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VALIDATION OF THE LOGICAL MODEL OF THE WORKFLOW OF A MEDICATION TEAM: A DESCRIPTIVE STUDY*

VALIDAÇÃO DO MODELO LÓGICO DO FLUXO DE TRABALHO DE UM TIME DE MEDICAÇÃO: UM ESTUDO DESCRITIVO

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RESUMO

Objetivo: Construir e validar um modelo lógico do processo de trabalho de um time de medicação. **Método:** Estudo de desenvolvimento tecnológico realizado em três etapas: i) construção do modelo lógico a partir de documentos oficiais e da literatura sobre a intervenção; ii) descrição e delimitação da intervenção com base nas atividades e objetivos do time; e iii) validação do modelo lógico por *stakeholders*. **Resultados:** Para clareza, os itens alcançaram *scale-level content validity index*, *universal agreement* (S-CVI/UA) de 0,94, e a média do *item-level content validity index* (I-CVI) do instrumento foi 0,91. Para relevância, o S-CVI/UA foi 0,95, e a média do I-CVI foi 0,95. **Conclusão:** A validação de 30 itens quanto à clareza e relevância permitiu a construção do modelo lógico, fundamentado na operacionalização da intervenção e em um esquema gráfico de seus componentes e do contexto. Foram identificados componentes de estrutura, processo e resultado do trabalho do time de medicação.

Descritores: Fluxo de trabalho; Estudos de avaliação; Avaliação de processos em cuidados de saúde; Unidades de terapia intensiva neonatal; Uso de medicamentos.

ABSTRACT

Objective: To construct and validate a logical model of the workflow of a medication team. **Method:** A technological development study conducted in three stages: i) construction of the logical model based on official documents and literature on the intervention; ii) description and delimitation of the intervention based on the team's activities and objectives; and iii) validation of the logical model by stakeholders. **Results:** For clarity, the items achieved a scale-level content validity index, universal agreement (S-CVI/UA) of 0.94, and a mean item-level content validity index (I-CVI) of 0.91. For relevance, the S-CVI/UA was 0.95, and the mean I-CVI was 0.95. **Conclusion:** The validation of 30 items for clarity and relevance enabled the construction of a logical model grounded in the operationalization of the intervention and in a graphic scheme of its components and context. Structural, process, and outcome components of the medication team's work were identified.

Descriptors: Workflow; Evaluation studies; Health care process assessment; Neonatal intensive care units; Drug use.

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INTRODUCTION

Medication teams, composed of nurses, are established to reduce medication errors. Their objectives include monitoring adverse events, developing and evaluating medication-related protocols, and performing other functions associated with implementing a new process in the medication system of a neonatal unit[1].

The *Guidelines for the Prevention of Intravascular Catheter-related Infections*[2] recommend the involvement of intravenous therapy teams, recognizing their effectiveness in reducing catheter-related infections, complications, and costs. Moreover, the risk of infection increases, among other factors, with the reduction of specialized nursing staff.

Considering patient safety and the goal of mitigating harm — especially among preterm infants, the most vulnerable neonatal population to adverse drug events — this workgroup was established as an intervention focused on the medication area[3]. Evaluating its workflow supports planning, the accumulation of knowledge on the topic, and the improvement of practices, since objectives and processes are already described, allowing the assessment of products, components, practices/activities, services, and goals.

Health evaluation aims to measure the value and methods of a technology to guide improvements or adjustments in interventions addressing problems in the field[4]. Among evaluation approaches, implementation assessment of programs or services through logical models[5] stands out as a graphical representation of the workflow[6]. This approach accounts for the specificities of health processes, promoting communication and planning of activities and actions for improvement[7].

To conduct an implementation evaluation, it is first necessary to construct a logical model (LM) that describes all activities performed by the group. From this model, evaluative questions can be formulated, and intervention progress can be guided, in addition to establishing methodological parameters for implementing similar programs, organizing activities and elements that promote the achievement of positive outcomes in new workflows[8].

