

ORIGINAL ARTICLE

VALIDATION OF AN ELECTRONIC TOOL FOR MONITORING NEWBORNS WITH CONGENITAL SYPHILIS

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ABSTRACT

Objective: To validate the content and appearance of an electronic tool for the monitoring of newborns with congenital syphilis.

Method: Methodological study of validation of content and appearance. Data were collected from June to August 2018 with the use of assessment instruments for validation by seven medical specialists who teach at a higher education institution, with experience in pediatrics and/or infectious diseases, and who have completed their undergraduate courses more than 16 years ago. Content Validity Index with an established value of 0.78 was used.

Results: Regarding structure and presentation, objectives and relevance, all items were considered validated by the experts. The global Content Validity Index was 0.97.

Conclusion: The electronic tool was validated for content and appearance, and its contribution to nurses and doctors in primary care was the production of an easy-to-use tool for effective clinical monitoring of infants with congenital syphilis.

DESCRIPTORS: Validation Studies; Educational technology; Congenital syphilis; Newborn; Primary Health Care.

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VALIDAÇÃO DE PROGRAMA ELETRÔNICO PARA SEGUIMENTO DO RECÉM-NASCIDO COM SÍFILIS CONGÊNITA

RESUMO

Objetivo: validar o conteúdo e a aparência de um programa eletrônico para seguimento clínico do recém-nascido com sífilis congênita.

Método: estudo metodológico, de validação de aparência e conteúdo. Os dados foram coletados de junho a agosto de 2018 com instrumentos de avaliação para validação por sete especialistas médicos docentes de uma Instituição de Ensino Superior, com experiência em pediatria e/ou infectologia, com tempo de formação superior a 16 anos. Na análise dos dados, utilizou-se o Índice de Validade de Conteúdo com valor estabelecido de 0,78.

Resultados: quanto à estrutura e apresentação, objetivos e relevância, todos os itens foram considerados validados pelos especialistas. O Índice de Validade de Conteúdo global foi 0,97. *Conclusão:* o programa eletrônico foi validado quanto ao conteúdo e aparência, tendo como contribuição, aos enfermeiros e médicos da Atenção Básica, a produção de uma ferramenta de fácil utilização para o efetivo seguimento clínico ao recém-nascido com sífilis congênita.

DESCRIPTORIOS: Estudos de Validação; Tecnologia Educacional; Sífilis Congênita; Recém-nascido; Atenção Primária à Saúde.

VALIDACIÓN DE UN PROGRAMA ELECTRÓNICO PARA EL SEGUIMIENTO DE RECIÉN NACIDOS CON SÍFILIS CONGÉNITA

RESUMEN:

Objetivo: validar el contenido y la apariencia de un programa electrónico para el seguimiento clínico del recién nacido con sífilis congénita.

Método: Estudio metodológico, validación de apariencia y contenido. Los datos fueron recopilados de junio a agosto de 2018 con instrumentos de evaluación para su validación por parte de siete especialistas médicos del cuerpo docente de una institución de enseñanza superior, con experiencia en pediatría y/o infectología, con un período de formación de más de 16 años. Los datos se analizaron utilizando el Índice de Validez de Contenido con un valor establecido de 0,78.

Resultados: en lo que respecta a la estructura y presentación, los objetivos y la relevancia, todos los ítems fueron considerados validados por parte de los especialistas. El Índice de Validez de Contenido global fue de 0,97.

Conclusión: el programa electrónico fue validado en cuanto a su contenido y apariencia, en el cual contribuyeron enfermeros y médicos del área de Atención Básica y la producción de una herramienta de fácil utilización para un efectivo seguimiento clínico del recién nacido con sífilis congénita.

DESCRIPTORIOS: Estudios de validación; tecnología educativa; sífilis congénita; recién nacido; atención primaria de salud.

INTRODUCTION

Syphilis is a systemic infectious disease that can be prevented and when not treated early, can progress to serious complications and irreversible sequelae. Transmission can occur through sex, blood (blood transfusion) or mother-child (vertical transmission) ⁽¹⁾.

