes
Professor responsible for advising this research at the *Stricto Sensu* Postgraduate Program of the Academic Master's Degree in Nursing of the Federal University of Juiz de Fora

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