Accordingly, the aim of this study was to construct and validate an LM of the workflow of a medication team (MT).

METHOD

This was a study of technological development, with data collection performed between June and December 2021. The project met all ethical requirements and was approved by the Research Ethics Committees of both participating institutions under opinions no. 3,898,500 (proposing institution) and no. 3,973,252 (co-participating institution). The CAAE number is 28148619.6.3001.5259.

Donabedian's triad[9] was adopted as the theoretical framework for constructing the LM. In this framework, structure refers to the resources necessary for care delivery; process pertains to the performance of care itself; and outcome encompasses the effects or products of that care.

The study was conducted in three main stages: i) construction of the LM through identification of official documents and literature on the intervention; ii) description and delimitation of the intervention, considering the team's activities and objectives; and iii) content validation by stakeholders involved in evaluating the MT's workflow.

The preliminary model was developed as a systematic and visual representation of the MT, allowing the description and visualization of the interrelationship among its components—resources, planned activities, and expected effects[10]. This prototype served as an initial tool to guide the implementation, monitoring, and evaluation of the intervention[11].

The LM design considered components, practices/activities, objectives, and contextual factors[8], based on previous research on the MT's workflow[1,3]. A document review was also carried out, analyzing institutional instruments, protocols, minutes, legislation, and relevant literature on the topic.

All participants were informed about the study's objectives and signed a free and informed consent form.

The structure component was initially defined based on the importance of protocols, which, according to the literature, should be available for all stages of the medication system[12]. Communication tools that record events related to medication use are also essential for assessing care quality[13].

In addition to protocols, material and human resources must meet care demands[13]. Current legislation establishes that nurses and pharmacists are the only professionals authorized to prepare parenteral solutions, in a dedicated area with appropriate physical conditions[13].

The availability, adequacy, and timeliness of resource use are critical for care safety. Planning of specific actions, availability of permanent materials, adequate lighting, and organized furniture are determining factors for the group's efficient functioning[13].

Regarding protocols, nurses must maintain continuous updates on procedures and care under their responsibility[13]. In the medication domain, management and use must follow institutional norms, policies, or specific procedures[14].

The institution must also provide ongoing training and continuing education on the preparation and administration of parenteral solutions, ensuring consistent skill development and updates[13], particularly regarding the prescription, use, and safe administration of medications[12].

According to the Joint Commission International[15], the medication system comprises the following stages: prescription and transcription; preparation and dispensing; and monitoring of medication errors and near misses. All these stages relate to the MT's workflow — from transcribing medication labels and charts, scheduling medical prescriptions, and receiving medications from the pharmacy to preparation — and must follow institutional protocols.

Medication effects represent potential outcomes and must be monitored for adverse drug reactions (ADRs) and medication errors[12-13,15]. The National Coordinating Council for Medication Error Reporting and Prevention[16] defines types of medication errors, an essential aspect for identifying reportable ADRs.

Professional satisfaction was also considered a relevant outcome, associated with factors such as absenteeism, motivation, recognition, autonomy, workload, and interpersonal relationships[14], which influence organizational structure and medication safety.

Another expected outcome is the enhancement of knowledge regarding safe medication use and the MT's own workflow[15].

Based on the literature and the document review, a preliminary model was developed to graphically represent

the interaction among the elements that compose the group's workflow, in preparation for model validation.

The validation stage promoted in-depth discussion among researchers, managers, and practitioners, strengthening collective learning and the collaborative construction of the model.

