

EVALUATION OF LEPROSY CONTROL ACTIONS DEVELOPED IN PRIMARY CARE: A PROPOSED TOOL FOR MANAGERS

AVALIAÇÃO DAS AÇÕES DE HANSENÍASE DESENVOLVIDAS NA ATENÇÃO PRIMÁRIA: PROPOSTA DE UM INSTRUMENTO PARA GESTORES

EVALUACIÓN DE LAS ACCIONES DE LEPROA LLEVADAS A CABO EN LA ATENCIÓN PRIMARIA: HERRAMIENTA PROPUESTA PARA ADMINISTRADORES

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ABSTRACT

This is methodology development study. Its aim was to develop and validate an instrument to assess the performance of primary care services in leprosy control actions, according to managers' perspective. We hope that this instrument will become a support tool for municipalities in the self-assessment stage of the National Program for Improving Primary Care Access and Quality. The first version of the instrument, which was developed through literature review, consisted of 172 items. Face and content validity assessment by 15 experts resulted in the exclusion of 34 items. The administration of the instrument pre-test to 31 managers of the municipality of Betim was essential for the reduction of 50 items. The final instrument has 88 items, as well as face and content validity. Further studies should be conducted to test the psychometric properties of the instrument.

Keywords: Leprosy; Primary Health Care; Health Services Evaluation; Questionnaires.

RESUMO

Trata-se de um estudo de desenvolvimento metodológico que teve como objetivo elaborar e realizar a validação aparente e de conteúdo de um instrumento de avaliação do desempenho da atenção primária nas ações de controle da hanseníase na perspectiva dos gestores, visando ser uma ferramenta de apoio para os municípios brasileiros na etapa de autoavaliação do Programa Nacional de Melhoria do Acesso e da Qualidade da Atenção Básica. A primeira versão do instrumento, elaborado por meio de revisão da literatura, apresentava 172 itens. O exame de face e de conteúdo por 15 especialistas resultou na exclusão de 34 itens. A realização do pré-teste do instrumento com 31 gestores do município de Betim foi fundamental para a redução de 50 itens. O instrumento final tem 88 itens e validade de face e de conteúdo. Sugere-se a realização de novos estudos para o teste das propriedades psicométricas do instrumento.

Palavras-chave: Hanseníase; Atenção Primária à Saúde; Avaliação de Serviços de Saúde; Questionários.

RESUMEN

Estudio de desarrollo metodológico efectuado con el objetivo de construir y realizar la validación de la apariencia y contenido de una herramienta para evaluar el desempeño de la atención primaria en las acciones de control de la lepra desde la perspectiva de los administradores de salud. Dicha herramienta se utilizaría como herramienta de apoyo a los municipios en la etapa de auto-evaluación del Programa Nacional de Mejoramiento del Acceso y Calidad de la Atención Primaria. La primera versión de la herramienta desarrollada a través de la revisión de la literatura, presentó 172 elementos. El examen de la apariencia y de contenido por 15 expertos dio lugar a la exclusión de 34 artículos. La finalización de la prueba preliminar de la herramienta con 31 gerentes del municipio de Betim fue esencial para la reducción de 50 artículos. La herramienta final tiene 88 artículos y validez aparente y de contenido. Se sugiere llevar a cabo más estudios para probar las propiedades psicométricas de dicha herramienta.

Palabras clave: Lepra; Atención Primaria de Salud; Evaluación de Servicios de Salud; Cuestionarios.

