Vitamin A Supplementation Program in Brazil: evaluability assessment*

Wanessa Debôrtoli de Miranda,1 Eliete Albano Azevedo Guimarães,2 Daniela Souzalima Campos,3 Lais Santos Antero,3 Nathália Ribeiro Mota Beltão,3 and Zélia Maria Profeta da Luz1

ABSTRACT

Objective. To describe the steps of the Brazilian Vitamin A Supplementation Program (PNSVA) evaluability assessment.

Method. The present qualitative study employed the seven-element system proposed by Thurston and Ramaliu. The study involved document analysis, conceptual review of PNSVA, and meetings with technical experts to assemble a timeline and the Program’s theoretical and logical frameworks. The logical framework supported the elaboration of two questionnaires to be used for PNSVA evaluation. The questionnaires were validated using the Delphi method.

Results. The analysis revealed the evolution of vitamin A control and prevention strategies in the country, and provided information on the functioning of PNSVA and on its external context. The logical framework was found to be an invaluable tool for detecting specific priority areas for future assessments. The validation of the questionnaires indicated that they did in fact cover topics that are necessary to evaluate the implementation of PNSVA in municipalities. The Delphi step was essential to guide adjustments regarding question content and format, which served to increase the analytic power of the instruments.

Conclusion. The evaluability assessment indicated that future PNSVA evaluations will be possible. It is expected that the present results may be useful in countries developing similar initiatives as the one described in Brazil.

Keywords Health evaluation; vitamin A deficiency; vitamin A; health policy; Brazil.

Vitamin A deficiency (VAD) is one of the world’s most prevalent nutritional deficiencies, affecting a significant portion of children in the developing countries, mainly in the under-5 age group (1). A downward trend has been observed in global VAD prevalence, with substantial reductions reported in the period 1991-2013 in East and Southeast Asia and Oceania, where prevalence fell from 42% to 6%, and in Latin America and the Caribbean, where it fell from 21% to 11%.

Notwithstanding, VAD still is considered a serious public health problem in several Latin American countries, among them Mexico, Jamaica, Haiti, and Colombia, (2). The rates in sub-Saharan Africa and South Asia remained high and virtually unchanged during the same period, at 48% and 44%, respectively (3). In regions where VAD prevalence has decreased, the phenomenon is often attributed to government action, especially the mass administration of high doses of vitamin A over the past 20 years (4). Studies in Brazil have found that 10%–20% prevalence of serum retinol

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1 FIOCRUZ Minas, Instituto René Rachou, Belo Horizonte (MG), Brazil. Send correspondence to Wanessa Debôrtoli de Miranda, wanessa.debor-toli@hotmail.com

2 Universidade Federal de São João Del Rei (UFSJ), Faculdade de Enfermagem, São João Del Rei (MG), Brazil.

3 Secretaria de Estado de Saúde de Minas Gerais (SES-MG), Belo Horizonte (MG), Brazil.
levels below 0.70 μmol/L (a marker for vitamin A deficiency) is a moderate to serious public health problem (5–7). Since 1983, the Ministry of Health has been implementing a strategy for mass administration of megadoses of vitamin A to children aged 6-59 months for the prevention and control of VAD. Over the years, VAD control measures have been expanded and intensified under the National Vitamin A Supplementation Program (known as PNSVA, its Portuguese acronym) (8), structured in a similar manner throughout the country’s federative units.

The evidence of VAD in the country and the government’s efforts to prevent this deficiency demonstrate the need and importance of evaluating the implementation of PNSVA. Routine evaluation at all levels of the health system—including evaluation of the population’s health situation, the health services, and the outcomes of the actions taken—is one of the tools supporting the consolidation of the Unified Health System (SUS) (9, 10).

The evaluability assessment—that is, the stage prior to the evaluation itself—is an important strategy, since it provides an in-depth understanding of the intervention and allows preplanning of the form and focus of subsequent evaluations. One of the objectives of the evaluability assessment is, in fact, to identify the critical areas to prioritize in the evaluation (11).

The purpose of this study was to describe the stages of the PNSVA evaluability assessment, since the program had not yet been evaluated. The evaluability assessment included an exploration of the history of VAD control and prevention measures in the country, the internal and external context of the program, and the modeling and even the planning and verification of the possibility of evaluating its implementation in municipalities in the state of Minas Gerais. It is hoped that the results of this assessment can be used to support research on prevention and control activities in regions where VAD is still a major public health problem.