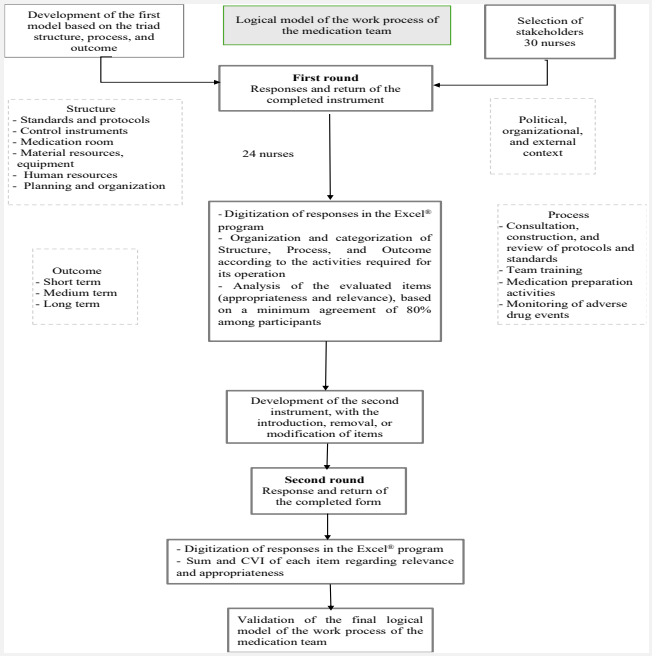
Stakeholders received by email instructions and a questionnaire to evaluate the LM for the clarity and relevance of its structure, process, and outcome components. A four-point Likert scale was used (1 = disagree; 2 = partially disagree; 3 = partially agree; 4 = fully agree). Items scored 1 or 2 were excluded. The instrument also provided space for suggestions to modify, remove, or improve items.

To calculate the content validity index (CVI), we used: i) scale-level content validity index, universal agreement (S-CVI/UA) — the proportion of items rated 3 or 4 by all judges; and ii) item-level content validity index (I-CVI) — the ratio between the number of judges who assigned ratings of 3 or 4 and the total number of evaluators. For content validation, a CVI ≥ 0.8 was considered acceptable[17].

The instrument was deemed valid with CVI ≥ 0.80[17]. For the overall assessment, the mean I-CVI was calculated as the sum of individual CVIs divided by the total number of items[17].

Responses were analyzed in Excel 2003. Items with CVI < 0.80 were revised according to the judges' suggestions and submitted to a second evaluation round. After these modifications, all items met the minimum required CVI, totaling two validation rounds.

At the end of the process, all stakeholder contributions were incorporated into the LM. The final instrument comprised 5 structure items, 9 process items, and 16 outcome items (short-, medium-, and long-term), as described in Figure 1.



Source: prepared by the authors, 2022.

Figure 1 – Steps in the validation of the logical model of the medication team's workflow. Rio de Janeiro, RJ, Brazil, 2022

RESULTS

The first stage of the study involved constructing the LM, grounded in Donabedian's framework, which considers the context, structure, process, and effects of the MT's work. This phase aimed to describe the components and factors that underlie the intervention based on an analysis of institutional and regulatory documents — including standard operating procedures (SOPs), communication instruments, minutes of team meetings, administrative forms, scientific literature, and relevant legislation.

Based on these sources, Chart 1 was prepared to relate the components of Donabedian's triad to the documents used to support the construction of the LM.

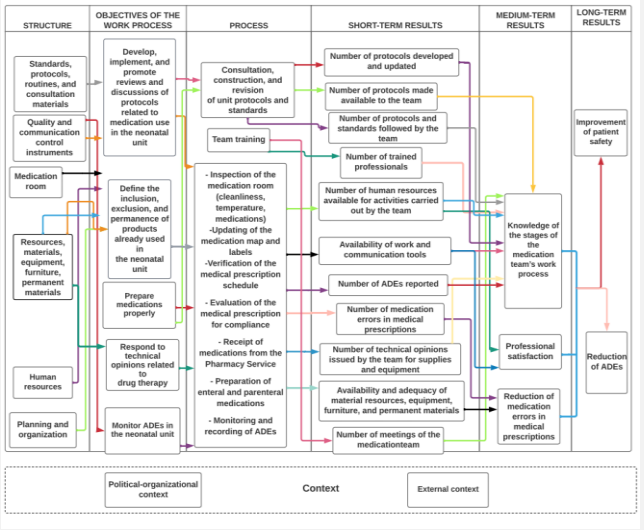
The second stage consisted of describing and defining the boundaries of the intervention, based on the activities and objectives identified in the SOPs for medication preparation and administration, communication instruments, and team meeting minutes. This phase was essential to establish the objectives of the MT's workflow as well as the process and outcome components represented in the LM (Figure 2).