Of the diseases that can be acquired during the pregnancy-puerperal period, syphilis has the highest rates of transmission. Unlike many neonatal infections, this pathology is a preventable perinatal disease and can be controlled through diagnosis and effective treatment during pregnancy ⁽²⁻³⁾.

Congenital Syphilis (CS) is caused by transmission of the bacterium *Treponema pallidum*, via the placenta of untreated or improperly treated pregnant women to their infants at any time during pregnancy. The infection can cause serious consequences for the fetus, from neurological sequelae to fetal death ^(1,4).

In 2016, about 87,593 cases of acquired syphilis were reported in Brazil, of which 37,436 cases of syphilis were detected in pregnant women, with 20,474 cases in the state of Santa Catarina. The mortality rate from syphilis in Brazilian children under one year of age is 18.1 deaths/1,000 live births ⁽⁵⁾.

The incidence of congenital syphilis is an important indicator of the quality of maternal and child health care. The persistence of high rates of disease incidence and vertical transmission reveal flaws in the coverage and quality of prenatal care ⁽⁶⁻⁷⁾.

The main factors responsible for the high rates of congenital syphilis in Brazil include serology for syphilis not performed in the recommended periods; inadequate interpretation of serology; failure to recognize symptoms; lack of treatment of the sexual partner, and failure in communication between health professionals ⁽⁸⁾.

Thus, the Ministry of Health launched the "Plan for Elimination of Congenital Syphilis", in accordance with proposals to control the disease in the Americas formulated by the World Health Organization, and set this pathology as one of the priorities for compulsory notification, implementation of prevention and control actions for sexually transmitted infections ^(5,9).

Although diagnosis and treatment are easily accessible and inexpensive, it is necessary to implement guidelines and systematic screening through electronic tools that improve the quality of care to individuals with congenital syphilis ⁽¹⁰⁾.

Therefore, given the concern with the delivery of high quality care, to reduce the risks for the patients, a validated electronic tool containing the lines of care for the prevention and monitoring of care to newborns (NB) with congenital syphilis is necessary ^(11,12).

The scientific validation for the use of electronic tools in the management of prenatal care and monitoring of pregnant women is key to improve the care provided by health professionals in primary care services ⁽¹¹⁻¹²⁾.

Therefore, the present study aimed to validate the content and appearance of an electronic tool for the clinical monitoring of newborns with congenital syphilis, in order to enable its use by health professionals, to promote adequate monitoring of these patients in Primary Health Care.

METHOD

Methodological study with a descriptive approach, developed according to the steps

proposed by Escher: one step for the development of the tool and a second step for content validation through the evaluation of the instruments by judges/specialists⁽¹³⁾.

In the first step, the elaboration of the tool was based on a theoretical survey on the monitoring of neonates with congenital syphilis. Subsequently, information on the Care Line for Comprehensive Care to infants with syphilis and the protocol adopted by the Ministry of Health was also collected. Then, the electronic tool was elaborated and validation of content and appearance was performed, as well as the adaptation of the material by specialists^(5,13-15).

The electronic tool was named "Monitoring of newborns with congenital syphilis", and was targeted to primary care professionals, physicians and nurses. The tool is an electronic medical record with the flow of the protocol for the monitoring of newborns with congenital syphilis, which can effectively assist healthcare professionals during patient care.

The tool has a patient registration page, with clinical data regarding birth (date, gender, weight and height), diagnosis (symptomatic or asymptomatic congenital syphilis; with or without neurosyphilis), the treatment of congenital syphilis performed (benzathine or procaine or crystalline penicillin) and data regarding the results of the tests (Venereal Disease Research Laboratory (VDRL) test, lumbar puncture, blood count and X-rays of long bones) performed in the hospital.

In the second step, medical professionals with experience in diagnosis and treatment of the referred pathology were selected to collaborate in the validation of content of the tool. An odd number of medical professionals was used to avoid draws in opinions during the validation process. Thus, an intentional sampling method was used to select the medical professors attached to the Coordination of the medicine course at a University Center.

