

Graphic protocol for assessing safe care for people with mental disorders in pre-hospital care

Protocolo gráfico para avaliação do cuidado seguro à pessoa com transtorno mental no atendimento pré-hospitalar
Protocolo gráfico para evaluar la atención segura a personas con trastornos mentales en la atención prehospitalaria

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Abstract

Objective: To describe the process of constructing and assessing the content and appearance of a graphic management protocol for assessing safe nursing care for people with mental disorders in mobile pre-hospital care.

Methods: This methodological study was conducted from July to November 2023, using three procedures: theoretical, through a scoping review to map scientific evidence; empirical, through the development of a protocol and checklist for assessing safe care; and analytical, for assessment. The Delphi technique was used with the participation of expert judges to achieve agreement. The items were developed according to Pasquali's psychometric methodological framework. Items with a Content Validity Coefficient (CVC) greater than 0.80 and a consensus of more than 80% in the Delphi technique were considered valid. Data were analyzed using descriptive and inferential statistics (binomial test).

Results: The overall score for the graphic management protocol and the checklist for appearance and CVC validity was 0.98 at the end of the second Delphi round. After the inclusion of suggested changes, 100% of judges recommended using the protocol and checklist.

Conclusion: The graphic protocol and checklist content and appearance proved to be valid, and their implementation in mobile pre-hospital care can contribute to patient safety and quality management by promoting safe nursing care directed at people with mental disorders in this specific care context.

Resumo

Objetivo: Descrever o processo de construção e avaliação do conteúdo e aparência de protocolo gráfico gerencial para avaliação do cuidado seguro de enfermagem à pessoa com transtorno mental no atendimento pré-hospitalar móvel.

Métodos: Estudo metodológico, realizado no período de julho a novembro de 2023, através de três procedimentos: teóricos, por meio de revisão de escopo, a fim de mapear as evidências científicas; empíricos, quando se realizou a construção do protocolo e *checklist* para avaliação do cuidado seguro; e analíticos, para a avaliação. Usou-se a técnica Delphi com a participação de juízes especialistas para o alcance da concordância. Foram desenvolvidos segundo o referencial metodológico da psicométrica de Pasquali. Consideraram-se válidos aqueles itens com Coeficiente de Validade de Conteúdo (CVC) maior que 0,80 e com consenso de mais de 80% na técnica de Delphi. Os dados foram analisados por meio das estatísticas descritiva e inferencial (teste binominal).

Resultados: A estimativa geral do protocolo gráfico gerencial e do *checklist* para validação da aparência e do CVC foi de 0,98 ao final da segunda rodada Delphi. Após inclusão de alterações sugeridas, 100% dos juízes recomendaram o uso do protocolo e do *checklist*.

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Conflicts of interest: nothing to declare.

Conclusão: O conteúdo e a aparência do protocolo gráfico e do *checklist* se mostraram válidos e, sua implementação no atendimento pré-hospitalar móvel pode contribuir para a segurança do paciente e para a gestão da qualidade, ao promover uma assistência de enfermagem segura e direcionada à pessoa com transtorno mental nesse contexto específico de cuidado.

Resumen

Objetivo: Describir el proceso de elaboración y evaluación del contenido y la apariencia de un protocolo gráfico de gestión para evaluar la atención segura de enfermería a personas con trastornos mentales en la atención prehospitalaria móvil.

Métodos: Estudio metodológico, realizado entre julio y noviembre de 2023, mediante tres procedimientos: teórico, a través de una revisión del alcance para mapear las evidencias científicas; empírico, con la elaboración del protocolo y la lista de verificación para evaluar la atención segura; y analítico, para la evaluación. Se utilizó el método Delphi con la participación de jueces especialistas para alcanzar el consenso. Se desarrollaron según el marco metodológico de la psicometría de Pasquali. Se consideraron válidos aquellos ítems con un coeficiente de validez de contenido (CVC) superior a 0,80 y con un consenso superior al 80 % en el método Delphi. Los datos se analizaron mediante estadísticas descriptivas e inferenciales (prueba binomial).

Resultados: La estimación general del protocolo gráfico de gestión y de la lista de verificación para la validación de la apariencia y del CVC fue de 0,98 al final de la segunda ronda Delphi. Tras la inclusión de los cambios sugeridos, el 100 % de los jueces recomendó el uso del protocolo y de la lista de verificación.

Conclusión: El contenido y la apariencia del protocolo gráfico y la lista de verificación demostraron ser válidos, y su implementación en la atención prehospitalaria móvil puede contribuir a la seguridad del paciente y a la gestión de la calidad, al promover una atención de enfermería segura y dirigida a las personas con trastornos mentales en este contexto específico de atención.

Introduction

Safety in mental healthcare is largely under-analyzed.^(1,3) Historically, the focus of safety in mental health research and practice has tended to focus on the risks of homicide, suicide, and fatalities.^(1,3) More recently, broader safety issues have been described and classified with regard to the organization of mental healthcare services.⁽⁴⁾

Existing research on safety in mental healthcare has almost exclusively prioritized inpatient services.^(1,3) It is noteworthy that over the past 15 years, the global mental health sector has largely focused on mental health neglect and efforts to address disparities in care across countries.^(5,6)

In Brazil, mental healthcare is guided by the Healthcare Network (In Portuguese, *Rede de Atenção à Saúde* - RAS). Thus, the Psychosocial Care Network, established by Ordinance 3,088/2011,⁽⁷⁾ republished on May 21, 2013, and subsequently revoked by Consolidation Ordinance 3 of September 28, 2017,⁽⁸⁾ is divided into disparate components.⁽⁹⁾ Among them are the Emergency Care Network⁽¹⁰⁾ and the Mobile Emergency Care Service, the focus of this study, with the aim of organizing the flow of assistance, providing early care and appropriate, fast and effective transportation to victims.

