Situational Assessment of SUS Assistance Protocols (ASPAS): A Survey Study

Avaliação Situacional de Protocolos Assistenciais do SUS (ASPAS): Um Estudo de Inquérito
Evaluación Situacional de los Protocolos de Asistencia del SUS (ASPAS): Un Estudio de Encuesta

RESUMO
Os Protocolos Clínicos e Diretrizes Terapêuticas (PCDTs) são documentos que orientam o diagnóstico, tratamento e monitoramento de condições pelo Sistema Único de Saúde (SUS). O objetivo deste estudo foi identificar as percepções dos profissionais usuários dessas diretrizes nos Estados e Municípios. Trata-se de um estudo transversal. A amostra compreendeu secretários estaduais e municipais de saúde, gestores ligados à atenção especializada e regulação, superintendentes, diretores e coordenadores de assistência farmacêutica. Dados sociodemográficos dos participantes e suas percepções acerca da implementação de PCDT foram coletados via questionário online. 108 participantes completaram os questionários, declarando conhecer os PCDTs (99,1%, n=107) e confiar muito neles (86,1%, n=93). A maioria dos respondentes acredita haver barreiras para a implementação de diretrizes no SUS (84,6%, n=88), sendo as principais de infraestrutura, de recursos humanos e logística/financeira. Apesar da baixa adesão à pesquisa, este trabalho apresenta relevância para políticas públicas e contribui para suprir a escassez de estudos sobre a implementação de PCDTs.
DESCRITORES: Protocolos Clínicos; Ciência da Implementação; Serviços de Saúde; Inquéritos e Questionários; Inquéritos Epidemiológicos.

ABSTRACT
Clinical Protocols and Therapeutic Guidelines (CPTGs) are documents that guide the diagnosis, treatment, and monitoring of conditions by the Unified Health System (SUS). The objective of this study was to identify the perceptions of professionals who use these guidelines in the States and Municipalities. This is a cross-sectional study. The sample included state and municipal health secretaries, managers linked to specialized care and regulation, superintendents, directors, and coordinators of pharmaceutical assistance. Sociodemographic data of the participants and their perceptions about the implementation of CPTGs were collected via an online questionnaire.108 participants completed the questionnaires, stating that they were aware of the CPTGs (99.1%, n=107) and that they trusted them a lot (86.1%, n=93). Most respondents believed that there were barriers to the implementation of guidelines in the SUS (84.6%, n=88), the main ones being infrastructure, human resources and logistics/financial. Despite the low participation in the research, this work is relevant to public policies and contributes to filling the gap in studies on the implementation of CPTGs.
DESCRIPTORS: Clinical Protocols; Implementation Science; Health services; Surveys and Questionnaires; Health Surveys.

RESUMEN
Los Protocolos Clínicos y Directrices Terapéuticas (PCDT) son documentos que orientan el diagnóstico, tratamiento y seguimiento de enfermedades por parte del Sistema Único de Salud (SUS). El objetivo de este estudio fue identificar las percepciones de los profesionales que utilizan estas directrices en los Estados y Municipios. Se trata de un estudio transversal. La muestra incluyó secretarios de salud estatales y municipales, gestores vinculados a la atención especializada y regulación, superintendentes, directores y coordinadores de asistencia farmacéutica. Los datos sociodemográficos de los participantes y sus percepciones sobre la implementación del PCDT se recopilaron mediante un cuestionario en línea. 108 participantes completaron los cuestionarios, afirmando que conocían los PCDT (99,1%, n=107) y confiaban mucho en ellos (86,1%, n=93). La mayoría de los encuestados cree que existen barreras para la implementación de directrices en el SUS (84,6%, n=88), siendo las principales de infraes-

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tructura, recursos humanos y logística/financiera. A pesar de la baja participación en la investigación, este trabajo es relevante para las políticas públicas y contribuye a llenar el vacío en los estudios sobre la implementación de los PCDT.
DESCRIPTORES: Protocolos Clínicos; Ciencia de la implementación; Servicios de salud; Encuestas y Cuestionarios; Encuestas de salud.

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INTRODUCTION

Clinical guidelines are a set of practical recommendations regarding the diagnosis, treatment and monitoring of a health condition, formulated based on the best available scientific evidence. [1] Health managers and professionals working in the Unified Health System (SUS) are instructed to follow the Clinical Protocols and Therapeutic Guidelines (CPTG) [2]. Assim, no âmbito do funcionamento do SUS, o acesso universal e igualitário à assistência farmacêutica implica que as prescrições médicas estejam de acordo com a Relação Nacional de Medicamentos Essenciais (RENAME - *Relação Nacional de Medicamentos Essenciais*) e os CPTGs, ou com lista complementar dos Estados e municípios. [3]

The body responsible for preparing and making CPTGs available is the Ministry of Health. [3] Thus, in Brazil, the term "clinical guidelines" becomes interchangeable with "protocol", as it is a normative document, with a regulatory role in the SUS. [4] However, once the Ministry of Health publishes the CPTG, it is expected that the states and municipalities will follow the new document, and it is up to them to implement actions to disseminate, train and/or educate professionals on a continuing basis. Thus, on the part of the Ministry of Health, there is no formal monitoring of the degree of implementation of the CPTGs, nor of the barriers and facilitators of their compliance.

