



DEVELOPMENT AND VALIDATION OF A CHECKLIST FOR THE SAFETY OF HOSPITALIZED CHILDREN

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ABSTRACT

Objective: to develop and validate a checklist of safety actions for hospitalized children.

Method: a methodological research study carried out from March 2017 to March 2020 in two phases: 1) Identification of the themes and elaboration of the checklist through the literature review; 2) Content validation with expert judges by means of the Delphi technique, applying the Content Validity Index (CVI), accepting values >0.8 for the CVI per item and >0.9 for the checklist. The data collection instrument was organized using an ordinal progressive valuation scale, of the Likert type. The content validation stage was performed in three rounds using a Google Forms® electronic form. Fifteen experts participated in the survey in the first round and 14 in the second and third rounds. The statistical analysis of the data was performed with the aid of Google Forms® and of the Excel® software, and the results were presented descriptively and in a table.

Results: the final version of the checklist consisted of 6 categories and 23 check items, validated with a Content Validity Index of 0.98. The checklist was also validated in relation to the objectives (0.95) and to the structure and presentation (0.98).

Conclusion: validation of the content, objectives, structure and presentation of the checklist allows this tool to be implemented in any pediatric hospitalization unit, contributing to the care practice aimed at the safety of hospitalized children.

DESCRIPTORS: Patient safety. Validation studies. Checklist. Hospitalized child. Children's health. Pediatric Nursing.

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ELABORAÇÃO E VALIDAÇÃO DE LISTA DE VERIFICAÇÃO PARA A SEGURANÇA DA CRIANÇA HOSPITALIZADA

RESUMO

Objetivo: elaborar e validar uma lista de verificação de ações de segurança para a criança hospitalizada. **Método:** pesquisa metodológica realizada no período de março de 2017 a março de 2020 e desenvolvida em duas fases: 1) Identificação dos temas e elaboração da lista de verificação por meio da revisão de literatura; 2) Validação de conteúdo com os juízes especialistas por meio da técnica Delphi, mediante a aplicação do Índice de Validade de Conteúdo (IVC), aceitando-se o valor de >0,8 para o IVC por item e de >0,9 da lista de verificação. O instrumento de coleta de dados foi organizado por meio de uma escala ordinal de valoração progressiva, tipo *Likert*. A etapa de validação de conteúdo foi realizada em três rodadas por meio do formulário eletrônico Google Forms®. Participaram da pesquisa 15 especialistas na primeira rodada e 14 na segunda e terceira rodadas. A análise estatística dos dados foi feita com o auxílio do Google Forms® e do *software* Excel® e os resultados apresentados na forma descritiva e em tabela.

Resultados: a versão final da lista de verificação foi composta por 6 categorias e 23 itens de checagem, sendo validada com Índice de Validade de Conteúdo de 0,98. A lista de verificação também foi validada em relação aos objetivos (0,95) e à estrutura e apresentação (0,98).

Conclusão: a validação do conteúdo, dos objetivos, da estrutura e apresentação da lista de verificação permite que essa ferramenta seja implementada em qualquer unidade de internação pediátrica, contribuindo para a prática assistencial voltada à segurança da criança hospitalizada.

DESCRITORES: Segurança do paciente. Estudos de validação. Lista de checagem. Criança hospitalizada. Saúde da criança. Enfermagem pediátrica.

ELABORACIÓN VALIDACIÓN DE UNA LISTA DE VERIFICACIÓN PARA LA SEGURIDAD DE NIÑOS HOSPITALIZADOS

RESUMEN

Objetivo: elaborar y validar una lista de verificación con medidas de seguridad para niños hospitalizados. **Método:** investigación metodológica desarrollada de marzo 2017 a marzo 2020 en dos fases: 1) Identificación de los temas y elaboración de la lista de verificación por medio de la revisión de la literatura; 2) Validación del contenido a cargo de evaluadores especialistas por medio de la técnica Delphi, aplicando el Índice de Validez de Contenido (IVC), y aceptando valores de >0,8 para el IVC por ítem y de >0,9 para la lista de verificación. El instrumento para recolectar los datos se organizó por medio de una escala ordinal de valoración progresiva, del tipo *Likert*. La etapa de validación del contenido se realizó en tres rondas por medio de un formulario electrónico de Google Forms[®]. 15 especialistas participaron en la primera ronda de la investigación, y 14 en la segunda y en la tercera ronda. El análisis estadístico de los dados se llevó a cabo con la ayuda de Google Forms[®] y del *software* Excel[®] y los resultados se presentaron en forma descriptiva y en una tabla.