INTRODUCTION

Leprosy is a strategic area of performance of primary care in Brazil. This is because although there is a downward trend in the absolute number of new cases diagnosed, it still remains an important public health problem in the country. In 2012, 33,303 new cases of leprosy were diagnosed. 63% had multibacillary clinical forms and 6.7% had grade 2 disability, which suggests late diagnosis.¹ The World Health Organization emphasizes that early diagnosis, treatment with multi-drug therapy and integration of control actions in primary health care (PHC) remain the key strategies for reducing the burden of the disease worldwide.²

The Ministry of Health (MH), with the creation of the Community Health Teams (1991) and the Family Health Strategy (1994), advocates for the diagnosis and treatment of leprosy, the prevention of physical disabilities and the surveillance of contacts in PHC. Ordinances 3125 and 594, published in 2010, reaffirm the desired role of PHC in disease control, with the support of secondary and tertiary care, to reduce endemic disease and ensure quality of care.^{3,4}

Ensuring quality of care is currently one of the main challenges faced by the Unified Health System (SUS). The National Program for Improving Primary Care Access and Quality (PMAQ) was launched in 2011 with the aim of expanding access to and qualified provision of health care services in the context of Unified Health System's PHC. The PMAQ has four phases, namely: self-assessment, monitoring, external evaluation and re-contractualization. These phases complement one another and assess practices considered strategic in PHC (including leprosy), and potential change-inducing actions in the everyday of services.⁵ In the self-assessment phase, PHC teams identify strengths and weaknesses in the development of surveillance, diagnosis, treatment and monitoring actions for existing leprosy cases in the territory, in order to plan interventions.⁵

In the second phase of PMAQ, after the implementation of the solutions listed in the self-assessment phase, the PHC team will be evaluated through the monitoring indicator "mean number of leprosy cases cared for", which is calculated by dividing the number of consultations with a doctor or nurse gone through by leprosy patients in a given place and time by the number of persons with leprosy registered in the same place and at the same time. However, the PMAQ manual makes the caveat that this indicator "does not allow the assessment of the actual coverage or access of leprosy patients. It only allows the assessment of the adequacy of the volume of cases seen to the potential needs of the population registered by the team".^{6,67}

Considering that leprosy is still a challenge to public health in Brazil, due to the high rates of detection, the parameters set by the PMAQ are not sensitive to identify the real problems of

PHC in developing leprosy control actions (LCA). Thus, it becomes necessary to develop an assessment tool that is based on PHC attributes (gateway, access, comprehensiveness, longitudinality, coordination, person- and family-focus, appreciation of cultural aspects and community counseling) and on leprosy control actions recommended by the MH to be performed in PHC. This tool should help to managers in making decisions to improve the quality of care provided to users of primary care.

Thus, the aim of this study was to develop and validate an instrument to assess the performance of primary care services in leprosy control actions according to managers' perspective. We hope that this instrument will become a support tool for municipalities in the self-assessment stage of the PMAQ.

METHODS

This is methodology development study to create and validate the face and content of the "Instrument for the evaluation of performance of primary care services in leprosy control actions – managers' version".

The instrument design was based on the theoretical framework of PHC in Brazil⁷ and on leprosy control actions performed at this health care level.^{3,4} As there is a validated instrument to assess the extent of the essential and derivative attributes of PHC⁸, we decided to analyze Ministry of Health ordinances for the care of leprosy patients, according to the attributes present in the Primary Care Assessment Tool (PCAT). The "professional orientation" attribute is not included in the American^{9,10} and Brazilian⁸ versions of the PCAT. However, a study recommended its insertion in the Brazilian context, since trainings for primary health care professionals are continuously offered by the Unified Health System.¹¹ We used the Likert scale and the same answer options of the PCAT to create the answer sheet of the "Instrument for the evaluation of performance of primary care services in leprosy control actions - managers' version".⁸: one (surely not); two (probably not); three (probably yes); four (definitely yes); nine (do not know/cannot remember).

The first proposed version of the instrument consisted of 172 items divided into eight constructs (gateway, access, continued care, comprehensiveness of the available and provided services, coordination, family counseling, community and professional counseling) and was presented to a panel of experts for validation of face and content. Face validation is the qualitative evaluation of items in terms of their clarity and understanding.¹² Content validation analyzes the relevance of the proposed items and their ability to adequately grasp the assessed concept^{13,14}, i.e., it determines the degree to which an instrument reflects a specific domain of content of what is being measured.¹² During the process of content evaluation, experts

were also asked to make suggestions for the inclusion of new items into the questionnaire, if they felt that the available questions did not portray the fundamental aspects of care delivery to leprosy patients in PHC.