However, studies indicate that, in relation to the care of individuals with mental disorders, services routinely reproduce the implementation of attitudes that go against the Psychiatric Reform and the Brazilian

National Mental Health Policy, including mobile pre-hospital care (MPHC), with the use of physical and chemical restraints inappropriately and/or in situations where they are not strictly necessary.^(11,12)

It is important to emphasize that providing healthcare in a moving vehicle requires different safety considerations than in other environments. Seat belts are mandatory, and during ambulance transport, patients are secured to the stretcher with safety straps. However, these individuals may squirm or unfasten their safety straps, posing a threat to themselves and the ambulance staff in the event of an accident.^(11,12)

A study conducted in Brazil aimed to understand nursing staff's perceptions of the care provided to individuals in psychiatric emergencies situations in the Mobile Emergency Care Service (In Portuguese, *Serviço de Atendimento Móvel de Urgência* - SAMU). It revealed that the care provided in psychiatric emergencies and urgent situations is still predominantly mechanistic. This approach is characterized by a practice that disregards subjective and affective aspects, which directly influence the illness process.⁽¹²⁾

Nursing professionals, in their practice in MPHC, report difficulties, especially due to the absence of an integrated and articulated mental RAS, in addition to the lack of training to work in situations of psychiatric emergency.⁽¹²⁾

However, care for individuals with mental disorders in emergent situations requires welcoming, as-

sertive communication, understanding of the subjectivity that emerges during the worsening of mental distress, and ethical action to build citizenship and promote social justice for MPHC users.^(9,11-14)

Therefore, there is a need to incorporate the safety of patients with mental disorders into MPHC), and to achieve this, it is necessary to develop management strategies that support management decision-making. One way to systematize the assessment of health quality and patient safety (PS) is through the use of technological tools, such as protocols, which aim to guide healthcare services and professionals in assessing and monitoring the health situation in the short, medium, and long term, enabling early detection and correction of deviations from the identified standards, in addition to allowing for improvements in the assessed processes.^(13,15)

In this logic, it is pertinent to use protocols and checklists that help assess specific management criteria for assessing safe nursing care for people with mental disorders in MPHC, since the increase in emergency calls and the dispatch of ambulances for users with mental disorders have required more adequate knowledge and skills from ambulance personnel.^(13,14) It should be noted that there is a shortage of studies in the country's scientific literature on protocols on this topic.

Therefore, this study was guided by the following research question: What contents and appearance are essential for the construction of a graphic management protocol to assess safe nursing care for people with mental disorders in MPHC?

Therefore, the objective was to describe the process of construction and assessment of content and appearance of a graphic management protocol for assessing safe nursing care for people with mental disorders in MPHC.

Methods

This is a methodological study with a quantitative approach, developed according to the methodological framework of Pasquali's psychometrics.⁽¹⁶⁾ This type of research is suitable for examining methods of data acquisition, organization and analysis, with a view to

developing, validating and assessing instruments and techniques for the research context.⁽¹²⁾

The graphic protocol content and appearance assessment took place from July to November 2023, based on two stages: 1) protocol construction; 2) instrument content and appearance validity by Brazilian judges, using the Delphi technique.

The graphic protocol was developed from Avedis Donabedian's components,⁽¹⁷⁾ which involves a systematic construction and includes structure (organizational readiness and continuous training), process (effective management and leadership, safe care and comprehensive care measures), and outcomes (professional excellence, quantitative and qualitative improvements in healthcare services and acceptability of healthcare professionals).⁽¹⁷⁾

For construction, with a view to assessing the content and appearance of a graphic management protocol and a checklist intended for the assessment of safe nursing care for people with mental disorders in MPHC, a scoping review was carried out based on the international guide PRISMA-ScR⁽¹⁸⁾ recommendations and the method proposed by the JBI Reviewers Manual 2020,⁽¹⁹⁾ according to national and international scientific evidence (Appendix 1).

It is noteworthy that the electronic search for studies to carry out the scoping review was carried out in the MEDLINE via PubMed, Latin American and Caribbean Literature on Health Sciences (LILACS), CINAHL, Scopus, EMBASE, Web of Science, and Cochrane Library databases. In gray literature, the following resources were used: *Coordenação de Aperfeiçoamento de Pessoal de Nível Superior* (CAPES) Thesis and Dissertation Catalog; the National Library of Australia (Trove); Academic Archive Online (DIVA); The DART-Europe E-Theses Portal; the National ETD Portal South African theses and dissertations; *Red de Repositorios Latinoamericano*; World Cat Dissertations and Theses; and *Repositórios Científicos de Acesso Aberto de Portugal* (RCAAP), as well as national guidelines/protocols and international guidelines, without time limit. The search strategy for studies/documents used a combination of keywords and descriptors, adapted for each database and for gray literature: "Mental health" OR "Mental disorders"

OR “Psychiatric nursing” OR “Crisis intervention”) AND (“Patient safety” OR “Medication errors” OR “Safety culture”) AND (“Ambulances” OR “Emergency mobile units” OR “Mobile emergency units” OR “SAMU”).

It is noteworthy that, in this study, the indicators used to assess quality of care were appropriately adapted to MPHC. Thus, the structure relates to the essential means for providing care to patients with mental illness in MPHC, such as infrastructure conditions; the process addresses management and care practices, as well as PS protocols; and the outcomes conjecture the implications of care provided to individuals with mental disorders.

As for the protocol appearance, graphical representation was chosen, and the algorithms were developed according to Pimenta *et al.*'s proposal⁽²⁰⁾ since it accepts adding a set of actions and decisions focused on outcomes in a concise and clear manner.^(15,20)

During the graphic management protocol development (Appendix 2), a structured observation script was created, in the form of a checklist (Appendix 3), consisting of seven items for assessing the SAMU structure (current legislation, ambulance infrastructure - patient care location, standardization and compliance with routines, staffing, continuing education, human resources indicators, risk management) and their respective sub-items.

To assess the PS process with mental disorders in nursing care, six items were developed (PS standards; best practices in patient identification; best practices in effective communication between nursing professionals, patients and family members; best practices in preventing falls and accidents; best practices in preventing skin lesions; and best practices in the safe administration of medications), with their respective sub-items.

Regarding the “outcomes” element, five items were created to assess outcomes (data monitoring; notification and analysis of adverse events; satisfaction assessment; matrix support and monitoring of continuing education) and their respective sub-items.

