Original Article

Psychometric validation of a tool that assesses safety culture in Primary Care

Validação psicométrica de instrumento que avalia a cultura de segurança na Atenção Primária

Validación psicométrica del instrumento que evalúa la cultura de seguridad en la Atención Primaria

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Keywords
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Abstract
Objective: To analyze the reliability and validity of psychometric properties of the Brazilian version of the Survey on Patient Safety Culture in Primary Care.
Methods: A quantitative cross-sectional study conducted with multidisciplinary team professionals working in Primary Health Care in a city in the Northwest region of Rio Grande do Sul State, Brazil. The tool used was "*Pesquisa sobre Cultura de Segurança do Paciente para Atenção Primária à Saúde*" (Survey on Patient Safety Culture in Primary Care).
Results: Cronbach's alpha was considered satisfactory. Factorial analysis reached satisfactory loads in all its factors. The tool showed feasibility of application and potential structure assessment for which it is proposed.
Conclusion: The Brazilian version of the questionnaire proved to be valid and reliable and could contribute to research on Patient Safety Culture in Primary Care in the country.

Resumo
Objetivo: Analisar a confiabilidade e validade das propriedades psicométricas da versão brasileira do instrumento para Pesquisa sobre Cultura de Segurança do Paciente para Atenção Primária à Saúde.
Métodos: Estudo transversal quantitativo, realizado com profissionais da equipe multiprofissional atuantes na Atenção Primária à Saúde de um município da região noroeste do Estado do Rio Grande do Sul, Brasil. O instrumento utilizado foi "Pesquisa sobre Cultura de Segurança do Paciente para Atenção Primária à Saúde". Resultados: O Alfa de Cronbach foi considerado satisfatório. A análise fatorial alcançou cargas satisfatórias no conjunto de seus fatores. O instrumento apresentou viabilidade de aplicação e potencial de avaliação da estrutura para a qual se propõe.
Conclusão: A versão brasileira do questionário mostrou-se válida e confiável, podendo contribuir com pesquisas sobre a cultura de segurança do paciente na Atenção Primária à Saúde no país.

Resumen
Objetivo: Analizar la confiabilidad y validez de las propiedades psicométricas de la versión brasileña del instrumento "Encuesta sobre cultura de seguridad del paciente de Atención Primaria de Salud".
Métodos: Estudio transversal cuantitativo, realizado con profesionales del equipo multiprofesional que trabajan en la Atención Primaria de Salud de un municipio de la región noroeste del estado de Rio Grande do Sul, Brasil. El instrumento utilizado fue la "Encuesta sobre cultura de seguridad del paciente de Atención Primaria de Salud". Resultados: El alfa de Cronbach fue considerado satisfactorio. El análisis factorial alcanzó cargas satisfactorias en el conjunto de sus factores. El instrumento presentó viabilidad de aplicación y potencial de evaluación de la estructura para la que se propone.
Conclusión: La versión brasileña del cuestionario demostró ser válida y confiable, de esta forma puede contribuir con estudios sobre la cultura de seguridad del paciente en la Atención Primaria de Salud en el país.

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Introduction

Currently, patient safety is recognized as free from harm or harm to both caregivers and assisted patients,[1] regarded as primary attribute for ensuring quality healthcare.[2]

This theme has been the focus of discussion among leaders and managers from different countries, given the numerous Adverse Events (AEs) that occur during health care.[3-9] Discussions reflect organizations' efforts to adopt measures that enable coping and reduction of AEs, which are defined as incidents that result in damage when error reaches patients.[10]

In health services there are conditions that involve increased risks of AEs. In Primary Health Care (PHC), this fact is related to the high demand of users affected by multiple chronic health conditions, with advanced age, polymedicated and living in socially vulnerable situation, thus representing a public health problem.[11]

A pioneer study in Brazil, which measured incidents in 11,233 consultations at 13 Family Health Units (FHUs) in a microregion of Rio de Janeiro State identified 0.91% AEs, with prevalence of administrative errors, miscommunication, errors in treatment, performance of clinical and diagnostic tasks.[12]

A positive safety culture must be expressed in the services that make up the Health Care Network (RAS – *Rede de Atenção à Saúde*), with a view to reducing the occurrence of AEs and improving the safety climate, especially in PHC.[13] PHC is understood as care coordinator of RAS, as well as a communicating center among health services.[14] Therefore, assessing patient safety culture in PHC is fundamental, as it allows identifying aspects that directly interfere with care provided to users.