There are initiatives to assess knowledge, attitudes and practices related to breast cancer clinical protocols (Mexico) [5], induction of labour (New Zealand) [6] or infection prevention and control (Ireland). [7] In the Brazilian context, there have been smaller initiatives to investigate the implementation of guidelines: one such initiative used the evidence-informed policy method to discuss barriers to the implementation of natural childbirth care guidelines; [8] another study used a questionnaire and thematic analysis to observe barriers to implementing guidelines for early detection of breast and cervical cancer. [9] Field projects were also identified, such as the proposal for continuing education on protocols for preventing vertical transmission of HIV/AIDS, Syphilis and viral hepatitis. [10] Furthermore, another study investigated adherence to the Parkinson's Disease CPTG through a questionnaire addressed to prescribers and evaluation of their prescriptions. [11]

However, to our knowledge, the study Situational Assessment of SUS Care Protocols (ASPAS) is the first to investigate the implementation of CPTGs with national scope. Therefore, the objective of this survey was to understand the use of CPTGs in state and municipal management after their publication by the Ministry of Health, as well as to identify the

perception of the actors involved regarding the facilitators and barriers to their implementation.

METHODS

This is a cross-sectional survey study, conducted online. The Consensus-Based Checklist for Reporting of Survey Studies (CROSS) tool was adopted [12] to report this research. The ASPAS study was approved by the Research Ethics Committee of the Hospital Alemão Oswaldo Cruz (CAAE: 53806821.9.0000.0070).

Context

Preliminary meetings were held with the Ministry of Health, the National Council of Health Secretaries (CONASS) and the National Council of Municipal Health Secretariats (CONASEMS) to evaluate and approve the research questionnaires and prioritize the specific CPTGs to be evaluated. Thus, in addition to the overall evaluation of CPTGs as a policy, three CPTGs were prioritized: CPTG for venous thromboembolism (VTE) prophylaxis in pregnant women with thrombophilia; CPTG for rheumatoid arthritis (RA); CPTG for age-related macular degeneration (AMD).

Data source

Seven electronic questionnaires were formulated, namely: i) sociodemographic characterization, ii) evaluation of implementation of guidelines for health secretaries (group 1); iii) for superintendents, directors and coordinators of regulatory and specialized care areas (group 2); iv) for superintendents, directors and coordinators of pharmaceutical assistance (group 3); v-vii) evaluation of implementation of specific CPTGs. Forms 'v' to 'vii' were intended for superintendents, directors and coordinators of pharmaceutical assistance. The complete questionnaires are available on the Open Science Framework platform for consultation. [13]

The survey was administered through the RedCap® Platform. Since the platform allows participants to start filling out the survey and return at another time, periodic reminders were sent to participants to complete the survey (via the RedCap® Platform), in addition to actions to raise awareness of the importance of the survey (via email, messaging apps, and virtual meetings). The survey was available between December 2022 and August 2023.

Sampling

The sample was a convenience sample, with an invitation to actors from the three aforementioned groups from the 27 federative units of Brazil. For the present study, no formal calculation of the sample size was performed.

Analysis of results

A descriptive analysis of the responses was performed, stratified by study group. The results are presented as frequency of occurrence (absolute and percentage) for categorical variables, while continuous quantitative data are described by means of means and standard deviations.

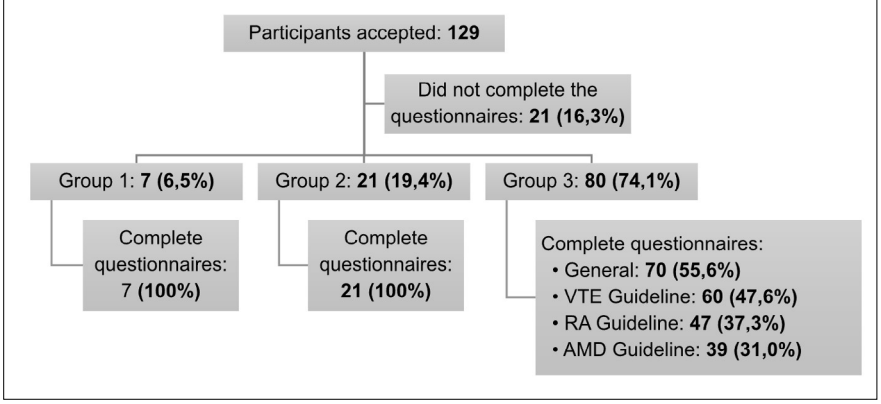
As this is a registry and exploratory study, statistical associations linked to predefined hypotheses were not performed for several questions associated with the implementation of CPTG.