The following criteria were used for the selection of experts: a minimum one year experience in management, leprosy education or leprosy care, or conduction of studies on leprosy or and/or primary health care. For the selection of the judges who conduct research on leprosy and primary health care, we searched the Lattes Platform directory of researchers. In total, 15 experts participated in this stage, which was conducted in person and remotely from March through April 2012. Five experts took part in the first panel and the remaining in the second panel. The experts' team was composed of five nurses, nine physicians and one biologist. 53.3% (n = 8) had PhD and 13.3% (n = 2) had MSc degrees.

In the first panel, experts were requested to answer the following question: "is the content measured by this question essential/useful/not essential to assess the organizational and performance characteristics of primary health care services in the care of leprosy?" In order for an item to be (considered) valid and maintained, more than 80% of experts had to have answered it affirmatively.¹⁵ The purpose of the second round was to evaluate not only the content of the question, but rather whether it was related to its respective primary health care attribute. In this second panel, we decided to carry out a qualitative assessment of each trial of the questionnaire items.

The instrument validated by the experts panel was subjected to a preliminary adjustments test from June through July 2012 in Betim, Minas Gerais. 31 managers participated in the pretest. All participants were duly informed about the purpose of their participation in this stage of the research: to assess the suitability of the instrument and answer sheet, as well as the time required for its administration. Thus, all participants answered the questionnaire questions based on their own realities. In addition, they were requested to make suggestions to improve the understanding of the items. Data were collected through interviews performed at the participants' workplace by three nurses who were members of the research group.

Pre-test results were discussed in a focus group session led by the main investigator of this study. During this session, six members of the research team conducted a qualitative assessment of the instrument items: whether they actually reflected the concepts involved; whether they were relevant; whether they were understandable; and whether they were adequate to achieve the proposed objectives.

Although the final version of the instrument was administered in the municipalities of Almenara, Teófilo Ottoni and Governador Valadares from July through December 2012, it was not possible to validate construct validity and reliability

due to the inadequacy of the sample size: only 14 managers. The analysis of the psychometric properties of the instrument will be performed in four municipalities in the metropolitan region of Belo Horizonte - including the state capital. The presence of managers in each PHC unit of these municipalities is guaranteed.

The study was approved by the Research Ethics Committee (COEP) of the Federal University of Minas Gerais, under Opinion n ° ETIC 0095.0.203.000-11 All participants - experts and managers from Betim, Almenara, Teófilo Ottoni and Governador Valadares - signed two copies of the Informed Consent Form. This study was funded with grants from the Research Support Foundation of Minas Gerais (FAPEMIG), Edict 01/2011 - Universal Demand, process number CDS-APQ-01438-11.

RESULTS AND DISCUSSION

This study, which is part of a larger project still in progress, presents the preliminary results of the validation of the "Instrument for the evaluation of performance of primary care services in leprosy control actions - managers' version".

The instrument consists of 172 items and was designed from a literature review, which is the first step in the validation procedure of assessment instruments. During this review, the domains derived from the literature are defined in detail.¹³ Since the tool presented here was created for assessing the performance of PHC services in leprosy control, we used the definitions of PHC and LCAs proposed by the Ministry of Health, as well as a validated instrument that served as a reference for designing the constructs of this study. Some authors suggest that, when designing questionnaires, researchers should take into account pre-existing instruments and check what items are included in assessment instruments with similar constructs.¹⁴ Since there are no questionnaires to assess the performance of PHC services in the prevention and control of leprosy, and the PCAT is based on the operational definition of PHC - essential and derivative attributes - adopted by the Ministry of Health, using the theoretical framework of the PCAT for the elaboration of the construct and some items of the instrument was valid, as well as the choice to use the same scale of responses, the five-point Likert scale ranging.