Resultados: a versión final de la lista de verificación estuvo compuesta por 6 categorías y 23 ítems de verificación, siendo validada con un Índice de Validez de Contenido de 0,98. La lista de verificación también fue validada en relación con los objetivos (0,95) y con su estructura y presentación (0,98).

Conclusión: la validación del contenido, de los objetivos, de la estructura y de la presentación de la lista de verificación permite implementar esta herramienta en cualquier unidad de hospitalización pediátrica, contribuyendo así para la práctica asistencial enfocada en la seguridad de los niños hospitalizados.

DESCRIPTORES: Seguridad del paciente. Estudios de validación. Lista de verificación. Niños hospitalizados. Salud infantil. Enfermería pediátrica.

INTRODUCTION

Patient safety is one of the attributes of care quality. This theme has been increasingly discussed, both nationally and internationally, with the development of policies aimed at promoting safe care that includes actions to prevent or reduce incidents in the health services¹.

In 2013, the National Patient Safety Program was instituted through Ordinance No. 529 with the objective of improving care quality, proposing, through basic patient safety protocols, several actions to prevent and/or reduce the occurrence of unnecessary harms to the patient². For the purposes of this Ordinance, the definition of patient safety was adopted as "reduction, to an acceptable minimum, of the risk of unnecessary harms associated with health care"^{2:2}.

Hospitalized children are in a situation of significant vulnerability to the occurrence of adverse events related to health care. However, in the Pediatric Nursing practice, development of a patient safety culture is observed in the provision of care to hospitalized children, as well as recommendations for strategies to promote safe care to this clientele³.

It is imperative that there is an increase in safe practices in pediatric units and investments by health institutions, both through their managers and health professionals, with implementation of strategies related to human resources, materials, equipment and continuing education, aiming to reduce the risks of patient safety incidents related to failures in health care, thus ensuring the development of safe care for hospitalized children⁴.

Given this context, interest in developing and validating a Checklist based on the basic patient safety protocols to prevent incidents related to the care of hospitalized children emerged, aiming to guide and direct Nursing professionals to adopt safe actions.

A checklist-type tool to verify the safety actions for hospitalized children can promote development of evidence-based safe practices and of the organizational safety culture and, consequently, identification and reduction of risks, errors and adverse events, from a situational diagnosis.

Considering, therefore, the nonexistence of an instrument for the verification, at the bedside, of pediatric patient safety actions and the importance of a tool aimed at improving the quality of care provided to this vulnerable clientele, this study was developed to answer the following research question: which items should comprise a checklist to validate an instrument that assesses the actions to prevent incidents and identify risks to hospitalized children?

To answer this question, the objective of the study was to develop and validate a checklist of safety actions for hospitalized children.

METHOD

This is a methodological research study, carried out from March 2017 to March 2020, on the elaboration and validation of the checklist, which was developed through content validity consisting of two phases: development of the instrument and evaluation of the instrument through experts' analysis⁵.

The research was carried out in two phases, divided into four stages: 1) Identification of the themes and elaboration of the checklist; 2) First content validation round with expert judges; 3) Second content validation round with expert judges; and 4) Third content validation round with expert judges, reaching consensus.

Initially, identification of the themes was carried out to compose the checklist in order to enable categorization and recording of the hospitalized children's safety indicators. The items for elaboration of the checklist were selected from the six basic protocols of the National Patient Safety Program, through a literature review and recommendations from national and international health organizations, with the objective of contributing to improving the quality of care provided to hospitalized children.

The basic patient safety protocols, which were the basis to develop the instrument, are the following: patient identification; safe surgery; pressure ulcer prevention; hand hygiene practice in health services; safety in the prescription, use and administration of medications; and prevention of falls².

For each title of the protocol, check items were elaborated to assess safety of the hospitalized children so that verification may be performed by a nurse with a bedside check.

The verification instrument (checklist) was called "Checklist for the Safety of Hospitalized Children - Bedside Check" and includes items that must be verified during the hospitalization period.