In Brazil, so far, there are two validated tools that measure patient safety culture in PHC. There is the Safety Attitudes Questionnaire Ambulatory Version (SAQ-AV), created in 2007 in the United States of America (USA), translated and adapted for use in Brazil,[15]; and the Survey on Patient Safety Culture in Primary Care, adapted and validated semantically for Brazil[13] from the original MOSPSC, developed in the USA in 2007.[16]

MOSPSC stands for Medical Office Survey on Patient Safety Culture, and has been translated, validated linguistically and psychometrically in Spain,[17], Yemen,[18] and Portugal.[11] In Brazil, the tool was translated, adapted and validated, with semantic analysis and assessment of item clarity and comprehension,[13] making it necessary to perform psychometric validation.

A valid, reliable and consistent measurement tool for the measurement of safety culture in PHC provides relevant evidence to ensure the reliability of study results, assisting in the overall analysis, with support for establishing strategic planning for improvement. quality of services, as well as providing comparisons of national and international surveys.

Therefore, the objective of the study was to analyze reliability and validity of psychometric properties of the Brazilian version of the Survey on Patient Safety Culture in Primary Care.

Methods

A quantitative cross-sectional study conducted in 17 Family Health Units (FHUs), located in a municipality in Rio Grande do Sul State, Brazil. Data collection took place from December 2017 to April 2018. In the month prior to collection, FHUs had 228 professionals from the multidisciplinary team. Participants were selected by convenience sampling.

Inclusion criteria were being a professional of the multidisciplinary team that provided direct and indirect assistance to patient, working in the unit for at least 30 days and working at least 20 hours per week. This established time and workload allows employees to gain insight into individual and group values, attitudes, perceptions, and competencies that determine patient safety commitment and proficiency in the institution in which they operate.[19] The exclusion criteria were: being on sick leave or other type of leave during the data collection period.

After applying these criteria, 24 professionals were excluded because they were on maternity or

health leave and 10 because they had not worked in the unit for at least 30 days, resulting in 194 professionals. Of these, six refused to participate. 188 professionals participated, including physicians, dentists, nurses, nursing assistants/technicians, community health agents, nutritionists, pharmacists, psychologists, physiotherapists, occupational therapists, dental assistants, social workers, physical educators and administrative assistants.

To perform data collection, initially, the researched institution was requested a list with the names of employees and their respective work shifts. Unit managers were contacted to define the best time and date to apply the questionnaire. Data collection was performed in the professionals' work environment by a researcher during the team meeting. All participants received information regarding the research, such as objective, justification, risks and benefits, as well as legal and ethical issues. After agreeing to participate, they received an envelope containing the questionnaire accompanied by the Free and Informed Consent Term (FICT), in two copies. Respondents privacy was assured.

The researcher remained in the room in order to answer questions, if any, and receive the questionnaire answered. The time taken by professionals to complete the questionnaire ranged from 20 to 45 minutes. The Brazilian version of the Survey on Patient Safety Culture in Primary Care, which assesses patient safety culture in PHC, was used as a tool.[13]

The original tool consists of 51 questions that measure 12 dimensions of patient safety construct, which include Communication Openness, Communication About Error, Information Exchange with Other Institutions, Office Process and Standardization, Organizational Learning, Overall Perceptions of Patient Safety and Quality, Owner/Managing partner/Leadership Support for Patient Safety, Patient Care Tracking/Follow-up, Patient Safety Issues and Quality, Staff Training, Teamwork and Work Pressure and Pace.[16] MOSPSC questionnaire was translated, adapted and semantic validated for Brazil, and the tool consisted of 12 constructs that measure patient safety culture.[13]

To assess Patient Safety Culture in population in which the questionnaire was applied, a positive perception was considered as the dimension where Patient Safety Indicators (PSI) was> 3 and a clearly positive perception when PSI was ≥ 4.[9]

Data were organized in the Epi-Info® 6.04 program, with independent double entry. After correcting errors and inconsistencies, statistical analysis was performed using the Statistical Package for Social Sciences (SPSS®), version 18.0 for Windows. Categorical variables are expressed as absolute frequencies and proportions, and quantitative variables are described by measures of central tendency (mean or median) and dispersion (standard deviation or interquartile range) according to the normality distribution assessed by the Kolmogorov-Smirnov test.