The third stage — content validation — involved the participation of 24 nurses, described in Table 1, who served as stakeholders in evaluating the MT's workflow.

Regarding the distribution of CVIs, the results were organized according to the criteria of clarity and relevance, as shown in Table 2 and Table 3, respectively.

Based on stakeholders' feedback on the preliminary model, the structure was detailed with resources now subdivided into materials, equipment, furniture, and permanent supplies. In the process domain, the medication-preparation stage was broken down into sub-stages to more precisely describe the activities performed in the medication room. In the outcomes domain, the scope was expanded to include medium-term outcomes; among short-term outcomes, the number of protocols and standards followed by the team and the number of protocols made available to the team were added.

Accordingly, the structure incorporated all components related to physical and material resources, work instruments, personnel, and organization linked to the MT's activities. In the process, the group's activities, the capacity to carry them out, and the application of available knowledge were listed. Outcomes were classified as short-, medium-, and long-term and described as changes or products resulting from the group's workflow (Figure 2).



Source: prepared by the authors, 2022.

Figure 2 – Logical model of the medication team. Rio de Janeiro, RJ, Brazil, 2022

Chart 1 – Documents related to the construction of the logical model

Structure	**Documents**
Standards, protocols, and reference materials	Patient Safety Basic Protocols[12]; COFEN Resolution No. 564/2017[18]
Quality-control and communication instruments	Patient Safety Basic Protocols[12]; RDC No. 45 of March 12, 2003[13]
Human resources	RDC No. 45 of March 12, 2003[13]; Ordinance No. 930 of May 10, 2012[19]
Material resources, equipment, and furniture	RDC No. 50 of February 21, 2002[20]; RDC No. 45 of March 12, 2003[13]
Physical space of the medication room	RDC No. 50 of February 21, 2002[20]
Process	**Documents**
Nurses' participation in training related to medication use	Patient Safety Basic Protocols[12]; RDC No. 45 of March 12, 2003[13]
Use of quality-control forms in the medication room	Patient Safety Basic Protocols[12]; RDC No. 45 of March 12, 2003[13]
Recording information in order/occurrence logs	RDC No. 45 of March 12, 2003[13]
Team meetings for planning group activities	RDC No. 45 of March 12, 2003[13]
Proper functioning of equipment, furniture, permanent materials, lighting, and supplies	RDC No. 50 of February 21, 2002[20]; RDC No. 45 of March 12, 2003[13]
Consultation of materials related to medications	Joint Commission International[15]; RDC No. 45 of March 12, 2003[13]
Development and revision of protocols and standards related to medication use	Joint Commission International[15]; RDC No. 45 of March 12, 2003[13]
Preparation of reports for material resources and equipment	Joint Commission International[15]; RDC No. 45 of March 12, 2003[13]
Proper updating of the medication chart and labels	Joint Commission International[15]; Patient Safety Basic Protocols[12]
Correct scheduling and timely review of medical prescriptions	Joint Commission International[15]; Patient Safety Basic Protocols[12]
Verification of medications delivered by the Pharmacy Service	Joint Commission International[15]; Patient Safety Basic Protocols[12]; RDC No. 45 of March 12, 2003[13]
Timely preparation of enteral and parenteral medications	Joint Commission International[15]; Patient Safety Basic Protocols[12]; RDC No. 45 of March 12, 2003[13]
Outcome	**Documents**
Knowledge about the workflow	Reference literature on evaluation[4]
Professional satisfaction	Reference literature on evaluation[4]
Reduction of errors in medical prescriptions	Joint Commission International[15]; Patient Safety Basic Protocols[12]; RDC No. 45 of March 12, 2003[13]

COFEN = Conselho Federal de Enfermagem; RDC = Collegiate Board Resolution.
Source: prepared by the authors, 2022.