Therefore, the essential patient safety actions that take place during the Nursing care practice were identified, which can be observed and checked at the bedside, to minimize risks and/or avoid incidents at pediatric patient care points, in any hospitalization unit.

To select the study specialists aiming to validate the instrument's content, the following inclusion criteria were used: being a nurse; having a PhD degree; and having experience in teaching, research and/or assistance in the areas of children's health and patient safety.

It was decided to select nurses to validate the instrument because they have theoretical and practical contents in their academic training related to leadership of the Nursing team that is responsible for direct patient care. In addition to that, nurses play a fundamental role in care management, planning and implementation of good care practices.

The specialists were selected through the curriculum made available in the *Lattes* Platform of the National Council for Scientific and Technological Development (CNPq) portal, using the keyword "patient safety", associated with another keyword: "children's health" or "pediatric nursing".

Sampling was intentional, which occurs when the researcher purposely selects the participants because he/she understands that they have knowledge about the issues studied, a method that is widely used when the intention is to obtain a sample of experts⁶.

The search in the *Lattes* Platform, using the keywords "patient safety" and "children's health", resulted in 459 researchers, 18 of which were selected, and with the keywords "patient safety" and "pediatric nursing", 302 researchers were obtained, 36 of which were selected. Duplicates were excluded, resulting in a final selection of 41 researchers.

Subsequently, an electronic invitation via the *Lattes* Platform was sent to those selected to participate in the study, 19 answered and agreed to participate as expert judges.

The electronic form was developed by the researcher through the Google Forms® application for data collection and analysis. For development of the electronic form, a data collection instrument was elaborated. The experts who did not answer the electronic form within the deadlines set for each round were excluded from the study.

After each round, an email message was sent to each expert judge, with a report attached, describing the analysis of items, the results obtained and the items validated, removed or modified.

Fifteen experts participated in the study in the first round, 14 in the second and 14 in the third. One expert did not participate in the second round for not having answered the online questionnaire in a timely manner. The number of participants was in accordance with what is recommended in the literature, which indicates between 6 and 20 subjects⁵.

The data collection instrument consisted of two parts: 1) Characterization of the expert judges; and 2) Evaluation by the experts for content validation of the checklist.

The first part, referring to the characterization of the specialists, was carried out by obtaining the following information: gender; age; Brazilian region where the expert lives; professional training time; academic degree; current professional practice area; time as a specialist in the area of children's health; time of experience in the area of children's health care; time of experience in teaching in the area of children's health; participation in a research group or project in the area of patient safety; participation in scientific events in the area of patient safety; publication of articles in the area of patient safety.

The second part, referring to the evaluation by the experts for validation of the checklist content, was subdivided into four evaluation stages: 1) Actions related to pediatric patient safety described in the checklist; 2) Checklist objectives; 3) Structure and presentation of the checklist; and 4) Final evaluation of the checklist.

For stages I, II and III, the data collection instrument was organized using an ordinal progressive valuation scale, of the Likert type, with degrees of agreement from 1 to 4, where 1=Totally disagree, 2=Partially disagree, 3=Partially agree and 4=Totally agree. In stage IV, the instrument was organized in Yes/No questions.

To obtain the experts' consensus, the Delphi technique was used, which consists of a systematic method of judging information, used to obtain experts' consensus, focusing their judgments on a topic of interest, through validations articulated in sequential phases or rounds^{6–8}.

In this study, the Content Validity Index (CVI) was used as a quantitative method, which "measures the proportion or percentage of judges who agree on certain aspects of the instrument and its items. Initially, it allows analyzing each item individually and then the instrument as a whole"^{5:3065}.

The CVI per item (CVI-I) was calculated by the sum of agreement of the items that were classified as 3 or 4 by the experts, and the items that received a score of 1 or 2 were reviewed or removed⁵. For the minimum agreement, a Content Validity Index value per item (CVI-I) of 0.8 was considered.

To assess the instrument as a whole, the mean of the values of the individually calculated items was calculated⁵. This calculation was performed to obtain the Content Validity Index by category (CVI-C) and the Content Validity Index of the checklist (CVI-L). For the minimum agreement of the instrument as a whole, a CVI-C and CVI-L value of 0.9 was considered.