An advanced search was made for the selection of the experts, considering the following inclusion criteria: being a PhD holder, researcher or health professional; work in one of the following areas: primary care, infectious diseases and/or pediatrics, as recommended in the scoring system of specialists in validation studies; with a resume updated resume in the last 60 months; and who has published papers or articles on the subject in the last 5 years. Experts who worked in other areas, who were on vacation or on leave, and those who did not respond within the deadlines set by the study schedule were excluded.

Subsequently, the selected experts were contacted by email through a formal invitation explaining the study proposal. A date (and time) was scheduled for the specialists who accepted the invitation, for the evaluation in the process of validation of the electronic tool.

The sample of this study consisted of the seven experts who agreed to participate in the research. Data were collected from June to August 2018, through an instrument for the characterization of the experts, which included information on professional training and experience, in addition to an electronic protocol assessment instrument consisting of objective questions related to the information contained in the electronic tool regarding 'objectives', 'structure and presentation' and 'relevance', with space for additional comments and suggestions, adapted from a pre-existing questionnaire⁽¹⁶⁾, with the necessary adaptations to fit the theme addressed in the electronic tool evaluated in the present study.

A Likert-type scale with a score of 1 to 4 was used in the evaluation instrument, with the following correspondences: 1- Inadequate, 2 - Partially Adequate; 3 - Adequate, 4 - Totally Adequate. The items that received the scores "3" or "4" were considered valid and the items scored with "1" or "2" were eliminated or revised.

As recommended by the literature, a CVI equal to or greater than 0.78 is necessary for an acceptable level of agreement between the specialists. To calculate the CVI per item, the number of responses "3" or "4" was added and divided by the total number of

responses. The average CVI of each block (Objectives, Structure and Presentation, and Relevance) was calculated based on the arithmetic average of the CVI of each item⁽¹⁷⁾.

To obtain the global CVI of the electronic tool, the average CVI value of the items was calculated, through the sum of all CVIs calculated separately, divided by the number of items considered in the evaluation. The results were presented in tables according to the blocks⁽¹⁷⁾.

The present study was approved by the Research Ethics Committee under protocol no 2.628.947, on April 30, 2018⁽¹⁷⁾.

RESULTS

Four (57.1%) specialists and three (49.2%) masters participated in this study. All of them have teaching experience and work in the area of interest and in the area of interest and in health education. It was found that three (42.9%) specialists had published studies on the theme of congenital syphilis and two (28.6%) had previous experience with validation of educational materials, four (57.2%) provided guidelines in the area of interest (Table 1).

Table 1 - Characterization of the specialists according to age, time elapsed since graduation, degree (titles), scientific production and professional experience in the areas of interest. Teresina, PI, Brazil, 2018 (continues)

Variables	N	%
Age		
30 – 50 years	4	57.2
> 50 years	3	42.8
Time elapsed since graduation		
> 16 years	7	100
Titles		
Specialist	4	57.2
Master	3	42.8
Publications on related themes		
Congenital syphilis	3	42.8
Validation of educational technologies	2	28.6
Other themes	2	28.6
Teaching experience and clinical practice in the areas of interest		
Yes	7	100
Previous experience with validation of educational materials		
Yes	2	28.6
No	5	71.4
Experience in the health education area		
Yes	7	100
Mentoring of thesis/dissertation/end of course paper in the area of interest		

Yes	4	57.2
No	3	42.8
Thesis or Dissertation in the area of interest		
Yes	1	14.3
No	6	85.7

In the block "Objectives", the specialists evaluated the items related to consistency with professional needs and attitudes, promotion of changes in behavior and attitudes and possibility of circulation in the scientific community. Since the three items in this block obtained a CVI equal to 1.0, the average CVI was also equal to 1.0 (Table 2).