MATERIALS AND METHODS

An evaluability assessment was conducted using a qualitative approach based on the seven-elements system of Thurston and Ramaliu (11), which consists of: a) a description of the program, identifying the goals, objectives, and activities that constitute it; b) identification and review of the documents available in the program; c) modeling of available resources, expected activities, expected impacts, and presumed causal connections (Logical Model of the Program); d) supervising the program, or obtaining a preliminary understanding of how it operates; e) development of a Theoretical Model of Evaluation (TMA); f) identification of evaluation users and other key stakeholders; and g) agreement on the procedure for the evaluability assessment.

For the description of PNSVA, the technical documents and legal framework available on government websites for the period 1988 (the year the SUS was created) to 2016 were analyzed in conjunction with a review of the scientific literature. Concomitantly, four visits were made to the Minas Gerais Ministry of Health (SES/MG) to learn how the program was implemented in the municipalities and identify stakeholders who could contribute to and assist with the evaluation. These procedures supported systematization of the available knowledge for the period in question to aid in the construction of the PNSVA theoretical and logical models and obtain an agreement on the procedure for the evaluability assessment.

The PNSVA model, which is based on the logical model (12) and summarizes the program’s main components through a figure depicting how the system is supposed to work, guarantees the identification of the components and presumed causal relationships, permitting the construction of evaluative questions to study the program in the municipalities of Minas Gerais. The model consisted of: components based on the specific objectives of PNSVA; subcomponents, or the activities in each component necessary for achieving the desired impact; 3) the structure, or physical, organizational, or symbolic resources necessary for operationalizing PNSVA; 4) activities, of the means used in each subcomponent to obtain specific results; 5) outcomes; and 6) the impact of PNSVA.

To identify relevant indicators for evaluating the program, evaluative questions were constructed using the logical model. Questions on the structure, activities, and results of all the subcomponents were selected and classified according to the relevance criteria: priority, utility, capacity to generate important information, and viability.

Considering the need for municipal PNSVA stakeholders to answer the questions, two questionnaires were constructed: one on program management (to be completed by a PNSVA technical health advisor in the municipality), containing 43 questions, and the other on care (to be completed by primary health care professionals), with 49 questions.

The Delphi technique was used to validate questionnaire content (13). Twenty-two individuals were invited to participate in the panel of judges, including doctors, nutritionists and program representatives from the Ministry of Health, the SES/MG, the regional health offices, and municipalities in Minas Gerais.

Using the LimeSurvey software, each of the judges was asked to evaluate each question in the questionnaires in terms of relevance, need, and clarity of wording, classifying the question according to the following scale of opinions: C: Strongly agree; C: Agree; NN: Neither disagree nor agree; D: Disagree; DP: Strongly disagree. Panelists could also suggest new criteria or changes in those presented.

The degree of concordance among the responses was calculated using the percentage of questions classified as CP and C. The cut-off point for consensus was any value above 70% (13).

The PNSVA evaluation project in the state of Minas Gerais was approved by the Research Ethics Committee of Instituto René Rachou, FIOCRUZ Minas (CAAE: 57957316.6.0000.5091).

Participants were asked to sign a voluntary informed consent form, with anonymity guaranteed by personal identification codes.

RESULTS

Based on the analysis of a) the description of the program, identifying its goals, objectives, and activities, and b) identification and review of the available documents, we verified that the expansion of VAD control measures occurred with the creation of the National VAD Control Program by the Ministry of Health in 1994 (14). In 2001, vitamin A supplementation was expanded to recent mothers, and in 2005, PNSVA was introduced, intensifying VAD control measures and culminating in the program's expansion
to the rest of the country in 2012. It should be noted that in July 2016, VAD supplementation for recent mothers was suspended nationwide after extensive discussions with experts, who argued that while supplementation increased vitamin A availability in breast milk, there was no clear-cut evidence of the benefits for maternal and child health (15).

Figure 1 presents a timeline showing some PNSVA benchmarks and the VAD prevention strategies adopted by the country. PNSVA regulations were issued in 2005, but as early as 1983, Brazil had already begun vitamin A supplementation activities for children aged 6–59 months during national vaccination days in areas considered at high risk for the deficiency (16).

The theoretical PNSVA model in Figure 2 describes the external context of the program.

PNSVA is one of the programs of the National Food and Nutrition Policy’s (PNAN) Strategy for the Prevention and Control of Nutritional Disorders, overseen by the Food and Nutrition Coordination Office (CGAN) under the Ministry of Health’s Department of Primary Health Care (DAB).