The statistical analysis of the data was performed using Google Forms® and the Excel® software. The results were presented descriptively and in a table.

The study was approved by the Research Ethics Committee of *Universidade Federal do Estado do Rio de Janeiro*. The expert judges who participated in the research signed the Free and Informed Consent Form (FICF).

RESULTS

Of the total number of experts who agreed to participate in the research, 15 were included in the sample from the first validation round, 14 in the second and 14 in the third.

Most of the specialists are female (85.7%), with a mean age over 40 years old, live in the Southeast region (57.1%), with a mean training time in the Nursing area over 20 years, having PhDs as their highest degree (85.7%); 14.3% have a post-PhD degree, acting mainly in teaching (92.9%), having worked in the areas of children's health (71.4%) and patient safety (50.0%) for more than 10 years and with participation in research studies (92.9%), scientific events (92.9%) and publication of articles in the area of patient safety (92.9%).

The specialists answered the online form containing items that assess the checklist in relation to the safety actions for hospitalized children, objectives, structure and presentation, and the final assessment.

Results of the evaluation by the expert judges in the validation rounds in relation to the safety actions for hospitalized children

Table 1 presents the patient safety actions, the content validity indices per item (CVI-I), per category (CVI-C) and of the checklist (CVI-L) after the three Delphi rounds. The results were subdivided into the following categories: 1 - Actions related to safety in the identification of pediatric patients; 2 - Actions related to safe hand hygiene practices; 3 - Actions related to safe surgery in Pediatrics (if the child is in the preoperative period); 4 - Actions related to safety in the intravenous administration of medications in Pediatrics; 5 - Actions related to the prevention of falls in Pediatrics; and 6 - Actions related to the prevention of pressure ulcers in Pediatrics.

Table 1 – Checklist actions and Content Validity Index after the three Delphi rounds. Rio de Janeiro, RJ, 2020. (n=14)

	Actions	CVI* per item
1	Actions related to safety in the identification of pediatric patients	
1.1	Identification through white bracelet.	0.93
1.2	The identification on the bracelet contains the patient's full name without abbreviations and at least another valid identifier.	1.0
1.3	The identification on the bracelet is legible.	1.0
1.4	If the patient is allergic, there is due identification using a standardized bracelet.	1.0
1.5	Use of another form of identification due to unavailability or lack of members to put the bracelet on the patient.	0.93
	CVI-C [†]	0.97
2	Actions related to safe hand hygiene practices	
2.1	Immediate access to alcohol-based preparations for hand hygiene at the point of assistance.	1.0

	Actions	CVI* per item	
	CVI-C†	1.0	
3	Actions related to safe surgery in Pediatrics (if the child is in the preoperative period)		
3.1	The patient (when possible) and the companion are instructed regarding the surgical procedure and about signing the assent/consent form.	1.0	
3.2	Preoperative fasting is established.	1.0	
3.3	No adornments.	1.0	
3.4	No soft teeth.	1.0	
3.5	Laterality of the demarcated surgical site.	1.0	
3.6	No nail polish.	1.0	
3.7	Clear intravenous access.	1.0	
	CVI-C†	1.0	
4	Actions related to safety in the intravenous administration of medications in	Pediatrics	
4.1	Intravenous infusions identified with the patient's full name without abbreviations and at least another valid identifier.	1.0	
4.2	Intravenous infusions identified with the name of the medication, administration route, doses or volumes, infusion rate, and date and time of infusion start.	0.93	
4.3	Equipment/Perfusors of intravenous infusions identified with the installation and change dates.	1.0	
4.4	Potentially dangerous medications highlighted with standardized color label on the vials/equipment/perfusors/burettes/syringes.	1.0	
	CVI-C†	0.98	
5	Actions related to the prevention of falls in Pediatrics		
5.1	The patient (when possible) and the companion are instructed regarding prevention of falls.	1.0	
5.2	Patient aged ≤ 3 years old accommodated in a crib with bars raised at maximum height.	0.93	
5.3	Patient aged > 3 years old accommodated in bed with bars raised at maximum height.	0.86	
5.4	The professional/companion (if there is no assistance from another person) keeps the opposite bed bar raised during the patient's clothes/diapers changes or hygiene.	1.0	
	CVI-C [†]	0.95	
6	Actions related to the prevention of pressure ulcers in Pediatrics. If the patient is sedated, immobilized or with very limited mobility, unable or very difficult to turn around alone in the bed		
6.1	Use of special mattresses.	1.0	
6.2	Use of cushions.	1.0	
	CVI-C†	1.0	
Checklist for the Safety of Hospitalized Children – Bedside Check			
	CVI-L‡	0.98	

^{*}Content Validity Index;† Content Validity Index per Category;‡ Content Validity Index of the Checklist.