Table 2 – Content Validity Index (CVI) obtained for the items of the block "Objectives" of the electronic tool, according to the valuation of the specialists. Teresina, PI, Brazil, 2018

Objectives	Inadequate	Partially adequate	Adequate	Totally Adequate	CVI
Consistent with the needs of the physicians and the actions they should take in the monitoring of newborns with congenital syphilis	0	0	0	7	1.0
Promotes changes in behavior and attitudes	0	0	0	7	1.0
Can circulate in the scientific community of the area of monitoring of newborns with congenital syphilis	0	0	0	7	1.0
Average CVI					1.0

Table 3 shows the answers obtained by the specialists for each item in the second evaluation block, composed of 10 items, through which the specialists' opinion regarding the structure and presentation of the electronic tool was verified. Six items reached the maximum CVI (1.0) and four items obtained a CVI = 0.86, and the average CVI of this block was 0.94.

Table 3 – Content Validity Index (CVI) obtained for the items in the "Structure and Presentation" block of the electronic tool, according to the evaluation of the specialists. Teresina, PI, Brazil, 2018 (continues)

Structure and Presentation	Inadequate	Partially Adequate	Adequate	Totally Adequate	CVI
The electronic tool is appropriate for the care and guidance in the monitoring of newborns with congenital syphilis	0	0	1	6	1.0

The information presented is scientifically correct	0	0	7	1	1.0
There is a logical sequence in the proposed content	0	0	7	1	1.0
The instrument is appropriate to the social and cultural level of the proposed target audience	0	0	7	1	1.0
The information is well structured in agreement and spelling	0	0	7	1	1.0
The wording is suitable to the level of knowledge of the target audience	0	0	1	6	1.0
Information on the presentation of the tool is consistent	0	1	1	5	0.86
The illustrations are expressive and sufficient	0	1	0	6	0.86
The size (dimension of the tool) seems adequate	0	1	0	6	0.86
The title and topics shown are appropriate	0	1	0	6	0.86
Average CVI					0.94

Table 4 shows the answers obtained by the specialists and the CVI of each item in the third evaluation block, composed of four items related to the degree of significance (relevance) of the electronic tool. Of the four items evaluated, three obtained maximum CVI (1.0) and only one obtained CVI = 0.86. The average CVI of the block was 0.96.

Table 4 – Content Validity Index (CVI) obtained for the items of the block “Relevance” of the electronic tool, according to the evaluation of the specialists. Teresina, PI, Brazil, 2018

Relevance	Inadequate	Partially Adequate	Adequate	Totally Adequate	CVI
The themes depict the key aspects that must be reinforced	0	0	0	7	1.0
The tool proposes to primary care professionals the acquisition of knowledge that can assist in monitoring newborns with congenital syphilis	0	0	0	7	1.0
The tool addresses issues necessary to prevent and cope with congenital syphilis	0	1	1	5	0.86
The tool can be used by primary care professionals in health education activities	0	0	2	6	1.0
Average CVI					0.96

The global CVI of the electronic tool was 0.97, which confirmed the validation of appearance and content. The suggestions made by the specialists were carefully considered

and the programmer was told to make the necessary changes in figures and texts. Thus, the final validated version of the electronic tool was obtained.

Figure 1 shows the interfaces of the electronic tool: the registration of patients' personal data, recording of the results of the patients' exams for systematic monitoring and the basis for information on the clinical monitoring of newborns with congenital syphilis, according to the protocol of the Ministry of Health, data from subsequent consultations, graphs comparing and representing variations in the VDRL, weight, height and the clinical profile of patients assisted in the health unit.

