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QUALITY OF THE PRACTICE CLINIC GUIDELINES FOR COPD

Cristian García Cano (1), Juan Carlos Sánchez López (2) and Ana Peñalver Peñalver (3).

(1) Primary Care Nurse at Hospital of Vinalopó (Health Departament Elche-Crevillente). Alicante. Spain.

(2) Nurse in Elche City Hall. Alicante. Spain.

(3) Veterinarian of Public Health Center of Orihuela. Alicante. Spain.

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ABSTRACT

Background: World Health Organization deem Chronic Obstructive Pulmonary Disease as the fourth leading cause of death in the world. Because of its impact on Public Health, it represents a great burden from an international economic point of view, despite it is an avoidable and treatable disease. Hence it is suitable to use Clinical Practice Guidelines which are recommendations systematically developed to aid decision making about health care to improve quality, and they must be subject to a review and update of an enriching methodological rigor. There is currently many Clinical Practice Guidelines for Chronic Obstructive Pulmonary Disease but there is insufficient evidence to determine if they have the degree of methological quality for been used in clinical practice. For which, we have evaluated the quality of these Clinical Practice Guidelines in Spanish using the AGREE II instrument.

Methods: We carried out a systematic search to find the Clinical Practice Guidelines for Chronic Obstructive Pulmonary Disease published in Spanish between 2010-2017 and put a quality evaluation into effect by means of AGREE II instrument.

Results: We got six guidelines wich achieved inclusion criteria of the study and we draw the compliance of the domains in these guidelines by means of AGREE II instrument: Scope and purpose (55.56-92.59%), Stakeholder involvement (37.04-79.63%), Rigour of development (29.86-84.72%), Clarity of presentation (90.74-100%), Applicability (5.56-63.89%) and Editorial independence (5.56-94.44%).

Conclusions: Only one guideline got the score to classify as Very Good Fulfilling/Very Hight Score; another four got Good Fulfilling/Hight Score; and last one got Low Fulfilling/Low Score.

Key words: Clinical Practice Guideline, Chronic Obstructive Pulmonary Disease, Evaluation and AGREE.

RESUMEN

Calidad de las guías de práctica clínica para la EPOC

Fundamentos: La Enfermedad Pulmonar Obstructiva Crónica es considerada por la Organización Mundial de la Salud como la cuarta causa de muerte en el mundo. Dado su impacto en la Salud Pública supone una gran carga desde un punto de vista económico a nivel internacional, pese a ser una enfermedad evitable y tratable. De ahí que resulte conveniente el empleo de Guías de Práctica Clínica, las cuales son recomendaciones elaboradas sistemáticamente para ayudar a la toma de decisiones respecto a los cuidados de salud para la mejora de la calidad asistencial, debiendo estar sujetas a revisión y actualización, a fin de enriquecer su rigor metodológico. Actualmente existen numerosas Guías de Práctica Clínica para la Enfermedad Pulmonar Obstructiva Crónica, pero no tenemos evidencia suficiente para determinar su grado de calidad metodológica para ser utilizadas en la práctica clínica. Por tanto, nuestro objetivo fue evaluar la calidad de las Guías de Práctica Clínica en español para la Enfermedad Pulmonar Obstructiva Crónica mediante el instrumento AGREE II.

Métodos: Realizamos una búsqueda sistemática para localizar las Guías de Práctica Clínica para la Enfermedad Pulmonar Obstructiva Crónica publicadas en español entre 2010-2017 y ejecutamos una evaluación de la calidad mediante el instrumento AGREE II.

Resultados: Obtuvimos seis guías que cumplían los criterios de inclusión en el estudio y de la aplicación del instrumento AGREE II extrajimos el cumplimiento de los dominios en las distintas guías: Alcance y Objetivo (55,56-92,59%), Participación de los implicados (37,04-79,63%), Rigor en la elaboración (29,86-84,72%), Claridad en la presentación (90,74-100%), Aplicabilidad (5,56-63,89%) y Independencia editorial (5,56-94,44%).

Conclusiones: Podemos decir que solo una de las guías obtuvo puntuación para clasificarla como Muy Buen Cumplimiento/Muy Alta puntuación; otras cuatro obtuvieron Buen Cumplimiento/Alta Puntuación; y, finalmente, la última Bajo Cumplimiento/Baja Puntuación.