Content and face validity of the instrument items was assessed by a panel of 15 experts: 10 experts in leprosy and five experts in PHC. There is controversy in the literature as to the appropriate number of judges necessary to perform content and face validity. However, the researchers who developed the PCAT-Child edition⁹ and -Adult edition¹⁰ used nine experts.

In the first round of evaluation of the "Instrument for the evaluation of performance of primary care services in leprosy control actions" only seven items obtained less than

80% agreement of positive responses (essential and useful). In addition, participants suggested the inclusion of five items and the performance of semantic change in 17 items to improve clarity and understanding of the questions (results not shown). According to experts who participated in the first round, the purpose of the proposed instrument was reached. However, maintaining all 170 items in the instrument would render data collection unfeasible.

Faced with a result that brought little contribution to the reduction of items, and which can be justified by the exclusive participation of leprosy experts in the first panel, we decided to conduct a second panel, featuring the participation of five PHC experts. The relevance and suitability assessment of the proposed items resulted in the exclusion of 32 items and in changes in the construct of 25 items. Four items were moved to form the block of open questions entitled "Information on the organization of PHC and leprosy care in the municipality" (results not shown).

Content validity "refers to the analysis of the instrument, whether it really covers all aspects of its object and does not contain elements that can be assigned to other objects. It is not determined statistically [...], but results from the judgement of different examiners and experts, who analyze the representativeness of the items in relation to the content areas and the relevance of the objectives that are supposed to be measured"^{16,87} After the first and second expert panels had been carried out, the instrument version administered in the pre-test consisted of 134 items. 31 managers participated in the pretest. A description of the sample is presented in Table 1.

Table 1 - Description of the pre-test sample. Pre-test conducted in the municipality of Betim

Variables	n	Percentage (%)
Area of performance:		
PHC Coordination/Leprosy Technical Area	2	6.4
Manager of the PHC unit	29	93.6
Training in LCA:		
Yes	17	54.8
No	14	45.2
Leprosy case in the health care unit:		
Yes	20	64.5
No	11	35.5

As Brazilian municipalities still face difficulties in the implementation of LCAs in PHC, both at the individual level - due to the absence of professionals trained to perform the diagnosis and treatment of leprosy - and at the collective level - through the performance of isolated/punctual actions for community education, search of contacts and epidemiological surveillance¹⁷ -, using this leprosy-specific tool, even though the validation process is still incomplete, will help managers in the assessment of leprosy care delivery both in endemic municipalities and in those municipalities that need to maintain control actions, given that leprosy is considered a public health problem in Brazil.

We will use the same methodology validated for the Brazilian PCAT to calculate the scores of this instrument.⁸ After data input, the values of items C3, C4, C5 and F4 should be inverted. These items the higher the value assigned in the answer, the lower the orientation to PHC. Thus, these items should have their values inverted as follow: (value 4=1), (value 3=2), (value 2=3) and (value 1=4).

The calculation of scores for each attribute of PHC will be performed based on the mean answer values of the items in each attribute. The essential score of PHC in leprosy control will be measured by the sum of the mean score of the components that belong to the essential attributes - gateway, access, continued care, comprehensiveness of services available and provided - divided by the number of components. The derivative score of PHC will be measured by the sum of the mean score of the components that belong to the derivative attributes - family counseling, community and professional counseling - divided by the number of components. The overall score will be measured by the sum of the mean score of the components that belong to the essential attributes (added to the derivative attributes and divided by the total number of components). The overall score represents the overall performance of PHC in leprosy control. In order to evaluate the score results, we followed the same standardization of the PCAT, which determines: scores equal to or above 6.6 indicate high service orientation in the performance of LCAs in PHC; scores below 6.6 indicate that weaknesses in the performance of LCAs in PHC.