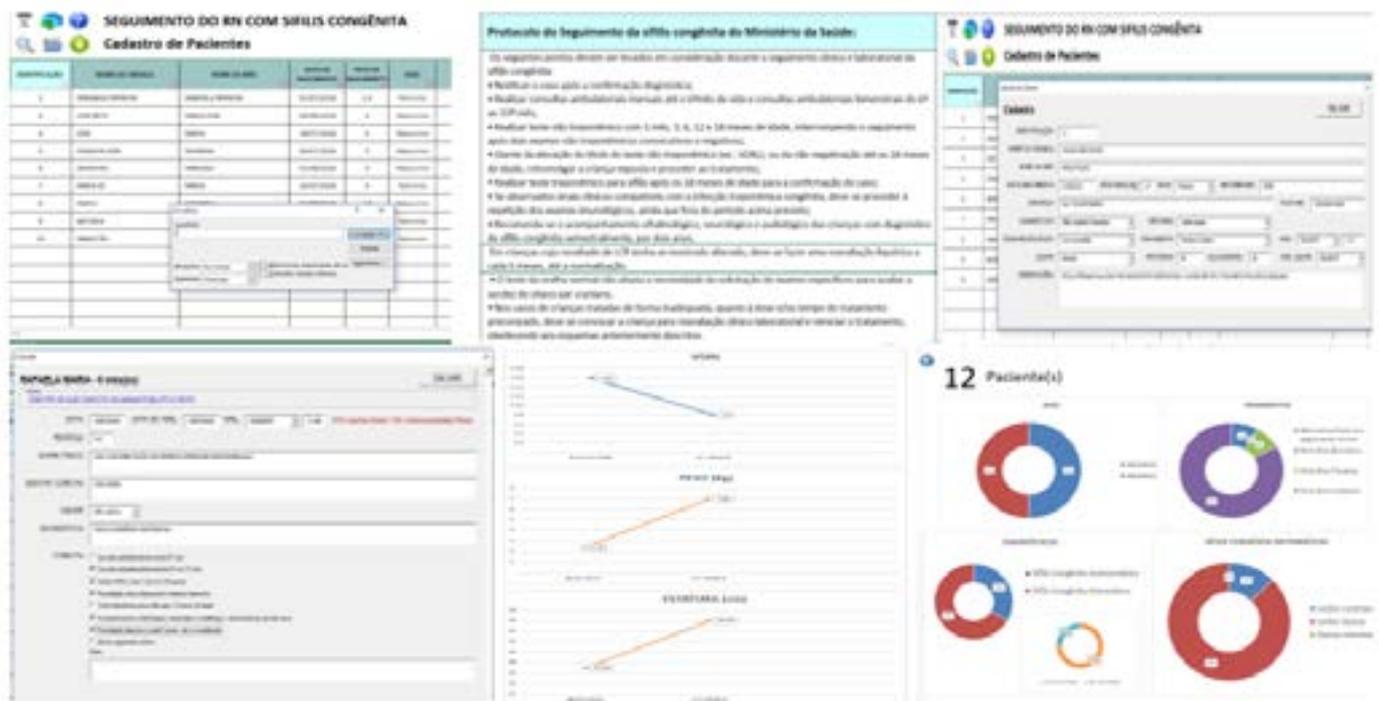


Figure 1 – Final version of the electronic tool for the monitoring of newborns with congenital syphilis and the clinical profile of patients assisted in the health unit. Teresina, PI, Brazil, 2018

DISCUSSION

In this study, the electronic tool “Monitoring of newborns with congenital syphilis” was validated by medical doctors who are specialists in infectious diseases or pediatrics, with experience in the area of validation of educational technologies and/or in congenital syphilis.

The maximum agreement rate was obtained for all items in the step Content Validity Index and experts' evaluation of the objectives to be achieved with the use of the electronic tool.

Regarding the step of structure and presentation of the electronic tool, in the search for consensus among the specialists four items rated partially adequate had to be reviewed. In order to ensure the consistency and cohesion of the tool, changes were made in the cover, back cover, acknowledgments and/or presentation, to allow a better understanding of the tool. Changes were also made in the illustrations to make them more expressive,

and the number of pages and the size of the title were reduced.

Therefore, during the validation of the degree of relevance of the electronic tool, changes were made in subjects necessary for the prevention and coping with congenital syphilis. The tool was considered understandable by the specialists. Still, they suggested that some information on the topic should be included.

This technology is innovative, since although the topic congenital syphilis and preventive aspects in primary care is discussed in the scientific literature, few validated technologies on the theme, particularly those targeted for nurses and health professionals in primary care, were found.