Furthermore, an implementation guide for the graphic management protocol and checklist for assessing safe nursing care for people with mental

disorders in MPHC was created to guide nurses in implementing these instruments. It is noteworthy that this guide provides a script for applying the graphic management protocol and checklist developed and validated in this study. These instruments aim to broadly identify care and management risks, supporting nursing professionals' actions and contributing to the prevention of harm to people with mental disorders, their family members/companions, and professionals working in MPHC.

For clarification, in the document “Implementation Guide for the Graphic Management Protocol and Checklist for Assessing Safe Nursing Care for People with Mental Disorders in Primary Care”, “Implementation Guide for the Graphic Management Protocol and Checklist for Assessing Safe Nursing Care for People with Mental Disorders in Primary Care”, it is recommended that the assessment be conducted by at least two previously trained evaluators. These evaluators should conduct a non-participant observation of the unit using the protocol and checklist as a reference. It should be emphasized that as the number of observations increases, the likelihood of identifying the assessed requirements also increases. It is essential that the evaluators do not communicate during the observations to avoid interference in the responses.

Throughout the assessment, the protocol and checklist must be used in an integrated manner. Each evaluator must complete them individually, indicating the presence (yes) or absence (no) of the items checked (Appendix 3). At the end, the checked items are added together, assigning a rating by dimension based on the percentage of compliance: adequate (100% “yes” responses); partially adequate (between 50% and 99.9% “yes” responses); and inadequate (less than 50% “yes” responses).

The criteria examined in the checklist are graphically represented in the protocol using diamonds, which indicate three decision possibilities (adequate, partially adequate, and inadequate) (Appendix 2). Next to each diamond, a solid line connects it to an explanatory box, which indicates the checklist items corresponding to that dimension. Each dimension receives a score according to the degree of adequacy observed: adequate = 2 points; partially adequate =

1 point; and inadequate = 0 points. The sum of the points assigned to all areas allows the care provided in MPHC to be classified in terms of its safety: 0 to 12 points - unsafe care; 13 to 25 points - partially safe care; and 26 to 38 points - safe care.

It is recommended that these tools be applied periodically to promote continuous assessment of safe nursing care for people with mental disorders in MPHC, contributing to the identification and correction of opportunities for improvement in the unit, as well as to strengthening the institutional safety culture.

Regarding the validity process, it was carried out electronically and conducted using the Delphi technique, in two rounds, as suggested by Skulmoski *et al.*,⁽²¹⁾ who recommend two to three rounds to achieve consensus or saturation, especially in homogeneous samples. It should be noted that, in this study, the first round was called Delphi I, and the second round, Delphi II.

In the protocol validity stage, they must reach the number of judges recommended by Pasquali,⁽¹⁶⁾ i.e., from six to 20 judges. This process was guided by the analysis of experts selected for the research, through the assessment of CVs on the *Lattes* Platform of the Brazilian National Council for Scientific and Technological Development (<http://lattes.cnpq.br/>). The population consisted of 325 judges/experts/specialists on the topic. The initial sample consisted of 60 researchers who met the criteria pre-established by Fehring,⁽²²⁾ adopting a minimum score of five points for professionals to be included in the research (Chart 1).

It should be noted that feedback was provided to experts between Delphi I and II, including a

summary of means, qualitative suggestions, justification for the changes, and an invitation to reassess. Therefore, feedback was provided to judges, always preserving participant anonymity, in order to avoid group bias.

These judges received an email invitation, along with the Informed Consent Form and instructions for analyzing and assessing the protocols, and had up to 20 days to respond. The validity instrument was developed using Google Docs® and contained information on participant characteristics, graphic algorithms, and corresponding guidelines. At the end of each protocol, a space was provided for these experts to record suggestions for modifications and improvements.

Judges who did not respond or declined to participate were automatically excluded from the study. Therefore, the final Delphi I sample included 23 judges, a stage in which changes to the graphic protocol and checklist were recommended for improvement. After analyzing the Delphi I data and reformulating the graphic protocol and checklist in accordance with recommendations of consulted experts, a new electronic form containing all adjustments made was developed and submitted for a second round of assessment (Delphi II), in which 18 judges participated. Completing the form took an average of 40 minutes, and once the assessment process began, it could not be interrupted.

The data collection instrument was constructed using Google Forms®, composed of four parts: 1) judge characterization, with guarantee of their anonymity; 2) management graphic protocol and checklist content relevance analysis based on the criteria established by Pasquali,⁽¹⁶⁾ such as behavior,

Chart 1. Adaptation of the expert scoring system based on Fehring's content validity model

Fehring's criteria	Points	Adapted criteria	Adapted points
Master's degree in nursing	4	Master's degree in nursing or related field (required)	0
Master's degree in nursing - dissertation with content relevant to the clinical field	1	Master's thesis in MPHC and/or mental health and/or PS	2
Publications and research related to diagnostics	2	Research, published in the last four years in MPHC and/or mental health and/or PS	3
Article published in the field of diagnostics in an indexed journal	2	Articles published in a reference journal, in the last four years, in MPHC and/or mental health and/or PS	2
Doctoral degree in diagnostics	2	Doctoral degree in MPHC and/or mental health and/or PS	4
Practical clinical experience in nursing in a medical clinic lasting at least one year	1	Minimum of two years' practical experience in MPHC and/or mental health and/or PS	2
Certificate in clinical medicine accompanied by clinical practice	1	Specialization in MPHC and/or mental health and/or PS	1
Maximum score	14	Maximum score	14

objectivity, simplicity, clarity, relevance, accuracy, variety, modality, typicality, credibility, breadth, and balance. It should be noted that there was a table explaining each of these 12 criteria, and they were assessed using a Likert scale. Regarding the assessment of judges'/experts' agreement index, a 5-point Likert scale was applied, where: 1 - inadequate (I), classified as the degree of disagreement; 2 - partially adequate (PA); 3 - not sure (N); 4 - adequate (A); 5 - totally adequate (TA); 3) protocol and checklist appearance judgment, carried out according to revised Suitability Assessment of Materials (SAM) criteria,⁽²³⁾ such as content, language, illustrations, layout, motivation, and culture. The same five items from the second part of this instrument were used for assessment; 4) graphic protocol and checklist assessment as a whole (does it meet its proposed objectives and is its use/application in MPHC recommended), with alternatives "yes" or "no".