All analyses were developed using Stata® 13.0 software (StataCorp LP, College Station, Texas USA).

RESULTS

In total, 129 individuals participated in the survey and 108 completed the questionnaires completely (Figure 1). The participant who sent the informed consent form (ICF) and completed the questionnaires was considered a "respondent".

Figure 1: Flowchart of research participants



Participants were on average 40.7 years old (SD: 8.1), were predominantly women (68.5%, n=74), self-declared white (72.2%, n=78) or brown (20.4%, n=22) skin color, married (60.2%, n=65), with a specialization (60.2%, n=65) or master's degree (17.6%, n=19), monthly income between 5 and 10 minimum wages (47.2%, n=51) and worked mainly in São Paulo (17.6%, n=19), Minas Gerais (14.8%, n=16), Santa Catarina (12.0%, n=13), Paraná (9.3%, n=10) and Rio Grande do Sul (7.4%, n=8) (Table 1).

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Tabela 1: Características sociodemográficas dos participantes.

	State / Municipal Secretary N, %	Specialized/ regulatory areas N, %	Pharmaceutical Assistance N, %	Total N, %
N (%)	7 (6,5)	21 (19,4)	80 (74,1)	108 (100)
Age - mean (sd)				
Calculated by RedCap, in years	41,6 (8,4)	42,4 (10,0)	40,2 (7,5)	40,7 (8,1)
Gender				
Male	5 (71,4)	9 (42,9)	20 (25,0)	34 (31,5)
Female	2 (28,6)	12 (57,1)	60 (75,0)	74 (68,5)
Color / race				
White	5 (71,4)	17 (81,0)	56 (70,0)	78 (72,2)
Black	0 (0,0)	0 (0,0)	4 (5,0)	4 (3,7)
Brown	2 (28,6)	4 (19,0)	16 (20,0)	22 (20,4)
Yellow	0 (0,0)	0 (0,0)	4 (5,0)	4 (3,7)
Marital status				
Single	2 (28,6)	4 (19,1)	23 (28,8)	29 (26,9)
Married or in a stable union	4 (57,1)	13 (61,9)	48 (60,0)	65 (60,2)
Divorced or separated	1 (14,3)	2 (9,5)	9 (11,2)	12 (11,1)
Widow	0 (0,0)	2 (9,5)	0 (0,0)	2 (1,8)
Level of education				
Incomplete higher education	0 (0,0)	0 (0,0)	0 (0,0)	0 (0,0)
Complete higher education	2 (28,6)	1 (4,8)	10 (12,5)	13 (12,0)
Specialization	3 (42,8)	13 (61,9)	49 (61,2)	65 (60,2)
Master	0 (0,0)	1 (4,8)	18 (22,5)	19 (17,6)
Doctorate	2 (28,6)	6 (28,5)	3 (3,8)	11 (10,2)
Monthly income (considering the minimum wage of R$1,100.00)				
1 - 5 minimum wages	3 (42,9)	3 (14,3)	32 (40,0)	38 (35,2)
5 - 10 minimum wages	3 (42,9)	8 (38,1)	40 (50,0)	51 (47,2)
10 - 15 minimum wages	0 (0,0)	4 (19,0)	7 (8,8)	11 (10,2)
Above 15 minimum wages	1 (14,2)	6 (28,6)	1 (1,2)	8 (7,4)
Position held within the Health Department				
State and Municipal Secretary	3 (42,8)	0 (0,0)	0 (0,0)	3 (2,7)
Director	1 (14,3)	2 (9,5)	3 (3,8)	6 (5,6)
Coordinator	2 (28,6)	5 (23,8)	17 (21,2)	24 (22,2)
Manager	0 (0,0)	1 (4,8)	5 (6,2)	6 (5,6)
Other	1 (14,3)	13 (61,9)	55 (68,8)	69 (63,9)

Caption: SD = Standard deviation. N = sample size

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All three groups stated that they were aware of the CPTGs/DDTs (99.1%, n=107) and that they had great confidence in the guidelines published by the Ministry of Health (86.1%, n=93). Furthermore, the majority believed that both the Ministry of Health (86.5%, n=90) and the States would be responsible for providing logistical support for implementing the guidelines (79.8%, n=83). A significant proportion of respondents believed that the CPTGs/DDTs were capable of handling the complexity of oncology care in their state/municipality/service as they are (63.0%, n=68). Furthermore, the minority felt that the State/Municipal Health Department had the necessary human and financial resources to implement them (25.0%, n=26) and believed that lawsuits could increase after implementing a new guideline (26.9%, n=28) (Table 2). The minority of respondents do not believe that CPTGs are aligned with local realities (30.8%, n=32), mainly due to demand (29.0%, n=30) and judicialization (29.0%, n=30). Furthermore, respondents stated that there are differences between what is expected and the "real world" (90.4%, n=94), mainly due to supply shortages (71.3%, n=67) and the difficulty in carrying out exams with the required frequency (69.1%, n=65).