Table 2 - Items of the final version of the "Instrument for the evaluation of performance of primary care services in leprosy control actions – managers' version"

PHC Attributes and items of the instrument
Information on the organization of PHC and leprosy care in the municipality (open questions)
A1. What health services do users seek when presenting signs and symptoms of leprosy?
A2. What health services can make the diagnosis of leprosy?
A3. What health services are responsible for monitoring leprosy cases?
A4. When leprosy patients present any health problems related to leprosy (eg., neuritis, drug reactions, leprosy reactions), in which health services are they seen or to which are they referred?
Gateway
B1. Is the PHC unit the first health service that users seek when presenting signs and symptoms of leprosy?
B2. Do leprosy patients seek the PHC unit to perform family contacts examination or to receive counseling on prevention of disabilities?
B3. Do leprosy patients seek PHC unit when they need an appointment due to the appearance of new disease-related health problem (such as neuritis, drug reactions or leprosy reactions)?
B4. Do leprosy patients always have go through a consultation at the PHC unit before they are referred to a leprosy specialist?
Access
C1. Are PHC units open after 6 pm at least one day during the week?
C2. During the operation hours of the PHC unit, is there a phone number to call for information?
C3. Do users have difficulties reaching the PHC unit in their territory?
C4. Do users have to use motorized transport to reach the PHC unit in their territory?
C5. Do users have to skip work or cancel important appointments in order to be seen in the PHC unit in their territory?
C6. When users seek the PHC with reported signs and symptoms of leprosy, do they get a consultation appointment with a health professional (doctor or nurse) within 24 hours?
C7. When the PHC unit is closed, is there another network service (eg., emergency care) that the patient can seek in case of leprosy-related health problems?
C8. When leprosy patients present neuritis, drug reactions or leprosy reactions, do they receive care within 24 hours?
Continued care
D1. Are leprosy patients always seen by the same PHC team?
D2. Are leprosy patients always seen by the same PHC physician?
D3. Are leprosy patients always seen by the same PHC nurse?
D4. If patients with leprosy have any questions about the disease or questions about treatment, are they able to speak to the same PHC professional who usually cares for them?
Comprehensiveness of services available
Are the following services available at the PHC units?
E1. Vaccines
E2. Child care
E3. Adolescent care
E4. Adult care
E5. Elderly care
E6. Family planning or contraception
E7. Prenatal care
E8. Screening test for cancer of the cervix
E9. Care of sexually transmitted diseases, including counseling and HIV testing request
E10. Care of endemic diseases (dengue, tuberculosis, schistosomiasis)
E11. Care of chronic diseases (hypertension, diabetes, asthma)
E12. Care of mental health problems
E13. Dressings

Continues...

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Table 2 - Items of the final version of the "Instrument for the evaluation of performance of primary care services in leprosy control actions – managers' version"