The external context was defined from socioeconomic, demographic, and epidemiological data for the city and the state of Rio de Janeiro. The region shows indicators such as average income, Human Development Index, gross domestic product per capita, and the proportion of the population with income < 1/2 of the minimum wage that are higher than those of the Southeast Region and of Brazil.

Regarding epidemiological indicators, although the ratio of nurses per 1,000 inhabitants in the state (2.12) is lower than that observed in countries such as Switzerland (15) and the United States (10), the nurses-to-beds ratio is higher in the state (32.2) than nationwide (21.2). Even so, the multiplicity of roles performed by nurses in Brazil (direct care, administrative activities, management, and leadership) leads to work overload.

In the state of Rio de Janeiro, there has been a decline in neonatal mortality in recent years (33%), a trend similar to that of the Southeast Region. Although the supply of neonatal beds does not fully meet legal requirements, the number of accredited beds (38.29%) is considered high when weighted by the state's population.

As for the internal political-organizational context, the MT is part of the nursing team hierarchy (organizational chart) and has an organizational structure consistent with current legislation and literature. However, the MT does not have the resources required for its full operation. Although the institution is large and has multiple specialties — which, in principle, would facilitate access to equipment, supplies, and technologies — financial resources are not managed by the MT and remain restricted to a monthly service cap. Whenever possible, these resources are directed to the purchase of non-standard materials and medications as well as some equipment.

DISCUSSION

For the LM to adequately represent the intervention, the participation of stakeholders (those interested in the evaluation) is essential, as consensus, diverse views, and different experiences enrich model validation[11]. Individual values and cultural and socioeconomic factors influence the construction of the LM. The involvement of multiple stakeholders fosters a shared, broadened perspective and can increase the likelihood of successful implementation[8].

Another important point for patient safety is professional experience. The longer the time in practice, the greater the development of competencies in the specific area. To ensure that nurses acquire skills and knowledge in the medication domain — especially for the drugs most used in the unit, including prescription transcription — it is desirable to reduce rotation across shifts[3]. Although a 30-hour workweek is considered appropriate by international bodies such as the World Health Organization and the International Labour Organization, factors like inattention, fatigue, work overload, and multiple employment relationships contribute to errors in neonatal units[21].

The literature identifies construction of the LM as an important step to support program evaluation and as a tool that enables replication in other services[22]. Developing the LM made it possible to understand the existing structure, visualize the interaction between activities and expected outcomes, and support planning, implementation, and the definition of the evaluative study[8]. The model serves as a tool for ongoing monitoring and organization of work, contributing to the promotion of neonatal health[23].

Table 1 – Socioprofessional profile of medication team stakeholders. Rio de Janeiro, RJ, Brazil, 2022

Sociodemographic data		
Sex	**N**	**%**
Female	22	91.7
Male	2	8.3
Age (years)		
30-35	3	12.5
36-40	4	16.6
41-45	7	29.2
46-50	7	29.2
51-55	2	8.3
56-60	1	4.2
Work shift		
Daytime	14	58.3
Nighttime	10	41.7
Years since graduation		
< 10	1	4.2
10-20	9	37.5
21-30	14	58.3
Undergraduate institution		
Public school	20	83.3
Private school	4	16.7
Years working at the institution		
< 1	3	12.5
1-10	5	20.8
11-20	14	58.4
21-30	2	8.3
Years working in the neonatal unit		
< 5	0	0
5-10	4	16.7
11-20	14	58.3
21-30	5	20.8
> 30	1	4.2
Years in the medication team		
< 1	5	20.8
1-5	3	12.5
6-10	4	16.7
> 10	12	50
Type of employment		
Permanent public employee	18	75
Temporary contract	6	25
Weekly workload (hours)		
30	24	100
Weekly workload (hours)		
1	4	16.7
2	16	66.6
3	4	16.7

Source: prepared by the authors, 2022.