Table 2: Perception of state and municipal secretaries, professionals from specialized and regulatory areas and pharmaceutical assistance managers on CPTG and DDT.

Answers	Group 1: State/ Municipal Secretary (n=7; 6,5%)	Group 2: Specialized/ regulatory areas (n=21; 19,4%)	Group 3: Pharmaceutical Care Managers (n=80, 74; 1%)	Total (n=108)
Knows the CPTG/DDT published by the Ministry of Health	7 (100,0%)	21 (100,0%)	79 (98,8%)	107 (99,1%)
Understands how the CPTG/DDT published by the Ministry of Health are prepared	3 (42,9%)	17 (81,0%)	62 (77,5%)	82 (75,9%)
Understands that the DDTs, as they are, are capable of dealing with the complexity of oncology care in their state/municipality/ service	7 (100,0%)	17 (81,0%)	44 (55,0%)	68 (63,0%)
Understands that the CPTGs, as they are, are capable of dealing with the complexity of health care in their state/municipality/ service	7 (100,0%)	20 (95,2%)	74 (92,5%)	101 (93,5%)
Confia muito nos CPTG/DDT publicados pelo Ministério da Saúde	4 (57,1%)	18 (85,7%)	71 (88,8%)	93 (86,1%)
Trusts the CPTG/DDT published by the Ministry of Health a little	3 (42,9%)	2 (9,5%)	3 (3,8%)	8 (7,4%)
Believes that the roles and responsibilities of the actors involved in implementing the CPTG/DDT published by the Ministry of Health are well defined	6 (85,7%)	20 (95,2%)	*59 (74,7%)*	*85 (79,4%)*
Perceives that the impact of the CPTG and DDT on the health of the population served has improved a lot	4 (57,1%)	13 (61,9%)	32 (40,5%)	49 (45,8%)
Perceives that the impact of the CPTG and DDT on the health of the population served has improved a little	3 (42,9%)	5 (23,8%)	29 (36,7%)	37 (34,6%)
Believes that the CPTG and DDT published by the Ministry of Health can be implemented	7 (100,0%)	21 (100,0%)	76 (100,0%)	104 (100,0%)
Identifies differences between what is recommended in the CPTG/DDT and what is made available by the SUS	7 (100,0%)	20 (95,2%)	67 (88,2%)	94 (90,4%)
Reasons for the differences between recommendation and provision	5 (71,4%)	12 (60,0%)	50 (74,6%)	67 (71,3%)
Due to supply shortages	3 (42,9%)	13 (65,0%)	49 (73,1%)	65 (69,1%)
Due to difficulty in carrying out the tests according to the established frequency	4 (57,1%)	14 (70,0%)	33 (49,3%)	51 (54,3%)
Due to lack of state funds to purchase the technologies included in the guideline	3 (42,9%)	10 (50,0%)	38 (56,7%)	51 (54,3%)

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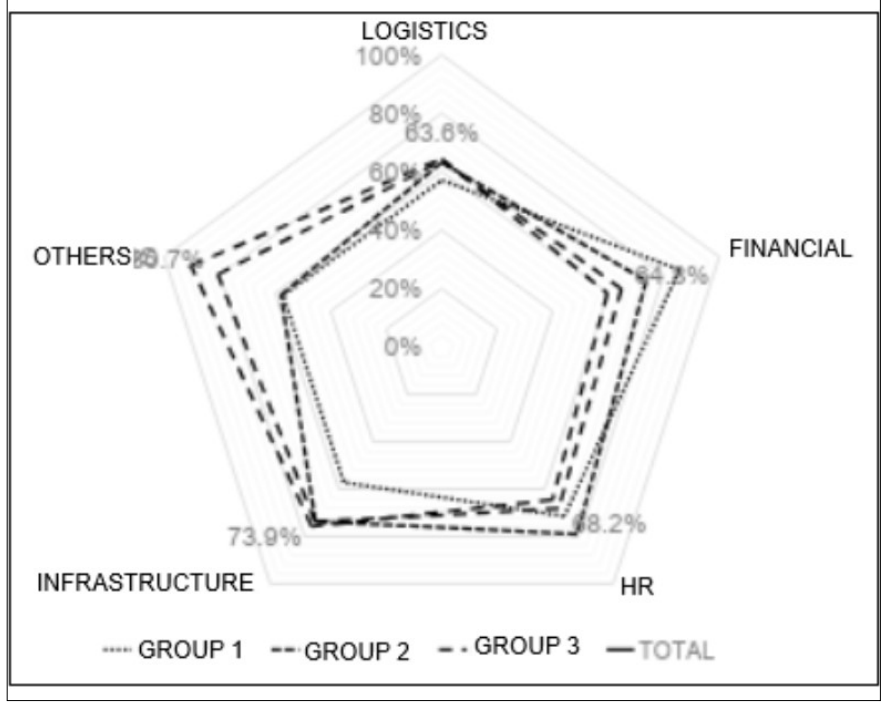
Due to non-supply or unavailability of diagnostic tests	5 (71,4%)	19 (90,5%)	66 (86,8%)	90 (86,5%)
Believes that the Ministry of Health would be responsible for logistical support for the implementation of the guideline	6 (85,7%)	14 (66,7%)	63 (82,9%)	83 (79,8%)
Believes that the States would be responsible for logistical support for the implementation of the guideline	1 (14,3%)	7 (33,3%)	18 (23,7%)	26 (25,0%)
Believes that the States would be responsible for logistical support for the implementation of the guideline	5 (71,4%)	6 (28,6%)	30 (39,5%)	41 (39,4%)
Feels that the SES/SMS has the necessary human and financial resources to implement the guideline	3 (42,9%)	7 (33,3%)	39 (51,3%)	49 (47,1%)
Does not feel that the SES/SMS has either the human or financial resources necessary to implement the guideline	3 (42,9%)	8 (38,1%)	21 (27,6%)	32 (30,8%)
Does not believe that the CPTG is aligned with local priorities	2 (28,6%)	15 (71,4%)	54 (71,1%)	71 (68,3%)
Believes that implementing a CPTG/DDT is too complex	4 (57,1%)	4 (19,0%)	21 (27,6%)	29 (27,9%)
Does not believe that implementing a CPTG/DDT is too complex	3 (42,9%)	5 (23,8%)	20 (26,3%)	28 (26,9%)
Believes that lawsuits may increase after the implementation of a new guideline	3 (42,9%)	10 (47,6%)	40 (52,6%)	53 (51,0%)
Does not believe that lawsuits may increase after the implementation of a new guideline	1 (14,3%)	5 (23,8%)	16 (20,3%)	22 (20,6%)
During the process of drafting the CPTG/DDT, usually participates in the public consultation	1 (14,2)	6 (28,6)	1 (1,2)	8 (7,4)