PHC Attributes and items of the instrument
Comprehensiveness of services available Are the following services available at the PHC units?
E14. Counseling or treatment for harmful use of tobacco
E15. Advice on healthy eating
E16. Evaluation of oral health and dental treatment
E17. Home care
Comprehensiveness of services provided With regard to leprosy, are PHC units prepared to offer the following actions?
E18. Raising a suspicion of leprosy
E19. Making the diagnosis of leprosy
E20. Monitoring leprosy cases
E21. Evaluation of household contacts
E22. Monitoring treatment of leprosy reactions
E23. Follow up after discharge due to cure
Coordination
F1. Is there a care protocol or flowchart for leprosy cases in the municipality?
F2. Do health professionals follow this protocol/flowchart when caring for leprosy patients?
F3. Do health professionals monthly fill in the Case Monitoring Bulletin for Epidemiological Surveillance?
F4. During the last six months, have there been any episodes of lack of leprosy medicines (MDT) in the municipal health services?
F5. Does the municipality prepare the Annual Work Plan for leprosy?
F6. Do you use the guidelines of Ordinance 3125 of the Ministry of Health to plan leprosy control actions?
F7. Are the guidelines of Ordinance 594 of the Ministry of Health (defining Comprehensive Leprosy Care in the three levels of health care delivery) used to define the performance of PHC units in leprosy control?
F8. Do you know if a leprosy pact was made with the Comissão Intergestora Bipartite (Inter-manager Bipartite Commission)?
F9. Can PHC units rely on the cooperation of a leprosy municipal supervision team to perform leprosy control actions?
F10. Do the leprosy municipal supervision team and PHC professionals hold regular meetings to discuss cases of leprosy?
F11. When the leprosy patient has any leprosy-related health problems (eg neuritis, drug reactions, leprosy reactions), can he/she be seen by a specialist?
On the referral of patients with leprosy to a specialist or specialized service, please answer:
F12. When scheduling an appointment with a specialist, does the leprosy patient receive any written proof of this appointment?
F13. Is the referral of patients with leprosy to a specialist accompanied by a form containing all the necessary information?
F14. Is the counter-referral of leprosy patients accompanied by form containing information on the care provided and guidance for his/her follow-up in the service of origin?
F15. Do you worry about the quality of care provided to the patient in specialized services?
Which specialized services are available in the municipality? Answer YES or NO
F16. Shoes and insoles confection
F17. Psychology
F18. Physical Therapy
F19. Occupational Therapy
F20. Social service
F21. Neurology
F22. Ophthalmology
F23. Orthopedics
F24. Outpatient referral center for leprosy

Continues...

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Table 2 - Items of the final version of the "Instrument for the evaluation of performance of primary care services in leprosy control actions – managers' version"

PHC Attributes and items of the instrument
Family counseling
G1. Are PHC professionals instructed to meet with family members of the leprosy patient?
G2. Are PHC professionals instructed to talk to family members of the leprosy patient?
G3. Are PHC professionals counsel the leprosy patient and his/her family members regarding the examination of household contacts?
Community counseling
H1. Do you know the epidemiological situation of leprosy in the municipality/health unit?
H2. Is leprosy a major health problem in the municipality/ area covered by this health unit?
H3. Do you analyze epidemiological data in order to plan leprosy control activities in the municipality/health unit?
H4. Do you monitor the Pacto pela Vida (Covenant for Life) and Programming of Health Surveillance Actions (PAVS) leprosy indicators?
H5. Is leprosy discussed in the Municipal Health Plan?
H6. Is leprosy discussed in the Municipal Health Council?
H7. Does the municipality promote the mobilization of community leaders to act in leprosy control?
H8. Does the municipality disseminate information on leprosy to the population (eg, radio, newspapers and others)?
H9. Do the PHC units perform educational activities to inform the community about leprosy?
H10. Do the PHC units establish partnerships with schools and churches to develop actions for the disclosure of information on leprosy?
H11. Do the PHC units conduct activities in the community to identify people who have blemishes or areas of skin with loss or lack of sensitivity?
H12. Does the municipality invest its own resources for leprosy control?
Professional counseling
I1. Do you consider yourself qualified to monitor leprosy control actions?
I2. Do you consider that the physicians in the PHC units are qualified to work with leprosy?
I3. Do you consider that the nurses in the PHC units are qualified to work with leprosy?
I4. Do you consider that the nursing technicians/assistants in the PHC units are qualified to work with leprosy?
I5. Do you consider that the community health workers in the PHC units are qualified to work with leprosy?
I6. Is there a regular system of continuing education on leprosy for PHC professionals?

CONCLUSION

The instrument had face and content validity in accordance with the proposed objective - to evaluate the performance of PHC services in leprosy control actions. The authors plan the administration of the instrument in the metropolitan region of Belo Horizonte in order to examine construct validity and reliability of the questionnaire.

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