Document analysis enabled the construction of the first diagram of relationships among structure, process, and outcome. Engagement with professionals was decisive for identifying internal contextual elements essential to implementation. In the care dimensions of the LM, professionals' observations stood out regarding team qualification, the absence of information for monitoring and evaluation, and weaknesses in workflow and training[24].

The structure component related to the MT's workflow includes material resources, work instruments, and human resources — attributes that are relatively constant in care delivery[10]. Regarding instruments, protocols and standardization are crucial to reduce variation in clinical practice and improve care quality from a humanized, multidimensional perspective[25]. Specialized teams such as the MT should be guided by protocols, routines, and reference materials, with activity planning and organization focused on patient safety.

The process refers to the care dimension, representing the work performed by professionals in delivering care and interacting with users. It involves applying specific knowledge and skills[10]. Activities inherent to the MT — such as medication preparation — were included and are grounded in protocols, standards, routines, and legislation. Identifying the stages and sub-stages of preparation, as well as critical links, supports the planning and implementation of interventions[1]. To strengthen medication-preparation safety in neonatal units, key actions include consulting SOPs for preparation/dilution, updating and making manuals and protocols available to the entire team, and training for the safe use of medications[26].

The outcome dimension reflects monitoring of the care provided. It considers the context of the units, with an emphasis on patient safety, and presupposes the commitment and reflection of professionals in a dynamic process[10]. It includes monitoring activities, identifying needs for modification, and evaluating results, linking the availability of resources, the activities performed, and the products achieved[11]. The intervention's objectives unfolded into short-, medium-, and long-term outcomes, according to items deemed pertinent by evaluation stakeholders. There is a clear correlation between the intervention and its outcomes, which are relevant to preventing adverse events[8].

Among the effects considered, professional satisfaction stands out—an aspect related to the MT's workflow that impacts the safety and quality of care and, when unfavorable, represents a significant risk to neonates[18]. Adverse drug reactions (ADRs) are central safety indicators related to medication use, and the MT aims to monitor them. To do so, knowledge about the topic and about the team's own workflows is fundamental. Studies describe the work of teams like the MT in identifying ADRs and point to training as a prerequisite for an effective prevention mindset, with influence on the satisfaction of nurses in intravenous therapy teams (71.4%)[27].

Accordingly, it is important to foster activities that develop care-specific competencies and skills, strengthen clinical judgment, and create conditions for solving everyday problems[28-29]. Such actions also promote ownership of results and a better understanding of evaluation.

Context analysis allows the identification of facilitators and barriers that influence observed effects and the implementation of the MT's workflow, including socioeconomic, demographic, epidemiological, and political factors. The external context proved favorable to implementation, since the state and the city — despite being populous — show socioeconomic indicators better than regional and national averages. In the internal political-organizational context, the MT's structure was adequate and embedded within a specific organizational chart.

As a study limitation, other stakeholders — such as higher-level coordinators and the institution's leadership — were not represented, which may limit the breadth of perspectives collected.

CONCLUSION

Building the LM of the MT's workflow made it possible to make the intervention's operationalization explicit through a graphic scheme of its components and context, systematically identifying structure, process, and outcome elements.

Table 2 – Distribution of content validity indices by clarity. Rio de Janeiro, RJ, Brazil, 2022