Legend: DDT = Diagnostic and Therapeutic Guidelines; CPTG = Clinical Protocols and Therapeutic Guidelines; SES = State Health Department; SMS = Municipal Health Department.

Most respondents believe there are barriers to implementing guidelines in the SUS (84.6%, n=88), the main one being related to infrastructure (73.9%, n=65), followed by lack of human resources (68.2%, n=60), and finally, logistical (63.6%, n=56) and financial (64.8%, n=57) barriers (Figure 2). Other barriers pointed out by participants for questions that allowed multiple answers were related to the lack of knowledge or interest of prescribers (81.0%, n=47), medication shortages (72.4%, n=42), the need for a referral center for treatment (69.0%, n=40), and the need to offer specialized services (62.1%, n=36). Despite the barriers identified, a minority of participants reported participating in public consultations (20.6%, n=22), mainly due to a lack of knowledge of the existence of public consultations (65.9%, n=27).

Figura 2: Barreiras à implementação de PCDT/DDT mais citadas no inquérito.



Caption: Group 1: State/Municipal Secretary; Group 2: Specialized/regulatory areas; Group 3: Pharmaceutical Assistance Managers.

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Participants indicated that the following factors facilitated the implementation of CPTGs/DDTs: adaptation/expansion of existing health services (90.4%, n=94), health professionals involved (83.7%, n=87), diagnostic services (75.0%, n=78) and referral centers (78.8%, n=82).

Regarding the participants' perception and implementation of the specified CPTGs (VTE, RA and AMD), it is important to note the lower response rate (39 to 62 participants) in relation to the general questionnaire (Table 3). In short, participants indicated that they understood the CPTGs (53.8% to 69.4% of participants, depending on the CPTG), with only a minority indicating that they were not clear (2.1% to 17.9%). It is noteworthy that only a minority of participants reported having received some training (10.3% to 27.7%) (Table 3).

Table 3: Participants' perception and knowledge about the implementation of clinical protocols and therapeutic guidelines for 'venous thromboembolism in pregnant women with thrombophilia', 'rheumatoid arthritis' and 'age-related macular degeneration'.