To perform a comparative analysis of all dimensions that make up the questionnaire, the original response scale for sections A (Patient Safety and Quality Issues) and B (Information Exchange with Other Institutions), which have six response categories, was transformed into a rating scale 1 through 5, like the rest of the sections, by applying the Original Scale Assigned Score (PEO - *Pontuação Atribuída na Escala Original*) formula x (4/5) + 0.2. In this process, it was taken into account that the questionnaire used contains questions posed positively and others negatively. The reverse questions of the tool refer to items C3, C6, C8, C10, C12, C14, D4, D7, D10, E1, E2, E4, F3, F4 and F6. After these transformations, a specific synthesis score of each dimension was calculated by averaging the scores assigned to the questions that make up the corresponding dimension.

PSI was defined as the mean score of all questions that make up the 12 dimensions analyzed. In all cases, the range was 1 to 5. Relative frequencies of each question were calculated and the composite indicators of each dimension were measured by the following formula:[9]

$$\frac{\Sigma \text{ (positive, neutral and negative) answers in items of one dimension}}{\text{Number of total responses on items in one dimension}}$$

Internal consistency of the MOSPSC scale was investigated by Cronbach's alpha internal coefficient, calculated separately for each domain. In addition, the reverse items were adjusted for Cronbach's alpha calculation. To validate the tool, it was tested for its factorial structure, using the exploratory factor analysis technique by the main component method and a factorial analysis by the principal axis extraction method, Varimax rotation.

Research project was approved by the Research Ethics Committee, under the Opinion 2,413,567 of 4th December 2017, respecting all ethical standards recommended by Resolution 466/2012.

Results

The population surveyed for psychometric validation of the tool was mostly female (87.8%), with a predominant age of 31 to 50 years (58%). The most frequent educational levels were high school (42.8%) and graduate (31,6%). Work time periods prevailed in the unit of more than 11 years (27.8%) and from 6 to 10.9 years (25.1%). Regarding the hours worked per week, most professionals worked over 32 hours (91.0%).

The assessed health team generally had a positive perception regarding patient safety culture (PSI=3.64) in most domains, including: Patient Safety and Quality (4.12); Information Exchange with Other Institutions (4.11); Staff Training (3.40); Office Process and Standardization (3.64); Communication About Error (3.89); Owner/Managing partner/Leadership Support for Patient Safety (3.19); Organizational Learning (3.87); Overall Perceptions of Patient Safety and Quality (3.72); Overall Patient Safety Assessment (3.48); and Overall Quality Assessment (3.45) (Table 1).

Considering the MOSPSC scale's original structure, consistency was investigated by Cronbach's alpha (αC). Estimates pointed to satisfactory reliability (αC≥0.700) in Patient Safety and Quality list (αC=0.848), Information Exchange with Other Institutions (αC=0.853), Owner/Managing partner/Leadership Support for Patient Safety (αC=0.703) and Overall Quality Assessment (αC=0.829) (Table 1).

Regarding acceptable reliability (0.600≤ αC <0.700), there were Teamwork (αC=0.603), Pressure and Work Pace (αC=0.683), Staff Training (αC=0.603), Communication Openness (αC=0.676), Patient Care Tracking/Follow-up (αC=0.660) and Overall Perceptions of Patient Safety and Quality (αC=0.620). Additionally, Office Process and Standardization (αC = 0.477) and Communication About Error (α=0.416) showed reliability below the acceptable minimum (Table 1).