DAB coordinates other activities, programs, and strategies in the country that, while part of PNSVA’s external context, essentially have the same objectives of supporting food and nutrition education and improving the health conditions of children. They include the *Amamenta e Alimenta Brasil* [Breast-feeding and Feeding] Strategy; the *Bolsa Família* [Household Cash Transfer] Program, a package of strategies for promoting adequate food intake and a healthy diet; the National Comprehensive Children’s Health Care Policy (PNAISC), the School Health Program (PSE); the Food and Nutrition Surveillance System, the Family Health Strategy (ESF), the Family Health Support Hubs (NASF), the Streetside Medical Clinics, and the River Primary Health Care Units (UBSF).

**Logical model, resources, activities, impact, and causal connections and preliminary understanding of how PNSVA operates**

With regard to element c) modeling (the logical model of the program) of the available resources, intended activities, expected impact, and presumed causal connections; and element d) supervision of PNSVA, that is, obtaining a preliminary understanding of how the PNSVA operates, activities are planned for two different components to achieve the program’s objective. The first is prophylactic vitamin A supplementation, an action that should be taken in the short term. The second is the promotion of a healthy diet to prevent VAD, a measure that should be employed in the medium and long term. The logical model presented in Figure 3 was used to develop the questionnaires for evaluating PNSVA implementation, thus contributing to the evaluation plan.

**Development of the theoretical model for the evaluation, identification of evaluation users, and evaluation procedure**

With regard to elements e) development of a TMA; f) identification of evaluation users and other key stakeholders; and g) obtaining an agreement on the evaluation procedure, this study was proposed and conducted by researchers from Instituto René Rachou of Fundação Oswaldo Cruz (FIOCRUZ Minas). Fifteen stakeholders working at different levels of PNSVA were also involved; this group included researchers and program technical staff at the state and regional level. Other stakeholders were also recognized in the evaluation, among them primary health care (PHC) professionals (municipal technical staff, nurses, and nutritionists) and program beneficiaries (children aged 6 months to 5 years).

Of the 22 people invited to participate in the Delphi validation, eight evaluated the questionnaires. The degree of concordance found in the content validation was 92.7% for the relevance and need for

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**FIGURE 1. Timeline of strategies for the prevention and control of vitamin A deficiency in Brazil**

1981: “Project to Combat Vitamin A Deficiency” (INAN)
1983: Introduction by INAN of vitamin A-fortified food
1988: Vitamin A distribution included in the National Immunization Program in risk areas
1994: Decree 2160 – “National Vitamin A Deficiency Control Program”
1997: Program paralyzed with the cancellation of INAN
1999: Program resumed by CGPAN
2001: Expansion of supplementation activities for recent mothers in risk areas
2005: Expansion of PNSVA for municipalities in the Legal Amazon region and some Special Indigenous Health Districts
2010: Decree 729 – “National Vitamin A Supplementation Program”
2012: Expansion of PNSVA with the introduction of Ação Brasil Carinhoso
2016: Countrywide suspension of vitamin A supplementation for recent mothers

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*CGPAN: Food and Nutrition Policy Coordination Office; INAN: National Food and Nutrition Institute; PNSVA: National Vitamin A Supplementation Program. Farmanguinhos: Farmanguinhos Federal Pharmaceutical Laboratory, Official Laboratory of the Ministry of Health of Brazil.*
FIGURE 2. Theoretical model of the National Vitamin A Supplementation Policy, Brazil

<table>
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<tr>
<th>Legal framework</th>
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<tr>
<td>-Law 8 080 of 19 September 1990</td>
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<td>-Decree 710 of 10 June 1999</td>
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<td>-Decree 2 246 of 18 October 2004</td>
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<td>-Decree 729 of 13 May 2005</td>
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<td>-Law 11 346 of 15 September 2006</td>
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<td>-Decree 648 of 28 March 2006</td>
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<td>-Decree 687 of 30 March 2006</td>
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<td>-Decree 154 of 24 January 2008</td>
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<td>-Decree 2 488 of 21 October 2011</td>
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<td>-Decree 2 715 of 17 November 2011</td>
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<td>-Decree 2 446 of 13 November 2014</td>
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<td>-Decree 2 436 of 21 September 2017</td>
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<td>-Consolidation Decree 02 of 28 September 2017: Annexes I, III, and XXII</td>
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<th>Technical documents</th>
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<tr>
<td>-Projeto Suplementação de megadoses de Vitamina A no pós-parto imediato nas maternidades/hospitais (2002)</td>
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<td>-Sisvan: orientações básicas para coleta, processamento, análise de dados e informação em serviços de saúde (2004)</td>
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<tr>
<td>-Cadernos de Atenção Básica: carências de micronutrientes (2007)</td>
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<td>-Guia alimentar para a população brasileira: promovendo a alimentação saudável (2008)</td>
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<tr>
<td>-Dez passos da Alimentação Saudável para crianças menores de 2 anos (2013)</td>
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Hubs; PNAISC: National Comprehensive Children’s Health Care Policy; PSE: School Health Program; SISVAN: Food and Nutrition Surveillance System; UBSF: Family Primary Care Unit.