The data were analyzed using descriptive statistics (absolute and relative frequencies, minimum, maximum, mean, median, and standard deviation).

To assess the graphic protocol and checklist content and appearance, the scores attributed to each item in judges' assessments were verified, considering Pasquali's criteria for content validity and adapted SAM criteria for appearance validity.^(16,23)

Item relevance was determined by applying the Content Validity Coefficient (CVC). CVC values were calculated using the formula suggested by Hernandez-Nieto, which determined the CVC for each adapted Pasquali criterion, for each adapted SAM criterion, and the total CVC of the protocol and checklist. Items were considered valid if they presented more than 80% agreement among judges (assessed as adequate) and a $CVC > 0.80$. It is noteworthy that the CVC was applied to all items individually, and for appearance criteria validity, the CVC was also used, as recommended by SAM analysis.⁽²³⁾ Consensus among judges and CVC scores were achieved using the Delphi technique in two rounds of assessment.

It should be noted that external validity of the graphic protocol has not yet been conducted, given that it is an instrument still under development. Only after its implementation will it be possible to

conduct a new assessment and, if necessary, make appropriate adjustments.

The research was approved by a Research Ethics Committee of a Brazilian federal university, under Opinion 6,260,550 (Certificate of Presentation of Ethical Consideration 67841422.1.0000.5545). This is a subproject of a "multimethod" research project entitled "*SAMU 192: avaliação, organização, capacitação e construção de protocolos e bundles*".

Results

When preparing the protocols, the changes made focused mainly on aspects related to simplicity, objectivity and clarity, relevance and variety (with appropriate language that favors the interactivity of the content), modality (appropriate vocabulary, without generating ambiguities), and typicality (use of terms consistent with the theme and pertinent concepts).

For clarification purposes, instructions were developed for applying the graphic management protocol to assess safe nursing care for people with mental disorders in primary care settings. The protocol (Appendix 2) was divided into three parts: "structure of safe care for people with mental disorders in primary care settings", "process of safe care for people with mental disorders in primary care settings", and "structure of safe care for people with mental disorders in primary care settings." The graphic representation organized possible actions, decisions, and outcomes in a clear and easily understandable manner.

To apply the protocol, we recommend consulting the checklist (Appendix 3), designed to support a comprehensive analysis of established requirements. Initially, each checklist dimension should be assessed for the presence or absence of the requirements described therein. A dimension is considered adequate when 100% of the items receive a "yes" answer; partially adequate when affirmative responses correspond to the range of 50% to 99.9%; and inadequate when the compliance percentage is less than 50%. Thus, each dimension receives a score corresponding to the level of adequacy of items, ranging from zero

to two points: adequate = 2, partially adequate = 1 and inadequate = 0. The sum of the scores attributed to the dimensions allows for the overall assessment of nursing care safety provided to people with mental disorders with MPHIC, being classified as safe (26 to 38 points), partially safe (13 to 25 points) or unsafe (0 to 24 points).

After the protocol was developed, the content and appearance validity process began. In the first round, 23 nurses participated, including ten doctoral degree and 13 master's degree holders, all with at least two years of healthcare experience. As for their current field of work, the majority work in healthcare (52.17%), followed by PHC management and/or mental health (34.47%), and teaching and research (13.36%). In relation to gender, in both rounds, five nurses were male. It is noteworthy that we did not obtain participation from any judge(s) from northern Brazil. Experts' minimum age was 26 years, and the maximum was 58 years (mean=32.12 and standard deviation=6.75 in Delphi I; mean=35.71 and standard deviation=7.80 in Delphi II), whose mean training time was 10.20 years (standard deviation=5.81 in Delphi I; mean=12.64 and standard deviation=5.84 in Delphi II).

After the first Delphi stage, judges' comments regarding the protocol and checklist were analyzed. Suggestions deemed relevant were incorporated into the material, which was then resubmitted for further assessment with the appropriate modifications. Proposals that were not accepted were returned to judges along with the corresponding justification for their non-implementation.

After the first Delphi stage, judges' comments regarding the protocol and checklist were analyzed. Suggestions deemed relevant were incorporated into the material, which was then resubmitted for further assessment with the appropriate modifications. Proposals that were not accepted were returned to judges along with the corresponding justification for their non-implementation.⁽¹⁰⁾ Another example was in item 4, which addresses ambulance infrastructure (patient care location), as, after recommendation, a nine-line question became objective and clear: Is there psychotropic medication in the Basic Life Support vehicle? (Table 1).

Table 1. Consensus among judges regarding the graphic protocol and checklist dimension and item content in Delphi I and II

Items assessed	CVC		Agreement %	
	Delphi I	Delphi II	Delphi I	Delphi II
Behavior	0.80	1.0	100	100
Objectivity	0.80	0.92	100	100
Simplicity	0.76	1.0	100	100
Clarity	0.76	0.97	100	100
Relevance	0.90	1.0	100	100
Feasible	0.74	1.0	86.9	100
Modality	0.80	1.0	100	100
Precision	0.84	1.0	73.9	100
Credibility	0.80	1.0	100	100
Variety	0.84	1.0	86.9	100
Typicality	0.80	0.92	91.3	100
Balance	0.76	1.0	100	100
Mean	0.80	0.98	94.9	100

*CVC - Content Validity Coefficient

As shown in Table 1, it was found that, in the first stage of content validity, only simplicity (CVC=0.76), clarity (CVC=0.76), feasible (CVC=0.74), and balance (CVC=0.76) did not reach a CVC above 0.80. Nevertheless, the initial stage resulted in a final agreement of 94.9% between the instruments. Regarding appearance validity, in the first round, an agreement of 96.5% was obtained, although illustrations (CVC=0.74) and layout (CVC=0.74) did not reach a minimum CVC of 0.80 (CVC=0.76). After adjustments, the final CVC reached 0.90 for appearance validity. Thus, the overall estimate of the instrument was CVC=0.80 in Delphi I and CVC=0.98 in Delphi II (Table 2).