Component	Item	No. in agreement	I-CVI
Structure	Standards and protocols	24	1.00
	Control instruments	20	0.83
	Medication room	22	0.91
	Material resources and equipment	22	0.91
	Human resources	20	0.83
	Planning and organization	20	0.83
Process	Consultation, development, and revision of protocols and standards	20–24	0.83–1.00
	Team training	23–24	0.96—–
	Activities for medication preparation	21–22	0.87–0.91
	Monitoring of adverse drug reactions	20–24	0.83–1.00
Outcome – Short term	No. of protocols developed and updated	24	1.00
	No. of protocols made available to the team	24	1.00
	No. of protocols and standards followed by the team	22	0.91
	No. of trained professionals	24	1.00
	No. of human resources available for team activities	23	0.96
	Availability of work and communication instruments	23	0.96
	No. of reported adverse drug reactions	24	1.00
	No. of medication errors in medical prescriptions	22	0.91
	No. of technical opinions issued for supplies and equipment	21	0.87
	Availability/adequacy of material resources, equipment, furniture, and permanent materials	24	1.00
	No. of team meetings	24	1.00
Outcome – Medium term	Knowledge of the MT workflow stages	24	1.00
	Professional satisfaction	23	0.96
	Reduction of medication errors in medical prescriptions	24	1.00
Outcome – Long term	Improvement in patient safety	24	1.00
	Reduction of adverse medication events	24	1.00

S-CVI/UA = proportion of items rated 3 or 4 by all experts; I-CVI = proportion of experts who rated the item as 3 or 4. The em dash (—) indicates I-CVI not reported.
Source: prepared by the authors, 2022.

Table 3 – Distribution of content validity indices for relevance. Rio de Janeiro, RJ, 2022

Component	Item	No. in agreement	I-CVI
Structure	Standards and protocols	24	1,00
	Control instruments	24	1,00
	Medication room	24	1,00
	Material resources and equipment	23	0,96
	Human resources	23	0,96
	Planning and organization	24	1,00
Process	Consultation, development, and revision of protocols and standards	20–24	0,83–1,00
	Team training	22–24	0,91–1,00
	Activities for medication preparation	23–24	0,96–1,00
	Monitoring of adverse medication events	24	1,00
Outcome – Short term	No. of protocols developed and updated	24	1,00
	No. of protocols made available to the team	20	0,83
	No. of protocols and standards followed by the team	20	0,83
	No. of trained professionals	24	1,00
	No. of human resources available for team activities	24	1,00
	Availability of work and communication instruments	20	0,83
	No. of reported adverse drug reactions	23	0,96
	No. of medication errors in medical prescriptions	24	1,00
	No. of technical opinions issued for supplies and equipment	20	0,83
	Availability/adequacy of material resources, equipment, furniture, and permanent materials	24	1,00
	No. of team meetings	20	0,83
Outcome – Medium term	Knowledge of the medication team's workflow stages	20	0,83
	Professional satisfaction	24	1,00
	Reduction of medication errors in medical prescriptions	24	1,00
Outcome – Long term	Improvement in patient safety	24	1,00
	Reduction of adverse medication events	24	1,00

S-CVI/UA = proportion of items rated 3 or 4 by all experts; I-CVI = proportion of experts who rated each item as 3 or 4.
Source: prepared by the authors, 2022.

Developing the LM characterized the MT as a specialized team with the potential to support evaluation processes focused on patient safety related to medications. The model can be replicated in other institutions interested in adopting teams of this nature and used as a criterion for constructing indicators and evaluation instruments.

Stakeholder participation — as the group directly involved with the intervention — was decisive for the model's collective construction, contributing to the MT's professional development and strengthening judgment about the workflow, skill development, and knowledge in the medication domain.

Finally, the LM is not static: it should be periodically reviewed as changes occur in the intervention or as new guidelines, strategies, legislation, or evidence are incorporated.

*Article derived from the Doctoral Dissertation entitled "Avaliação do processo de trabalho de um time de medicação em uma unidade neonatal" [Evaluation of the work process of a medication team in a neonatal unit] presented to the Academic Program in Health Care Sciences at Universidade Federal Fluminense, Niterói, RJ, Brazil, in 2021.

CONFLICT OF INTERESTS

The authors declare no conflicts of interest.

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All authors are responsible for the writing and critical review of the intellectual content, for the final published version, and for all ethical, legal, and scientific aspects related to the accuracy and integrity of the study.