the questions and 86.5% for the clarity of the questionnaire on the care provided by PNSVA. For the questionnaire on program management, the degree of concordance was 97.84% for the relevance and need for the questions and 92.97% for clarity.

The judges generally reported that the two questionnaires are clear and easily understood. Their main comments were about the number of questions. Some of them considered the questionnaires too long and suggested condensing some of the questions, rewriting others to clarify their meaning, and adding others considered relevant.

After the pertinent changes were made, the questionnaire on management, which started out with 43 questions, ended up with 29, one of them devoted to the program structure, 11 to the process, and 17 specifically to the activities related to supplementation with megadoses of vitamin A. The questionnaire on care, which started out with 49 questions, ended up with 37, five of them devoted to structure, 11 to promoting a healthy diet to prevent VAD, and 21 to supplementation with megadoses of vitamin A. Interested readers can access the questionnaires by contacting the author of this article.

DISCUSSION

This study found that the evaluability assessment was a useful tool for exploring the theory, purposes, and objectives of PNSVA in the development of models capable of shedding light on the internal and external context and verifying the plausibility of the association between the problem, the program structure, its activities, and the expected outcomes in the short, medium, and long term. The PNSVA evaluability assessment also facilitated the preparation of a plan for subsequent evaluations.

In the sphere of political action, including action centered on health policy, evaluation is taking center stage in the discussions. Recognition of the need for systems and strategies capable of providing expeditious, efficient, and timely feedback to health programs and services is leading to growing social pressure for the development of an evaluation culture in Brazil (17). This at least partly explains the significant increase in publications on health evaluation in the country, especially since the mid-2000s (18).

Evaluability assessments have been used to generate information to support and guide decision-making, helping to gain an understanding of the day-to-day reality of the work and transforming ideas and practices. In this context, the evaluability assessment is considered an important strategy for determining the extent to which an intervention can be evaluated, facilitating the preparation of a more consistent and credible evaluation plan (11). With this objective, in the context of PHC, there is growing interest among researchers in adopting this evaluation approach (19-21).

The logical model was essential for understanding the theoretical underpinnings of PNSVA and made it possible to construct the evaluative questions that were key to conducting the evaluation.
Through it, two components with the common objective of reducing VAD in children under 5 were identified: prophylactic vitamin A supplementation and the promotion of a healthy diet.

It should be noted that prophylactic supplementation is the main focus in most of the 80 countries with VAD control programs (22). The mass administration of high doses of vitamin A to children over the past 20 years is often credited with leading to the global reduction in vitamin A deficiency during the period, especially in poorer regions (4). Nevertheless, studies note that maintaining the coverage and sustainability of these programs is a constant challenge (23–25), making it even more important to evaluate them. Although vitamin A supplementation programs have contributed to lower mortality in children under 5, the general view is that, as an isolated activity, they do not address the underlying problem of inadequate dietary intake of VA and its chronic deficiency in pre-school children in developing countries (26). This justifies evaluation of the second program component presented in the logical model: promotion of a healthy diet.

Looking at the trajectory of food and nutrition education in official VAD control programs in the country, Rodrigues and Snored (27) showed that in the past 40 years, this activity was either absent or sporadic, occurring temporarily and
without evaluation. They believe, however, that PNSVA represents real progress, since it requires that food and nutrition education be provided along with supplementation, not as an ad hoc measure.

Another important element of evaluation in health, apart from exploration of the context of the intervention, is determining whether the results will be used and whether there are indications of the intervention’s sustainability (28). To accomplish this, the evaluation cannot be conducted by management alone.