Table 2. Consensus among judges in the Delphi I and II stages regarding the items for assessing the graphic protocol and checklist appearance according to the Suitability Assessment of Materials (adapted)

Items assessed	CVC*		Agreement %	
	Delphi I	Delphi II	Delphi I	Delphi II
Content	0.86	1.0	100	100
Language	0.80	1.0	82.6	100
Illustrations	0.74	1.0	82.6	100
Layout	0.74	0.90	82.6	100
Culture	0.90	1.0	100	100
Media	0.80	0.98	89.5	100

*CVC - Content Validity Coefficient.

In conclusion, no objections were recorded from the judges regarding the recommendation to use the graphic management protocol to assess safe nursing care for individuals with mental disorders in MPHIC. It is noteworthy that, in Delphi

II, 100% presented the recommendation, with no need for adjustments being identified. It is worth noting that external validity of the graphic protocol and checklist has not yet been performed; however, it is possible to conduct it based on the Delphi method literature.

Discussion

The development and assessment of a protocol and checklist for assessing safe nursing care for people with mental disorders in MPHC is crucial, as it identifies the requirements for safe care for these patients, based on legal regulations and scientific evidence that foster continuous improvement. Assessing indicators related to this care is crucial due to the importance of the care provided by nursing professionals, while also considering the vulnerability of patients, who have specific needs in terms of structure and processes, in addition to the high risk of adverse events.⁽¹⁵⁾

Studies indicate that one of the challenges in PS is the development and implementation of tools and strategies that allow organizations to measure and reduce harm inside and outside healthcare institutions, continuously and routinely.^(15,24) In this context, the use of valid instruments to assess PS is essential to identify sources of problems that may cause failures, enabling the recognition of issues and the search for solutions. These instruments have been successfully applied in various contexts.⁽²⁴⁾

Therefore, content and appearance validity processes are essential to guarantee the reliability of these instruments, aiming to make them safe for use in the services for which they are intended.^(2,15) To this end, the application of Fehring's criteria, adapted for this study, facilitated the selection of judges with experience in teaching, research, and healthcare, which was crucial to the validity process, ensuring the reliability of tools in such a specialized field. Studies highlight the importance of master's and doctoral degrees in developing research that can influence healthcare practices and thus contribute to the advancement of science.^(15,24)

It is important to emphasize that, although these instruments were developed and validated by nursing, the responsibility for harm-free care is shared by the entire multidisciplinary team. Nursing stands out as a partner in incident reduction because the provision and coordination of care are continuous, and the pursuit of safe care is intrinsically linked to their actions. This enables nurses and their teams to identify errors in conduct and processes early, helping to minimize potential harm.^(1,3,15,24)

Concerning the graphic protocol content and checklist items, it was observed that the organization, in accordance with PS goals, must and needs to guide that the requirements are met, as they are established nationally, in addition to directing the development of protocols for the prevention of risks associated with the care of people with mental disorders.

Thus, the instruments addressed the verification process, encompassing the local infrastructure for care delivery, the equipment and materials used in care, nursing records in medical records, staffing, continuing education, as well as the priority protocols of PS and their respective indicators. It is important to emphasize that the set of items must fully encompass the breadth and magnitude of the attribute being assessed.⁽¹⁴⁾ Thus, the validity of these criteria reinforces the relevance of a thorough analysis of the protocol developed to assess the safety of nursing care for people with mental disorders in MPHC.

Based on the initial draft, judges suggested relevant modifications for safe care of individuals with mental disorders treated in MPHC, as well as adjustments related to objectivity, simplicity, clarity, relevance, and appropriate language. This also allowed for the inclusion of elements related to neonatal mental healthcare. Thus, for the "structure" component, all questions were guided by current legislation and related literature, aiming to assess the minimum requirements for running MPHC.

In the "process" element, recommendations were made for expanded scrutiny of safety practices in MPHC regarding ethics in the care of individuals with mental illness, as well as best practices in effective communication between nursing professionals, patients, and family members. The role of various contributing factors across the broader system was

highlighted, including changes in national care guidelines, communication issues, and active failures. These accumulated risks, which successfully bypass the system's built-in defenses, are represented throughout the patients' care journey.⁽¹⁾

For the "outcome" element, an indicator related to matrix support, which is an organizational arrangement and interprofessional work model, was included. Transforming care practices for individuals in psychiatric emergencies and urgent care settings in MPHC also depends on the engagement of federal, state, and municipal managers of the Brazilian Health System in implementing new management arrangements for the necessary coordination between services that replace psychiatric hospitals, such as Psychosocial Care Centers and Therapeutic Residences, and the Primary Healthcare network.⁽¹²⁾

As for the level of agreement regarding content and appearance, at the end of the assessments, it was observed that all criteria presented adequate outcomes, with scores above 80%. This data demonstrates alignment in opinions regarding the protocol's relevance and its contribution as an assessment tool for MPHC units. Thus, it can be inferred that participants reached consensus on the protocol and checklist validity, which effectively address the criteria necessary to measure safe care.

During Delphi I, for content validity, it was identified that the sentences needed to be adjusted to use expressions compatible with the attribute. This resulted in the need to modify the content so that it could be revalidated and classified as applicable.⁽²¹⁾

Regarding face validity, the initial assessment revealed a lower-than-recommended level of agreement for the "language" component, specifically in the "attractive and non-tiring sentences" and "text clarity and objectivity" domains. This outcome may indicate limitations in the instrument's comprehension, with direct repercussions on its interpretation and, consequently, its use. Given this scenario, the changes suggested by judges were incorporated with the aim of achieving an adequate level of agreement.