For reliability analysis, the MOSPSC tool was tested for the factorial structure to identify item distribution in each domain, and it was similar to the preestablished structure. The MOSPSC scale

Table 1. Mental tendency measures and variability for the Medical Office Survey on Patient Safety Culture (MOSPSC) domains

Domains	Mean	Standard Deviation	Amplitude		Quartiles			αC
			Minimum	Maximum	1st	2nd Median	3rd	
Patient Safety and Quality	4.12	0.77	1.00	5.00	3.89	4.28	4.60	0.848
Information Exchange with Other Institutions	4.11	0.75	1.40	5.00	3.80	4.20	4.80	0.853
Teamwork	4.31	0.48	2.00	5.00	4.00	4.25	4.75	0.603
Work Pressure and Pace	2.38	0.76	1.00	5.00	1.75	2.25	2.75	0.683
Staff Training	3.40	0.75	1.00	5.00	3.00	3.33	4.00	0.603
Office Process and Standardization	3.64	0.63	1.00	5.00	3.27	3.75	4.00	0.477
Communication Openness	4.07	0.66	1.75	5.00	3.50	4.00	4.54	0.676
Patient Care Tracking/Follow-up	4.32	0.58	3.00	5.00	4.00	4.50	4.75	0.660
Communication About Error	3.89	0.65	2.00	5.00	3.50	4.00	4.25	0.416
Owner/Managing partner/Leadership Support for Patient Safety	3.19	0.77	1.00	5.00	2.75	3.25	3.75	0.703
Organizational Learning	3.87	0.70	1.00	5.00	3.67	4.00	4.33	0.568
Overall Perceptions of Patient Safety and Quality	3.72	0.61	2.00	5.00	3.50	3.75	4.13	0.620
Overall Patient Safety Assessment	3.48	0.73	2.00	5.00	3.00	3.00	4.00	- - -
Overall Quality Assessment	3.45	0.66	2.00	5.00	3.00	3.40	4.00	0.829
Patient Safety Indicators (PSI)	3.64	0.84	1.00	5.00	3.77	4.25	4.75	0.941

showed significant adjustment represented by the Kais test (Kaiser-Meyer-Olkin) of 0.835 and the significant Bartlett sphericity test [$c^2(1596) = 1914.773$; $p<0.001$], which attested to the possibility of performing the factor analysis. The anti-image matrix corroborates tool items' sample adequacy for the use of factor analysis, presenting all the high values in its diagonal, between 0.885 (in the variable "D11") and 0.977 (in the variable "A2"), suggesting the inclusion of all variables for factor analysis.

The latent underlying criterion or eigenvalue was met, where only eigenvalues ≥ 1 were considered significant. The Guttman-Keiser criterion estimated that 14 latent variables should be extracted, where the first had an eigenvalue of 5.232, carrying about 9.386% variance, while in the last factor (F14) the eigenvalue was 1.235, which managed explain 2.551% of variance. The factorial model reached a 63,444% explained variance ratio (Table 2).

Table 2. Extraction of rotational matrix factors, eigenvalues and explained variance ratio for MOSPSC scale

Factorial component (latent variable)	Eigenvalues	% Explained variance	
		Per factor	Accumulated
1	5.232	9.386	9.386
2	4.289	7.695	17.081
3	2.963	5.316	22.397
4	2.880	5.167	27.563
5	2.577	4.624	32.188
6	2.509	4.502	36.690
7	2.386	4.281	40.971
8	2.159	3.874	44.845
9	2.001	3.589	48.434
10	1.800	3.230	51.664
11	1.782	3.197	54.861
12	1.687	3.120	57.981
13	1.427	2.912	60.893
14	1.235	2.551	63.444

Extraction method: main component analysis; Varimax rotation

In the information regarding the items that made up each of the latent variables, it was initially found that the commonalities had the lowest contribution to explain the factorial structure in item A10 (0.528), while the item that contributed the most was C11 (0.783).

According to the results in Table 2, Factor 1, responsible for the greatest explanatory power on the scale (9.386%), grouped "Patient Safety and Quality Issues". These items made up the most important factor to explain the scale. Following, there is:

- Factor 2 (7.695%): Overall Quality and Safety Assessment (G1A, G1B, G1C, G1D, G1E);
- Factor 3 (5.316%): Communication Openness (D1, D2, D4, D10);
- Factor 4 (5.167%): Office Process and Standardization (C8, C9, C12, C15);
- Factor 5 (4.624%): Teamwork (C1, C2, C5, C13);
- Factor 6 (4.502%): Work Pressure and Pace (C3, C6, C11, C14);
- Factor 7 (4.281%): Information Exchange with Other Institutions (B1, B2, B3, B4);
- Factor 8 (3.874%): Staff Training (C4, C7, C10);
- Factor 9 (3.589%): Owner/Managing partner/ Leadership Support for Patient Safety (E1, E2, E3, E4);
- Factor 10 (3.230%): Patient Care Tracking/ Follow-up (D3, D5, D6, D9);
- Factor 11 (3.197%): Overall Patient Safety Assessment
- Factor 12 (3.120%): Communication About Error (D7, D8, D11, D12);
- Factor 13 (2.912%): Organizational Learning (F1, F5, F7);
- Factor 14 (2.551%): Overall Perceptions of Patient Safety and Quality (F2, F3, F4, F6).