Answers	TEV em gestantes com trombofilia	Artrite reumatoide	DMRI
	N=62, 100%	N=47, 100%	N=39, 100%
Answers to questions common to the three CPTGs			
Understands the guideline	43 (69,4%)	34 (72,3%)	21 (53,8%)
The CPTG is not clear in its language and recommendations	9 (14,5%)	1 (2,1%)	7 (17,9%)
Because the text is difficult to understand for non-specialist professionals	18 (66,7%)	10 (66,7%)	10 (62,5%)
Objectivity of the text/text not very recommendable	10 (37,0%)	6 (40,0%)	6 (37,5%)
Thinks that the guideline is too rigid, that is, rigorous in its criteria to the point of making its implementation difficult	38 (61,3%)	14 (29,8%)	14 (35,9%)
Believes that the guideline is complete enough to deal with the clinical condition	32 (51,6%)	*42 (89,4%)*	25 (64,1%)
The participant and his/her team prepared, received training or preparation to implement the guideline	9 (14,5%)	13 (27,7%)	4 (10,3%)
Nature of training [a]			
Discussion rounds	5 (8,1%)	10 (21,3%)	1 (2,6%)
Submission of digital material	2 (3,2%)	27 (57,4%)	2 (5,1%)
Meetings for presentation of the CPTG	4 (6,5%)	18 (38,3%)	3 (7,7%)
Believes that the disclosure of the guideline was adequate for dissemination and dissemination	36 (58,1%)	18 (38,3%)	8 (20,5%)
Believes that prescribers understand the information contained in this guideline and are able to follow the rules set out therein when filling out the necessary documents	10 (16,1%)	18 (38,3%)	SR [b]
For cases outside the protocol, the state/municipal conduct is to deny the request and not offer supplementary drug care	39 (62,9%)	29 (61,7%)	21 (53,8%)
There is a need for supplementation by the State/municipality of the Ministry of Health's line of care	37 (59,7%)	11 (23,4%)	SR [b]
The therapeutic arsenal is supplemented by state/municipal support	26 (70,3%)	8 (72,7%)	1 (25,0%)
The CPTG takes into account the needs of the service and the population, regarding: [a]			
Diagnosis	51 (82,3%)	38 (80,9%)	24 (61,5%)
Inclusion criteria	40 (64,5%)	44 (93,6%)	26 (66,7%)

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Exclusion criteria	57 (91,9%)	42 (89,4%)	35 (89,7%)
Treatment	55 (88,7%)	39 (83,0%)	27 (69,2%)
Monitoring	SR b	36 (76,6%)	25 (64,1%)
There is compliance with the ICD codes included in the CPTG	47 (75,8%)	39 (83,0%)	SR b
In the participant's experience, there is MODERATE pent-up demand generated by the CPTG	29 (46,8%)	20 (42,6%)	16 (41,0%)
There is a need for adjustments and adaptation of services to meet the requirements of the CPTG for correct supply and provision to the population	18 (29,0%)	18 (38,3%)	14 (35,9%)
There is a specialized medical team in sufficient quantity to meet the demand	SR b	7 (14,9%)	10 (25,6%)
A 'term of clarification and responsibility' is presented to the patient undergoing treatment	SR b	44 (93,6%)	28 (71,8%)
The technologies used are being monitored	28 (45,2%)	21 (44,7%)	6 (15,4%)
Mainly regarding the number of syringes/tablets/applications	25 (89,3%)	18 (85,7%)	5 (83,3%)
Guidelines regarding the use of enoxaparin	17 (60,7%)	SR b	SR b
Clinical improvement	SR b	13 (61,9%)	SR b
Adverse events	13 (46,4%)	13 (61,9%)	4 (66,7%)
Visual acuity	SR b	SR b	4 (66,7%)
Understands that patients apply/use the medications dispensed correctly	33 (53,2%)	23 (48,9%)	SR b
In the State/municipality, there is a switch between reference biological medication and biosimilar and between biosimilars	49 (79,0%)	34 (72,3%)	SR b
Estimates that up to 10% of patients do not continue treatment after first receiving the medications	38 (61,3%)	26 (55,3%)	18 (46,2%)
Considers that the unit where they work is capable of implementing the recommendations of this CPTG	51 (82,3%)	38 (80,9%)	24 (61,5%)
Believes that the summarized version of this guideline (if any) makes or would make a difference in the implementation of care and assistance for this health condition	47 (75,8%)	SR b	30 (76,9%)
Estimates that between 10 and 30% of patients have their request denied because they do not meet the CPTG eligibility criteria	19 (30,6%)	23 (48,9%)	10 (27,0%)
Main reasons for rejection, within the scope of the Specialized Component of Pharmaceutical Assistance, of the CPTG medication request processes: [a]			
Inadequacy of inclusion criteria/maintenance of CPTG criteria	46 (74,2%)	27 (57,4%)	SR b
Incorrect or inadequate completion of the report with the patient's criteria by the medical professional	41 (66,1%)	31 (66,0%)	SR b
Judicialization often impacts this CPTG	12 (40,0%)	8 (44,4%)	SR c
Answers to specific questions for the CPTG of VTE in Pregnant Women with Thrombophilia			
In the State/municipality, there is supply of: [a]			
IgG or IgM anticardiolipins (ELISA test)	30 (48,4%)	NA	NA
Functional protein C assay	28 (45,2%)	NA	NA