Finally, the percentage of judges who considered the protocol and checklist useful tools for assessing safe nursing care for people with mental disorders in primary care settings was satisfactory. In the first

Delphi round, 82.3% of experts recommended using/applying the protocol in primary care settings for people with mental disorders. In the second round, there were no objections to the protocol's use, and 100% of participants stated that, after the modifications made, it met its proposed objectives.

It is evident that psychiatric emergencies require immediate intervention and, due to the lack of similar protocols in Brazil, this graphic protocol can be a tool for managing safe nursing care for people with mental disorders in MPHC.

The main limitations of this study are the specificity of the topic, which was restricted to the assessment of safe nursing care for people with mental disorders in MPHC, in addition to the non-application of the graphic protocol and checklist in the field and a possible homogeneous composition of the sample of specialists, aspects that may restrict the generalization of results.

Therefore, further research is suggested to develop and validate instruments that integrate the multidisciplinary dimension. However, this study will significantly contribute to improving safe nursing care for individuals with mental disorders in MPHC.

Conclusion

The proposed graphic protocol and checklist for assessing safe care for people with mental disorders in MPHC are considered reliable and valid in terms of content and appearance, ready for clinical validity in SAMU practice. It is emphasized that periodic assessment of services and proposing improvements, using technological resources such as the protocol and checklist, is extremely important to make healthcare institutions as safe as possible. Further research on this topic is essential to expand knowledge about PS in São Paulo and MPHC, contributing to ensuring quality care.

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Collaborations

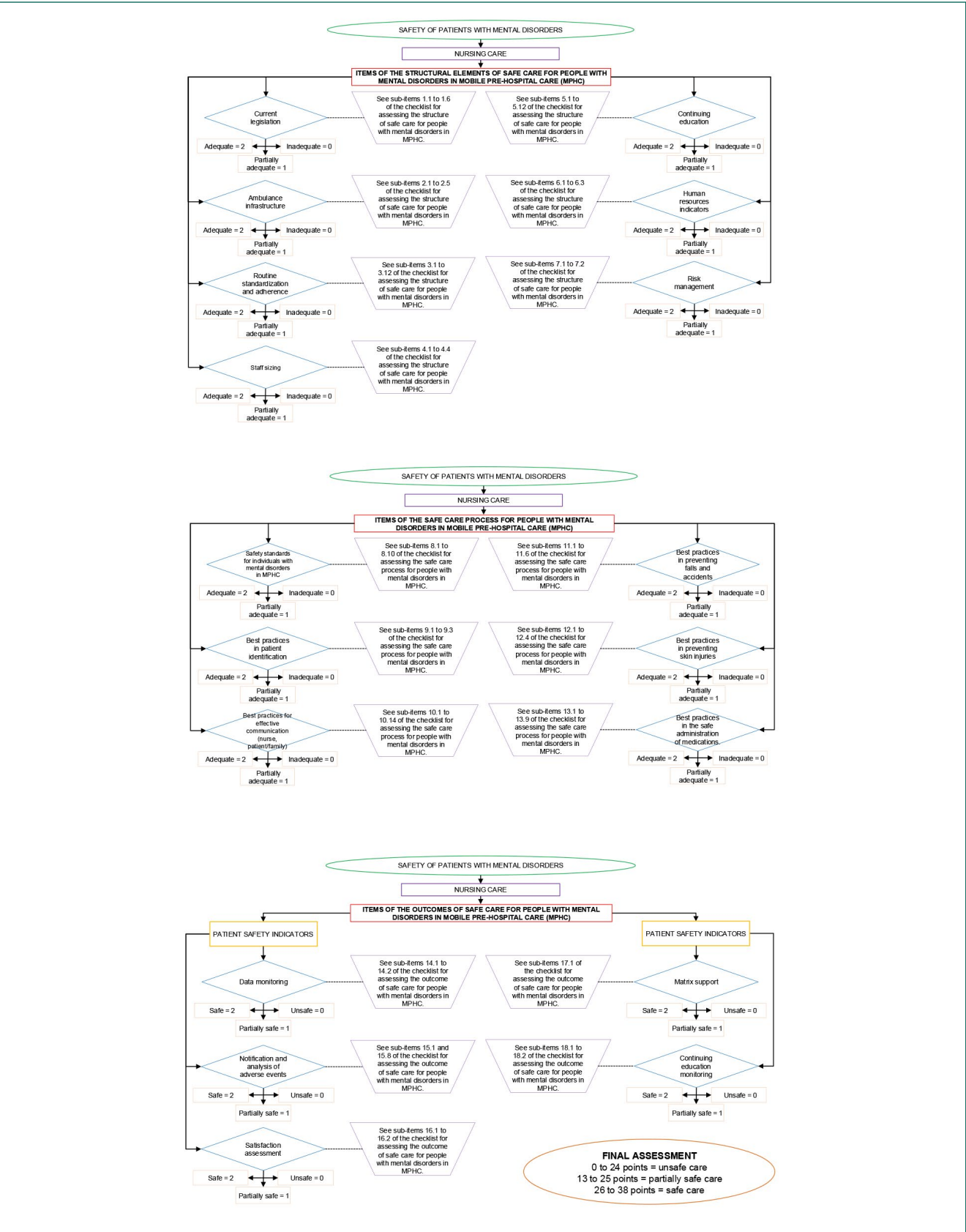
Pena L, Cortez DN, Machado RM, Santos LM, Fonseca DF, Barichello E, Santos VEP, Oliveira PP declare that they contributed to the project design, data interpretation, relevant critical review of intellectual content and approval of the final version to be published.