It should be noted that congenital syphilis is a major public health problem that requires health professionals capable to monitor these patients throughout the entire follow-up period⁽¹⁸⁾. The validation of electronic tools is considered relevant for health planning, considering that it may point to the need to introduce care and preventive measures⁽¹⁹⁻²⁰⁾.

Irregularities are frequent in the monitoring of congenital syphilis, particularly in the records. Also, absence of test results and lack of information in the medical records occur, revealing the lack of qualification and infrastructure faced by health professionals in care services⁽²¹⁻²²⁾.

The validation of an electronic tool for the clinical monitoring of newborns with syphilis can contribute to the qualification of the records, at all levels of care, making us capable of recognizing risk situations and providing care for the survival of neonates with syphilis⁽²³⁻²⁴⁾.

In view of the growing statistics of congenital syphilis in Brazil, the insecurity of health professionals regarding the systematization of outpatient monitoring of the pathology and the possibility of the onset of the disease in children, it is necessary to standardize the monitoring of this disease⁽²⁵⁾.

This tool is advantageous for nurses and health professionals, since it includes the following dimensions: initial clinical management, therapeutic follow-up, parameters of health services and knowledge of the disease, as well as data that enable statistics for planning preventive actions. Compared to the electronic medical record, this electronic tool has the advantage of being a low-cost mobile technology with potential for geographic coverage.

With the assistance of an electronic tool, health professionals can have easy access to a computerized protocol for monitoring patients, which makes it possible to send semiannual reports to the Health Department⁽²⁶⁾.

Moreover, other electronic tools, such as mobile applications, can notify treatment adherence through the attendance of mothers/children to previously scheduled appointments, carrying out complementary tests, evaluations of other specialties and complementary treatment with other health professionals, such as physiotherapists and speech therapists⁽²⁷⁾.

Thus, the development of this electronic tool also allows the monitoring of clinical parameters for the understanding of the dimensions of treatment and easy handling of these patients, as it will allow the detection of compliance with the requirements of self-care in postpartum and childcare.

The participation of specialists in the process of validation of educational technology promoted improvements in the tool until the final version was obtained, which made it valid in appearance and content in the scientific community. Assessment by specialists involves a network of health professionals with proficiency and competence in a specific area of relevant knowledge⁽²⁸⁾.

During the validation process, changes that contemplated the particularities of the

target population of the electronic tool were implemented, to ensure full understanding of the final version of the tool, so that it could be easily used by primary care health professionals.

A possible limitation of this study is the predominance of medical specialists from the Northeast of Brazil, which may suggest a tendency to local and regional habits. Thus, future studies evaluating the electronic tool by health professionals from other Brazilian regions should be conducted.

Also, it should be noted that despite the increase in the number of studies related to the validation of educational technologies in health, there are still scarce publications on the validation of technologies that make it possible to assist health professionals in monitoring, treatment and health education actions, mainly in the area of this study, for a better support of the analyzes of this research⁽²⁹⁻³⁰⁾.

It is suggested that future studies on the validation of the electronic tool by the target audience are carried out to improve this technology developed and validated by the specialists. After the validation, a link or a QR Code can be made available to professionals so that they can access the tool.

CONCLUSION

The electronic tool proposed was validated for content and appearance by specialists with experience in Primary Care and/or congenital syphilis, with a global CVI of 0.97. As a result, nurses and doctors in primary care were offered an easy-to-use tool for effective clinical monitoring of newborns with congenital syphilis.

In the process of adaptation of the electronic tool, the suggestions made by the specialists were key to ensure greater scientific rigor and easier use of the tool, to promote an adequate systematization of the clinical monitoring of the disease by health professionals.

Developing and validating this electronic tool contributes to improve clinical and scientific practice, as it represents an innovation for practical decision-making in the monitoring of newborns with congenital syphilis, in addition to contributing to the achievement of better results in the care of this population.

Thus, the results obtained in this study may trigger a reflection on the need to extend the validated tool to prenatal care and delivery, as well as to postnatal follow-up, in order to include all stages of a child's life.

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