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Lupus anticoagulant	24 (38,7%)	NA	NA
Free protein S assay	23 (37,1%)	NA	NA
Functional protein S assay	22 (35,4%)	NA	NA
Anti-beta2glycoprotein 1 IgG or IgM (ELISA test)	20 (32,2%)	NA	NA
None of these	19 (30,6%)	NA	NA
Factor V Leiden	18 (29,0%)	NA	NA
G20210A mutation in the prothrombin gene	13 (20,9%)	NA	NA
Believes that there is regular financing and distribution by the Union regarding enoxaparin (group 1A of CEAF)	32 (51,6%)	NA	NA
Believes that the state/municipal supply of enoxaparin sodium – injectable solution of 40 mg/0.4 mg is in accordance with the CPTG	53 (85,5%)	NA	NA
Answers to specific questions for the CPTG for rheumatoid arthritis			
The state/municipality uses its own protocol for the condition	NA	2 (4,3%)	NA
The state/municipality is facing difficulties in acquiring medications	NA	21 (44,7%)	NA
It believes that legal action is occurring due to irregularities in supply	NA	16 (34,0%)	NA
The impact of treatment scheduling is positive for the patient	NA	24 (51,1%)	NA
Once the change has occurred due to the unavailability of the medication, it is considered that the patient has moved on to the next line of therapy	NA	35 (74,5%)	NA
It uses the treatment flowchart available in the CPTG	NA	35 (74,5%)	NA
Believes that there is regular financing and distribution of CEAF group 1A drugs by the Union	NA	29 (61,7%)	NA
Believes that the state/municipal provision of non-drug treatments is in accordance with the CPTG	NA	28 (59,6%)	NA
Answers to questions specific to the CPTG for age-related macular degeneration			
The State/municipality has a reference center registered with the Health Surveillance of the State or Municipal Health Department to treat the condition	NA	NA	25 (64,1%)
It is considered that the State/municipality is organized to provide treatment for AMD as established by Joint Ordinance 18/2018	NA	NA	16 (41,0%)
The State/municipality followed or still follows the protocol for the use of bevacizumab in AMD established by the Ministry of Health	NA	NA	20 (51,3%)
In the State/municipality, there is or was an adequate place for fractionation of bevacizumab, as established by RDC 111/2016 of Anvisa, while it was in force (RDC extinguished due to the passage of time and revoked as of the deliberation of the 2nd Public Meeting of the Collegiate Board of Anvisa of 2020, held on 2/18/2020)	NA	NA	16 (41,0%)
The State/municipality still provides access to bevacizumab as recommended by the protocol	NA	NA	5 (12,8%)
In the State/municipality, access to AMD treatment occurs through the CPTG established by the Ministry of Health – Joint Ordinance 18/2018	NA	NA	25 (64,1%)
In the State/municipality, there is a contract for ophthalmological services to care for patients with AMD	NA	NA	26 (66,7%)

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Considers that APAC 03.03.05.023-3 regarding the application of anti-angiogenics has a value corresponding to the cost of the medication	NA	NA	11 (28,2%)
In the State/municipality, access to AMD treatment occurs through the participation of the Specialized Component of Pharmaceutical Assistance	NA	NA	12 (30,8%)
The State/municipality uses its own supplementary protocol for AMD treatment	NA	NA	4 (10,3%)
Considers that the incorporation of aflibercept and ranibizumab for the treatment of neovascular AMD in patients over 60 years of age (Ordinance SCTIE/MS No. 18 of 2021) can facilitate the organization of the provision of state/municipal anti-VEGF	NA	NA	26 (66,7%)
Contributing to: [a]			
Reducing judicialization	NA	NA	23 (88,5%)
Greater access for the population	NA	NA	22 (84,6%)

Caption: a – allowed multiple answers; b – question not present in this questionnaire; c – no answers regarding frequency. Anti-VEGF = anti-vascular endothelial growth factor; APAC = Authorization of Outpatient Procedure (High complexity/cost); CEAF = Specialized Component of Pharmaceutical Assistance; ICD = International Classification of Diseases; Conitec = National Commission for Incorporation of Technologies into the Unified Health System; DDT = Diagnostic and Therapeutic Guidelines; AMD = age-related macular degeneration; MS = Ministry of Health; NA = Not applicable; CPTG = Clinical Protocols and Therapeutic Guidelines; RDC = Resolution of the Collegiate Board; SCTIE = Secretariat of Science, Technology and Strategic Inputs; SR = no answers; VTE = venous thromboembolism.

According to the normative characteristics of CPTGs, in general, the state/municipal conduct for cases outside the protocol was reported as being the denial of the request and the refusal to offer the technology (53.8% to 62.9%). Even so, for cases covered by the protocol, respondents indicated the need for supplementation by the state/municipality (23.4% to 59.7%). It is indicated that some patients have monitoring of the technologies used (15.4% to 45.2%), and that there is a switch between reference biological drugs and biosimilars (79.0% for VTE and 72.3% for AMD) (Table 3).

It is believed that there is judicialization due to the shortage of technologies in the CPTG of RA (34.0%, n=16). Furthermore, once the switch has occurred due to unavailability, the patient is considered to have advanced to the next therapeutic line (74.5%, n=35) (Table 3).

Regarding the CPTG for AMD, only some of the respondents believe that their state/municipality has an organization to provide treatment (41.0%, n=16), and few indicate that there is an adequate location for fractioning bevacizumab (41.0%, n=16). Even so, it is indicated that ophthalmological services are contracted (66.7%, n=26) (Table 3).