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Appendix 1. References used as the basis for constructing the protocol

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Appendix 2. Graphic management protocol for assessing safe nursing care for people with mental disorders in mobile pre-hospital care

Appendix 3. Checklist for assessing safe care for people with mental disorders in mobile pre-hospital care

Checklist for assessing safe care for people with mental disorders in mobile pre-hospital care			
Structural element			
Items	Sub-items	Yes	No
1. Current legislation	1.1 Is the operating license issued by the competent health agency?		
	1.2 Is there an Occupational Health Medical Control Program?		
	1.3 Does the company providing services for the disposal of Healthcare Waste have an environmental license? (Resolution 358/2005)		
	1.4 Does the service meet the qualification requirements by presenting the SAMU 192 regional action plan, a declaration of operation of any software that guarantees call reliability, among other things? (See Ordinance 1010/2012 - Art. 28)		
	1.5 Are there service indicators that allow the Ministry of Health to assess its operation? (Ordinance 1010/2012 - Art. 2)		
	1.6 Does the service use the response time parameter for planning, implementing, and implementing regionalization, internalization, and expanded access to SAMU 192?		
2. Ambulance infrastructure (patient care location)	2.1 Do ambulance specifications comply with ABNT standards? (NBR 14561/2000)		
	2.2 Do ambulances have mechanical restraint straps made of durable material, reinforced stitching, washable, easy to handle, and appropriate width (10 cm for limbs and 20 cm for chest)? (Basic Life Support and Advanced Life Support Protocols - 2016)		
	2.3 Is the condition of ambulances constantly assessed?		
	2.4 Is the ambulance cleaned according to institutional protocol?		
	2.5 Is psychotropic medication available in the Basic Life Support ambulance?		
3. Standardization and compliance with routines	3.1 Do nursing professionals always wear uniforms and Personal Protective Equipment (PPE)?		
	3.2 Are materials and medications checked daily by the nursing team?		
	3.3 Is there a tool for checking and controlling materials and equipment?		
	3.4 Is there an institutional protocol focusing on psychiatric emergencies for nurses working at the Emergency Regulation Center?		
	3.5 Does the interventional nursing team provide care based on the specific guidelines for psychiatric emergencies described in the national protocol (Basic Life Support and Advanced Life Support Protocols/2016)?		
	3.6 Are existing protocols kept in easily accessible locations?		
	3.7 Are institutional protocols updated every two years?		
	3.8 Are quick-reference guidelines available on an institutional app?		
	3.9 Is there a standard operating procedure describing the procedures related to the management of Healthcare Waste (HSW) regarding generation, segregation, packaging, identification, collection, storage, transportation, treatment, and environmentally appropriate final disposal?		
	3.10 Is information related to the care provided to patients with mental disorders secured and stored, through mandatory registration on a care record (physical or electronic), with the stamp of the professional responsible for the care?		
	3.11 Is a copy of the record of the care provided to patients with mental disorders attached to the medical records of the receiving health unit?		
	3.12 Is there systematic communication between the mobile pre-hospital care nursing team and the in-hospital care team regarding the care provided to patients with mental disorders?		
4. Staffing	4.1 Is a nurse technically responsible for managing care and the organizational structure? (COFEN Resolution 713/2022)		
	4.2 Has the nurse been included in the Emergency Regulation Center as a member of the multidisciplinary team? (COFEN Resolution 713/2022)		
	4.3 Are Ground Basic Life Support Units staffed by at least one emergency vehicle driver and one nursing technician?		
	4.4 Are Ground Advanced Life Support Units staffed by at least three professionals: one emergency vehicle driver, one nurse, and one physician?		
5. Continuing education	5.1 Are there ongoing training and education programs in mental health in the form of in-service training?		
	5.2 Does the service have multiplier teams from the Emergency Education Center prepared to provide instruction related to psychiatric emergencies in decentralized regions?		
	5.3 Does the service have a team of qualified mental health instructors and multipliers who produce constantly updated teaching materials?		
	5.4 Are there laboratories for teaching health procedures as part of the Emergency Education Center? (Ordinance 1864/2003)		
	5.5 Do the instructors and multipliers of the Emergency Education Center have pedagogical training with certification in active methodologies?		
	5.6 Are there training programs based on problem-solving and practical activities through realistic simulations aimed at psychiatric emergencies?		
	5.7 Is there annual certification and recertification every two years for professionals working in emergency care?		
	5.8 Is there initial training covering topics, content, skills, and a minimum workload specific to the nursing professional category? (Ordinance 2048/2002)		
	5.9 Is there specific training addressing the topic of mental emergencies, including psychosis, suicide attempts, depression, and organic brain syndromes?		
	5.10 Is there at least one annual course addressing patient safety?		
	5.11 Is there ongoing education regarding the Psychosocial Care Network?		
	5.12 Is there education/training based on incidents that have occurred in the care of patients with mental disorders to prevent recurrences?		
6. Human resources indicators	6.1 Are all nursing staff members' work hours covered per hour/shift?		
	6.2 Does the service have control over nursing staff turnover and absenteeism?		
	6.3 Does the service have control over nursing staff's contractual relationships?		
7. Risk management	7.1 Are all adverse events related to the care of patients with mental disorders reported?		
	7.2 Does the service have a Patient Safety Center?		