According to the initial findings of the assessment, effective stakeholder cooperation in the implementation of an intervention supports analysis and interpretation of the data from the evaluation assessment and can generate support for improving the program (11). From its very conception, this assessment partnered with PNSVA management in the state of Minas Gerais. An effort was also made to identify other stakeholders and include them in the evaluation, especially through the Delphi technique.

Negotiation among the stakeholders involved in evaluability assessments is an important factor, which Guba and Lincoln (29) call “fourth-generation” evaluation, as opposed to the generations prior to the 1980s. Engaging stakeholders in the evaluation is the best way to identify problems and explanations of the object being evaluated and facilitates use of the results in decision-making for the improvement, expansion, or modification of the intervention (10).

Tanaka and Tamaki (10) state that in order to structure an evaluability assessment with the capacity to support decision-making by health managers and respond to stakeholder concerns, a series of principles must be considered: 1) utility: the guarantee that important issues will be addressed; 2) feasibility and viability: the assessment must have a good cost-benefit ratio; 3) propriety: the guarantee of ethics; and 4) accuracy: the guarantee that the findings can be considered correct. The inclusion of stakeholders is a way of guaranteeing a good-quality assessment, with attention to assessment standards, especially utility and propriety.

The utility standard was also guaranteed during the Delphi validation of the data collection tools. Selecting the evaluation questions is a critical point in the evaluation process. When these questions are vague or ambiguous, the result is not an evaluation but a diagnostic study. An absence of clarity will result in the accumulation of data and information that may not be useful in decision-making intended to alter a particular health situation in the population (10).

The assessment by the panel of judges indicated that the questions constructed address aspects necessary for understanding PNSVA implementation in the municipalities. This stage was very important for making the necessary changes in the content of the questions and their wording in some cases, which will certainly increase the analytic power of the tool.

The use of on-line questionnaires to implement the Delphi technique is considered one limitation of the assessment. Although this format enables more potential respondents to be reached, it leads to substantial sample losses.

The evaluability assessment confirmed the possibility of conducting a more extensive systematic evaluation. Adapting the historical process of VAD prevention activities and the theoretical and logical models of PNSVA will help determine whether the available structure, programmed activities, and products generated are sufficient to meet the proposed objectives. Furthermore, based on this assessment and with the participation of stakeholders interested in evaluation, relevant evaluative questions were constructed for future evaluation of the program’s implementation in the state of Minas Gerais. The evaluation plan increases the power of the assessment tool and the use of its findings by managers at the national, state, regional, and municipal level.

The purpose of this study is to contribute to the debate on the need for evaluation methodologies that facilitate the investigation of aspects that go beyond the coverage and effectiveness of the program to explore the relationships among program components and between the components and the context. It is therefore suggested that researchers from other regions planning to investigate VAD prevention activities conduct evaluability assessments like this one to ensure that their evaluation can reveal the effectiveness or ineffectiveness of the activities, highlighting strengths and weaknesses.

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RESUMEN

Objetivo. Describir las etapas del estudio de evaluación del Programa Nacional de Suplementación de Vitamina A (PNSVA) en Brasil.

Métodos. Estudio con enfoque cualitativo que adoptó como marco de referencia el sistema de siete elementos propuesto por Thurston y Ramaliu. Se realizó análisis de documentos, revisión teórica del PNSVA y reuniones con expertos técnicos para la elaboración del cronograma y los marcos teórico y lógico del Programa. El modelo lógico ayudó a elaborar dos cuestionarios para ser utilizados en la evaluación del PNSVA. Los cuestionarios fueron validados utilizando el método Delphi.

Resultados. El estudio permitió comprender la evolución de las estrategias para prevenir y controlar la deficiencia de vitamina A en el país, además del funcionamiento del PNSVA y su contexto externo. El modelo lógico representó una herramienta valiosa para identificar áreas específicas que deben ser priorizadas en evaluaciones futuras. La validación de los cuestionarios indicó que estos instrumentos abordan temas necesarios para la evaluación de la implantación del Programa en los municipios. La aplicación del método Delphi fue muy importante para guiar los ajustes pertinentes en cuanto al contenido y la forma de presentación de algunos temas, lo que con certeza aumentará el poder analítico de la herramienta.

Conclusión. El estudio de evaluación señaló la posibilidad de evaluaciones futuras del PNSVA. Se espera que los resultados de esta investigación ayuden a futuras evaluaciones en países que adopten acciones similares a las de Brasil.

Palabras clave: Evaluación en salud; deficiencia de vitamina A; vitamina A; política de salud; Brasil.