It is noteworthy that scale factors where there was compromised reliability estimated by Cronbach's alpha presented satisfactory factor loads in the set of their factors. Hence, the maintenance of these items will not compromise the scale results (Table 3).

Moreover, respecting the results obtained in the reliability and factorial validation of MOSPSC scale in this sample, there is evidence that the pre-established structure for this tool was reached. The tool showed feasibility of application and potential structure assessment for which it is proposed. Results were considered reliable due to the exploratory factor analysis model fit obtained through adequate free asymmetric distribution methods in order to estimate ordinal categorical items with nonparametric distribution.

Table 3. Varimax rotation factor analysis matrix and 14-factor Keiser normalization for the MOSPSC scale

ITEMS	F1	F2	F3	F4	F5	F6	F7	F8	F9	F10	F11	F12	F13	F14
A1	0.602													
A2	0.518													
A3	0.437													
A4	0.350													
A5	0.578													
A6	0.463													
A7	0.586													
A8	0.476													
A9	0.661													
A10	0.575													
B1							0.704							
B2							0.744							
B3							0.750							
B4							0.630							
B5														
C1					0.752									
C2					0.747									
C5					0.555									
C13					0.418									
C3						0.555								
C6						0.751								
C11						0.781								
C14						0.801								
C4								0.431						
C7								0.577						
C10								0.366						
C8				0.511										
C9				0.630										
C12				0.487										
C15				0.655										
D1			0.599											
D2			0.603											
D4			0.464					0.495						
D10			0.369					0.333						
D3										0.490				
D5										0.489				
D6										0.480				
D9										0.452				
D7												0.488		
D8												0.419		
D11												0.531		
D12												0.369		
E1									0.552					
E2									0.735					
E3									0.766					
E4									0.591					
F1													0.552	
F5													0.553	
F7													0.403	
F2														0.674
F3														0.466
F4														0.594
F6														0.463
G1A		0.689												
G1B		0.756												
G1C		0.640												
G1D		0.703												
G1E		0.731												
G2											0.686			

Eigenvalues <0.300 were omitted and variables were grouped by loads on each factor

Discussion

The tool was reliable and satisfactory for use in the Brazilian population, given its similarity to validation studies conducted in other countries.[11,17] It should be noted that, in the mentioned dimensions, the possibility of discarding items with low correlations would not significantly change the domains' alpha and the scale composition, which would go from 0.974 to 0.943 in the total scale composition, from 0.477 to 0.498 in the domain "Office Process and Standardization", 0.416 to 0.663 in "Communication About Error". Such changes are not justified because there is no way to guarantee that deleting the items would not impair content validity. [20]

When compared with validation studies conducted in different countries, tool use with all components of the scale yielded no harm to the safety culture assessment. Cronbach's α values obtained are similar to those reported by the Agency for Health Research and Quality (AHRQ), in most dimensions, which are considered adequate.[21]

The adaptation of MOSPSC in Spain[17] obtained an overallα of 0.96. In this adaptation, questions were added and, when assessing α for each dimension, unsatisfactory value was obtained for Staff Training and Patient Care Tracking/Follow-up. When validating for the Arabic version,[18] α ranged from 0.20 to 0.70, and Information Exchange with Other Institutions and List of questions on patient safety and quality due to high non-response and non-response rates were excluded. applicability. Similar results were found in the validation to Portuguese,[11] where α ranged from 0.52 to 0.88, and for the same reasons cited in the previous study both dimensions were excluded.