DISCUSSION

The ASPAS study was a population-based survey aimed at understanding the perception of state and municipal managers regarding the implementation of CPTGs/DDTs, in addition to identifying barriers and facilitators for their use. The three professional groups stated that they were very familiar with and trusted the documents and believed that the guidelines could be implemented. Furthermore, the stakeholders agreed that the main barriers to implementation were related to infrastructure, human resources and logistics/financial issues, while the main facilitators were related to the adaptation/expansion of existing services, including referral centers, in addition to the need for more professionals.

These barriers have already been identified in the literature, with other aspects considered, such as institutional factors, regulation of professionals' behavior and limited availability of resources. [14] This suggests that the process of developing guidelines and their subsequent evaluation and approval by the National Commission for the Incorporation of Technologies into the Unified Health System (CONITEC) has been partially successful. However, the literature indicates that, in addition to using evidence in the development of guidelines, it is necessary to adopt mechanisms for the translation, integration and application of the knowledge contained in these documents. [4] Only in this way can the effects on the quality and performance of the health system be obtained. [4]

Other barriers in the literature that were not prioritized by respondents include adherence and low health literacy among patients, political, social and cultural factors, and a lack of clarity about the responsibility of actors involved in implementation. [14] In a study conducted in Cascavel, the majority of respondents pointed out the lack of dissemination of CPTGs in services as the main barrier to implementation. [15] Other facilitators found in the literature include technical support and

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timely training for both professionals and patients. [14]

Questions about the functioning and obstacles perceived by professionals revealed that the implementation of guidelines in the SUS has been partially effective. Our findings are in agreement with a local cross-sectional study on the views of primary care professionals on CPTGs, in which 62% of managers were aware of the guideline, while none of them claimed to have sufficient knowledge. [15]

Since access to technologies is subject to CPTG/DDT eligibility criteria, it is notable that professionals point out the existence of pent-up demand, as well as the non-acceptance of prescribers and the unavailability of supplies. This is in line with what was identified in a study that evaluated access to medications indicated in the CPTG for Alzheimer's Disease in Minas Gerais. [16] In this study, it was observed that the majority of prescribers complied with less than 80% of the procedures set out in the CPTG [16], suggesting a barrier related to the divergence of criteria set out in the state CPTG and national CPTG. 16 This explanation is not supported by our findings, since most respondents indicated that there was no complementary state protocol for the conditions studied. However, other CPTGs were evaluated in the present research, other than the Alzheimer's CPTG. [16]

In another survey, all respondents pointed out the lack of institutional practices to facilitate implementation and the lack of dissemination as difficulties in using CPTGs. [15] The Minas Gerais study also suggested making the CPTG clearer and more accessible to prescribers, disseminating information about the process and making the administrative process less bureaucratic. [16] These considerations are consistent with the findings of this survey, since some respondents indicated that the guidelines were not clear and were not sufficiently disseminated. Furthermore, incorrect submission of documentation by the patient and inadequate completion of reports were indicated as barriers to the approval of the process.

Regarding the three CPTGs individually assessed, the most cited barrier to implementation, that is, specialized human resources, is reflected in the responses for the AMD and RA CPTGs. The need to expand, or even readjust, installed capacity is related to the need for public centers for infusion and fractionation of medications. Respondents indicated supplementation by the State/municipality, especially through contracting services and with the cost of procedures. Therefore, it is not surprising that the perception that judicialization impacts care in the event of shortages.

It is worth reflecting that the implementation of a guideline is, in fact, a complex process, inserted in complex health systems. [17] Therefore, it would be unwise to assume that guidelines can be implemented without additional resources or more efficient use of existing resources. [17]

Underutilization of clinical guidelines is itself a barrier to better patient care, hindering standardization of care across a geographic area, better use of resources, and improved health outcomes. [14] Thus, it is noted that well-formulated and high-quality guidelines will not necessarily produce results unless they are effectively implemented. [4] The literature suggests some implementation strategies, such as education, computerized systems, auditing and feedback, opinion leaders among patients, social media, as well as interventions focused on the organization. [4]

The limitations of this survey refer to common deficiencies in studies of this nature. Despite extensive publicity and the sending of reminders to complete the survey, the sample was reduced to a national survey. The reasons for this may have been the need to send a signed informed consent form and the length of the questionnaires. Furthermore, because it was a convenience sample, there is a possibility of selection bias, that is, the health professionals most interested and engaged with the topic may have been those who completed the questionnaires. Missing data were computed and are presented as frequency, but no imputation methods were applied because it was an exploratory analysis.

The ASPAS study was the first effort to understand how states and municipalities use CPTGs/DDTs after their publication by the Ministry of Health. It was concluded that health professionals working in the SUS are familiar with the documents, have great confidence in their content, and believe that they can be implemented. However, respondents pointed out limitations in infrastructure, human resources, and logistics/financial issues as obstacles to this implementation. This study can serve as a basis for outlining focused strategies and other implementation initiatives.

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