Process element			
Items	Sub-items	Yes	No
8. Safety standards for people with mental disorders in mobile pre-hospital care	8.1 When approaching the scene of an incident, is the siren turned off and only the light signals remain on (no flashing or strobe lights)?		
	8.2 Does the nursing team perform the three steps for scene assessment? (What is the situation? Where might the situation evolve? How can the situation be controlled?) (Basic Life Support and Advanced Life Support Protocols/2016).		
	8.3 Does the nursing team use the ACENA method to manage mental health crises? (Basic Life Support and Advanced Life Support Protocols/2016).		
	8.4 When encountering an unsafe scene, does the nursing team recognize the need to request the Emergency Regulation Center to activate other actors (firefighters and military police)?		
	8.5 Is equipment and materials securely secured/stored inside the ambulance?		
	8.6 Does the nursing staff properly dispose of sharps? (Do they use their own sharps disposal container? Dispose of sharps when it reaches 2/3 of its capacity. Do they not leave the container on the floor or loose on the ambulance counter?)		
	8.7 Does the nursing staff perform mechanical restraint for patient protection?		
	8.8 Is the nursing staff aware of the ethical aspects of physical and mechanical restraint? (CFM Resolution 1952/2010 and COFEN Resolution 427/2012)		
	8.9 Is the mechanical restraint procedure performed only when the minimum number of professionals required (five people) is available?		
	8.10 During the initial assessment, does the nursing staff assess potential clinical conditions associated with altered mental status?		
9. Best practices in patient identification	9.1 Does the nursing staff identify patients with mental disorders in the care record with two or more pieces of information, including full name without abbreviations, accompanied by full address, date of birth, and/or a document?		
	9.2 Does the nursing staff actively search for documents in the belongings of patients with mental disorders who are confused or unable to provide information and are unaccompanied?		
	9.3 In the absence of identification documents, does the nursing staff describe in detail in the care record two or more personal characteristics (gender, ethnicity, clothing, and location where the patient was found) of patients with mental disorders?		
10. Best practices in effective communication between nursing professionals, patients and family members	10.1 Does the nursing team use closed-loop communication?		
	10.2 Does the nursing team systematically hand over the clinical and psychiatric conditions of patients with mental disorders during the transition of care to the receiving unit?		
	10.3 Does the nursing team properly complete the patient care record for patients with mental disorders and deliver a copy to the receiving unit?		
	10.4 Does the receiving nurse/physician at the receiving unit record the patient care record for patients with mental disorders?		
	10.5 Is there communication between the intervention team and the Regulatory Center regarding psychomotor agitation, aggression, or post-sedation decline in consciousness among patients with mental disorders?		
	10.6 Does the nursing team use understandable language to communicate with patients with mental disorders and their families?		
	10.7 Is there communication with patients with mental disorders and/or their families regarding all procedures and referrals to be made?		
	10.8 Is there verbal de-escalation in the care process for patients with mental disorders?		
	10.9 During verbal interventions with patients with mental disorders, is only one mediator selected, considering the possibility of replacing them?		
	10.10 When approaching a suicide attempter, does an attempt to identify current events, people, and other stressors that may have precipitated the crisis?		
	10.11 Does the nursing team approach the topic of self-harm and/or suicide risk, demonstrating a caring attitude and, most importantly, avoiding judgment or pressuring the patient to provide details of the situation?		
	10.12 When approaching a suicide attempt, does the team assess the presence of risk and protective factors through mediation?		
	10.13 During the transfer of patients with mental disorders, does the nursing team avoid discussing new topics in the ambulance to avoid unexpected reactions, seeking only to respond to the patient's requests and reiterating a helpful/supportive attitude, never leaving the patient unanswered?		
	10.14 Does the Mobile Emergency Care Service work with other care centers in the Psychosocial Care Network to develop the Singular Therapeutic Project and ensure continuity of care?		
11. Best practices in preventing falls and accidents	11.1 Does the team bring the retractable stretcher as close as possible to the location of the patient with mental illness to avoid long transport on the stretcher?		
	11.2 On the stretcher, are patients with mental illness secured with at least three safety belts at different points?		
	11.4 Are there protective measures (rails and belts) to ensure the safety of patients with mental illness during transport?		
	11.5 When transporting patients with mental illness who are agitated, physically restrained, or at high risk of falling, is the stretcher always lowered?		
	11.6 Is there a note in the care record of patients with mental illness when there is a risk of falling?		
12. Best practices in preventing skin lesions	12.1 On long boards, are cushions used at the points most susceptible to pressure?		
	12.2 During prolonged transport of patients with mental disorders, are they positioned differently and are cushions or protection used in at-risk areas of the body?		
	12.3 Is mechanical restraint used as a last resort to prevent harm to patients with mental disorders and/or other disorders after verbal and chemical restraints have been attempted?		
	12.4 Is clinical monitoring of the level of consciousness, vital signs, skin conditions, and circulation in the restrained areas and limbs of patients with mental disorders performed?		

13. Best practices in the safe administration of medications	13.1 Does the nursing team check the medication backpack daily?		
	13.2 Does the medication label include the name, dose, volume, route of administration, expiration date, and appearance?		
	13.3 Do nursing professionals check whether a patient has taken the medication?		
	13.4 Do nursing professionals perform the nine-rights technique (right patient, right medication, right dose, right time, right route of administration, right documentation, right action, right form, and right response) when treating patients with mental disorders?		
	13.5 Are high-alert medications correctly identified with specific labels or warnings?		
	13.6 In cases of psychomotor agitation in patients with mental disorders, are pharmacological measures used only when non-pharmacological approaches fail, avoiding excessive sedation?		
	13.7 Are patients with mental disorders monitored after using medications for psychomotor agitation?		
	13.8 Are aseptic materials and techniques used when administering parenteral medications to patients with mental disorders?		
	13.9 Is positive information about allergies to any medication highlighted in the medical records of patients with mental disorders?		

Outcomes element			
Items	Sub-items	Yes	No
14. Data monitoring	14.1 Does the service monitor the number of chemical and mechanical restraints used on patients with mental disorders on a monthly basis?		
	14.2 Does the Mobile Emergency Care Service keep track of the number of psychiatric incidents that received support from the fire department and Military Police?		
15. Reporting and analysis of adverse events	15.1 Does the service monitor and analyze adverse events related to chemical and mechanical restraints?		
	15.2 Does the service report and analyze adverse events related to the transport of patients with mental disorders?		
	15.3 Are falls among patients with mental disorders reported and analyzed?		
	15.4 Are events related to medication errors among patients with mental disorders reported and analyzed?		
	15.5 Does the service report and monitor any accidents involving professionals or patients during psychiatric care?		
	15.6 In the event of a reportable event involving patients with mental disorders, are they and their families informed?		
	15.7 Are episodes of hetero-aggression and self-aggression among patients with mental disorders reported?		
16. Satisfaction assessment	15.8 Are episodes of suicide and suicide attempts reported?		
	16.1 Is the satisfaction of patients with mental disorders and their families assessed, including items related to the humanization of care provided?		
	16.2 Are ombudsman cases related to care for patients with mental disorders investigated and addressed with the team?		
17. Matrix support	17.1 Did the Mobile Emergency Care Service participate in matrix meetings in the last year?		
18. Continuing education monitoring	18.1 In the last year, have any training sessions been held on mental health emergencies?		
	18.2 In the last year, have any training sessions been held integrating the Mobile Emergency Care Service, Fire Department, and Military Police teams?		