In terms of the experts' opinion about the checklist objectives, the CVI-L was 0.95 after the third Delphi round. The experts agreed that the title of each category is appropriate for the safety actions for hospitalized children that are intended to be observed (CVI-I of 1.0); that the actions contemplate the context of the National Patient Safety Program adapted for pediatric inpatients (CVI-I of 1.0); that using the checklist can prevent incidents related to the care of hospitalized children (CVI-I of 0.93) and enables the identification of risks for incidents related to the care of hospitalized children (CVI-I of 0.93); that the checklist can be used in any pediatric hospitalization unit (CVI-I of 0.93); and that it verifies minimum actions related to the safety of hospitalized children (CVI-I of 0.93).

In relation to the experts' opinion on the structure and presentation of the checklist, the CVI-L was 0.98 after the third Delphi round. The experts agreed that the checklist is appropriate to be applied to hospitalized children (CVI-I of 0.93); that the actions are presented in a clear and objective manner (CVI-I of 1.0); that they are scientifically correct (CVI-I of 1.0); and that they are well structured in terms of agreement and spelling (CVI-I of 1.0).

As for the final assessment by the experts regarding the checklist, after the third Delphi round, 92.9% answered that there are no necessary items, but absent items; 85.7% stated that there are no unnecessary items; and 92.9% indicated that they did not wish to comment on the organization and presentation.

DISCUSSION

Patient safety, one of the attributes of health care quality, is of paramount importance in the pediatric area because it serves a highly vulnerable clientele. In addition to that, pediatric hospitalization units are technical and differentiated environments that require specific care and that can exert an impact on the care outcomes.

The care technology proposed in this study consists of the Checklist for the Safety of Hospitalized Children - Bedside Check, which should be used during the professional Nursing practice to ensure adherence to the good practices recommended by national and international organizations, something fundamental to promote safe and efficient care.

The validation stage was carried out in three rounds, which allowed refining and improving the checklist. Initially, the instrument listed 31 actions, categorized according to the national patient safety protocols. In the second round, the overall CVI would make the instrument validated with adjustments as it reached 0.92; however, in order to attain maximum agreement of the experts' answers, a new round was carried out with changes, inclusions and exclusions of items, and the instrument ended with 23 validated actions and an overall CVI of 0.98.

The category referring to safety in identifying pediatric patients was validated with a CVI-C of 0.97. A number of studies have shown that non-adoption of this practice and limitations in the process and technology result in inaccurate identification of patients, which may affect clinical decision-making and treatment, negatively interfering with the quality and safety of the care provided^{9–10}.

As for the safe hand hygiene practices, the category was validated with a CVI-C of 1.0, maintaining at the end of the rounds the action related to immediate access to alcohol-based preparations for hand hygiene at the assistance points. This result corroborates a study targeted at emergency units for adult patients that validated the "Is the alcohol-based solution close to the patient?" action with a 90% agreement rate¹¹.

Hand hygiene is considered a simple, low-cost and most effective measure to prevent dissemination of pathogenic microorganisms, spread of microbial resistance and reduction of HAIs. The implementation and promotion of compliance by the health professionals with safe hand hygiene practices have been the main concerns of current research studies on this topic. A number of studies have shown that compliance is still low in most care units and that it presents flaws in the process^{11–16}.

The category with items referring to safe surgery in Pediatrics ended with a CVI-C of 1.0, constituting effective and efficient actions for the safety of pediatric surgical patients and that can be adapted to other health care contexts.

In the preoperative phase, actions such as obtaining informed consent and confirming the patient's identity, the surgical site, demarcation of the site and the procedure to be performed must be implemented in order to avoid possible errors and adverse events^{17–19}.