According to the results of the on-screen investigation, the factor responsible for the greatest explanatory power on the scale (9.386%) grouped Patient Safety and Quality Issues. In studies conducted in Yemen[18] and Portugal,[11] this dimension was excluded by the high rate of non-response and non-applicability, contrary to the present study, which obtained 97% response rate. This high response rate is due to researcher availability to remain in the referred units. A study that assesses safety culture recommends that the maximum possible participation of professionals in safety culture assessments is obtained, because the higher the response rate, the more appropriate is its representation.[16]

The second largest factor (7.695%) was the Overall Quality Assessment (G1A, G1B, G1C, G1D, G1E). In the Arabic validation study[18], this domain also kept five questions, same as the original tool. In the Spanish version,[17] this dimension presents six questions, which included the question related to Overall Patient Safety Assessment (G2).

In the Spanish[17] and Arabic studies[18], factor 3 (5,316%), Communication Openness (D1, D2, D4, D10) remained present and with the same questions as the original tool. Factor 4 (5.167%), which refers to the Office Process and Standardization (C8, C9, C12, C15), also remained with the same questions in the Arabic study.[18] However, in the Spanish validation[17] an issue has been incorporated into this dimension (C19).

The results for Factor 5 (4.624%) for Teamwork (C1, C2, C5, C13) and for Factor 6 (4.502%), Working Pressure and Rate (C3, C6, C11, C14) had no modified questions in the Spanish[17] and Arabic validation studies.[18]

Information Exchange with Other Institutions (B1, B2, B3, B4) relates to factor 7 (4,281%). In Yemen[18] and Portugal validation studies,[11] this dimension was excluded by the high rate of non-response and non-applicability. In the Spanish study,[17] this dimension had an excluded question (B5), which was contained in the original MOSPSC tool, which refers to a question that could be described by the respondent, specifying the contact sector.

Staff Training (C4, C7, C10) is identified as factor 8 (3.874%) of the scale. In the Spanish version,[17] this dimension had duplicate questions for assistant and non-assistant professionals and had added questions (C16, C17, C17, C19). In an Arabic study,[18] this domain remained with the same issues as the original tool. N these countries,[17,18] factor 9 (3.589%), Owner/Managing partner/Leadership Support for Patient Safety (E1, E2, E3, E4), and factor 10 (3.230%), Patient Care Tracking/Follow-

up (D3, D5, D6, D9) did not have modified questions. Factor 11 (3,197%), related to G2 Overall Patient Safety Assessment, it was not separately measured in the other validation studies.[11,17,18]

Communication About Error (D7, D8, D11, D12) relates to factor 12 (3.120%), and the Spanish study version[17] had questions incorporated in the factorial solution (D13, D14). In the Arabic version,[18] the tool was kept with the same questions as the original tool. Finally, factor 13 (2.912%), referring to Organizational Learning (F1, F5, F7), and factor 14 (2.551%), referring Overall Perceptions of Patient Safety and Quality (F2, F3, F4, F6) had no modified questions in Spanish[17] and Arabic validation studies.[18]

This study shows that professionals interviewed had a positive safety culture. In organizations provided with a culture of positive security, this is through communication based on mutual trust, shared understandings of the importance of security, and confidence in preventive effectiveness measures.[16] A positive safety culture means service leaders and managers work to ensure care is delivered safely and quality, using different tools to identify gaps and create safer health processes.[22]

This study was conducted in a city in Rio Grande do Sul State, which may be a limitation for results generalization. Nevertheless, the results obtained in this research contribute to the dissemination of knowledge on the subject, as there is still little data in the literature.

It is noteworthy that this study of psychometric validation is unprecedented in Brazil, setting as a starting point for future investigations that can be performed in other Brazilian regions.

Conclusion

The Survey on Patient Safety Culture in Primary Care presented valid and reliable psychometric properties when applied to a municipality in the southern Brazilian region. Patient safety culture was positive in most of the tool domains, except for Work Pressure and Pace. The obtained results are fundamental for the tool application in studies that intend to assess patient safety culture in PHC in different regions of the country. Future studies can be developed with a psychometrically validated tool for Brazil, in order to know the present safety culture, thus recommending tool validation with professionals from other places, expressing the work process culture for patient safety and quality in their microregional spaces.

Collaborations

Dal Pai S, Langendorf TF, Rodrigues MCS, Romero MP, Loro MM and Kolankiewicz ACB contributed to the study design, data analysis and interpretation, article writing, relevant critical review of the intellectual content and approval of the final version to be published.

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