A study carried out with pediatric surgical patients found items that were not performed by the team in more than 50% of the children and that could pose risks to the safety of these patients. Among these, identification of softened teeth stands out, which was not performed in 75% of the cases, as well as removal of adornments in 71.6%, preoperative bathing in 55% and laterality of the surgery in 78.3%¹⁸.

The category referring to safety in the intravenous administration of medications in Pediatrics was validated with a CVI-C of 0.98. The errors related to drug administration are among the most common incidents that occur in health institutions and, in children, the consequences can be even more serious due to the immaturity of the adaptive defense mechanisms and to their accelerated metabolism, with an almost immediate effect, not having sufficient time to correct the error²⁰.

Identification of the patient through two means and adoption of protocols and guidelines for the administration of medications are essential Nursing actions to minimize the occurrence of errors²¹.

The "prevention of falls in Pediatrics" category was validated with a CVI-C of 0.95. The occurrence of falls in health services is considered a public health problem because it increases hospitalization times and hospital costs, as well as the patients' discomfort, disability and distress²².

Falls in hospitalized children can occur due to the characteristics of the children themselves, the environment and the caregivers. A number of studies show that stress, anxiety, low schooling level, low level of attention and the caregivers' habits directly interfere in the care provided to hospitalized children^{23–24}.

A study carried out in a children's hospital implemented specific interventions based on scientific evidence to reduce the harms related to falls and resulted in an increase in compliance of the package of measures for falls, from 27% to 88%, and no notification of falls in five of the six months after implementing the prevention program²⁵.

In relation to the prevention of pressure ulcers in Pediatrics, this category was validated with a CVI-C of 0.95. With the technological and scientific advances, there has been a change in the profile of the patients who are assisted in the health services, requiring increasingly complex care and specific knowledge to ensure patient safety. However, despite the advances, the incidence of pressure ulcers is high, resulting in high costs for the health systems due to increases in the hospitalization times, in the risk of infections and in the need for care related to the treatment of these patients^{26–28}.

The use of support surfaces for pressure redistribution such as mattresses, cushions and pillows, as well as to protect bony prominences, helps to reduce the risk and incidence of pressure ulcers in critically-ill patients at high risk for their development, as well as the implementation of prevention protocols to promoting improvements in care quality^{29–30}.

A study carried out in a Pediatric Cardiac Intensive Care Unit implemented interventions to reduce the pressure ulcer (PU) rates, such as a package of measures, multidisciplinary meetings, multidisciplinary weekly rounds, unit-specific work group and a form for recording information about the cause and prevention of each PU. The results of the study showed a reduction in the incidence of PU from 15.7 to 2.9 events per 1,000 patient-days, a reduction in the PUs related to immobility from 35 to 4, and a reduction in the PUs related to medical devices from 34 to 15 events³⁰.

The nurse plays a fundamental role in the prevention, assessment and treatment of pressure ulcers and must use instruments such as scales, protocols, systems, forms, checklists and questionnaires

to assist in the elaboration and implementation of an individualized care plan, based on scientific evidence²⁷.

It is to be noted that, to the present date, no validated instrument for the safety of hospitalized children has been found in the literature, with complete actions, encompassing the six basic national patient safety protocols, which highlights the relevance and uniqueness of the results of this paper for the health, nursing and patient safety areas.

As a study limitation, the slowness of some participants to answer the form sent is highlighted, as their contribution is voluntary and requires time availability.

In addition to that, it is suggested that the checklist elaborated and validated in this research is subjected to the clinical validation process to be implemented in the care of hospitalized children. It is therefore understood that this is another study limitation, and that it is necessary to continue the research in order to prevent incidents and identify risks to hospitalized children.

CONCLUSION

Validation of the content, objectives, structure and presentation of the checklist allows this tool to be implemented in any pediatric hospitalization unit, contributing to the care practice aimed at the safety of hospitalized children.

The use of checklist-type patient safety instruments with strong scientific basis can be considered a fundamental strategy in identifying and reducing risks, errors and adverse events.

However, for this tool to be adopted in the care routine, in order to ensure safe health care for patients, family members, health professionals and for the health system as a whole, it is indispensable to align the content with the objective to be attained. This content needs to be validated by experts in the field, and the research, therefore, fulfilled this purpose.

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CONTRIBUTION OF AUTHORITY

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Data analysis and interpretation: Melo AVOG, Nascimento MAL.

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