Palabras Clave: Guía de Práctica Clínica, Enfermedad Pulmonar Obstructiva Crónica, Evaluación y AGREE.

Correspondence:
Cristian García Cano
C/ Jaime Latour, Nº7
03203 Elche, Alicante, España
garciacanocristian@gmail.com

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INTRODUCTION

Chronic Obstructive Pulmonary Disease (COPD) is deemed as a pathologic condition characterized by an air flow limitation not completely reversible. The air flow limitation is usually progressive and connected with an anormal inflammatory answer of the lungs against nocive particles or gases[1].

In 2010, 210 million people in the world suffered from COPD[2]. Its being nowadays the fourth cause of death in the world, predicted as third in 2030[3].

In 2007 Spanish study EPI-SCAN showed that prevalence rate of COPD in our country rose to 10,2% (15,1% men and 5,7% women) to population between 40 and 80 years[4].

Practice Clinic Guidelines (PCG) are documents which, by means of a deep analysis of the scientific evidence about an relevance clinic trouble for a determinated population or institution, look for draw recomendations up since different perspectives (preventive, diagnostic, treatment and rehabilitation)[5], with the objective of optimize health care to the patients[6].

For its part, Health and Consumption Ministry published the Quality Plan for the National Health System in which 10th strategy promotes the quality promotion by means of the elimination of professional practice variability. Nevertheless, there is observed that exists a great variability in content and scope of these documents. This is due to that a lot of PCGs lack of appropriate methodological rigor which guarantee quality of analyzed information and drawn recommendations up[7].

For solving this problem, in 1998 it was created the international researchers and developers of guidelines group, The AGREE collaboration (Appraisal of Guidelines, Research and Evaluation) which principal objective was the creation of a tool which evaluate the development and report of PCGs. The first version of AGREE tool, published in 2003, was consolidated as an useful and easy application tool[8]. The original AGREE tool was redesigned in 2009 and, as outcome, was developed AGREE II tool which principal features are[9]:

– To set a framework to evaluate the quality of the guidelines.

– To indicate a methodological strategy for guidelines development.

– Setting which information and how PCGs must contain this one.

There are many studies which used AGREE II to evaluate PCGs works quality like Parra-Anguita[10], Uzeloto[11], which included COPD, and Acevedo[12].

The principal objective of this study was: to evaluate and analyse the quality of PCG in Spanish for COPD. As secondary objectives we proposed: know which PCGs for COPD was published in the last 7 years in spanish; to develop a comparison between PCGs with respect to its quality; and to organize and Rank PCGs with respect to its quality.

MATERIAL AND METHODS

We performed a systematic research to locate PCGs for COPD published in Spanish in the last 7 years (2010-2017) and ran a quality evaluation through AGREE II tool.

We carried out a systematic research at Medline database, at Índice Bibliográfico Español en Ciencias de la Salud (IBECS) and at Índice de Literatura Latinoamericana y del Caribe en Ciencias de la Salud (LILACS), also at webs of agencies and institutions such as:

Guía de la salud del Sistema Nacional de Salud; Google Scholar; la Biblioteca Internacional de Guías (G-I-N); Database of PCGs held by Canadian Medical Association; and the social scientific network ResearchGate.

The quality analysis of PCGs was performed using AGREE II tool, which is a tool to evaluate methodological rigor and transparency with which this guideline was developed. Consist of 23 items included in 6 Domains of Quality. Each item is qualified with values from 1 (very disagree) to 7 (very agree). The six Domains described are

– Domain 1: scope and purpose.

– Domain 2: stakeholder involvement.

– Domain 3: rigor of development.

– Domain 4: clarity of presentation.

– Domain 5: applicability.

– Domain 6: editorial independence.

Data collecting was carried out by the three members of the work group and authors of this paper, which independently checked every selected guideline. Before this collecting, group members accomplished a face to face training with the guideline, approaching and solving in accord with the doubts raised in guideline.

For the methodological quality evaluation also we followed the rules of using of the AGREE II handbook (traduced to Spanish by Health Guideline of the SNS)[15]. The steps followed were:

– Complete Reading of each PCG.

– Score of each one of the 23 items (since 1, minimum, to 7, maximum) until complete the 6 Domains.

– The total value obtained in percentage was the result of applying the formula of AGREE II, segregating by Domains (see tables 1 and 2).

– We established 4 categories[10]:

i) More than 75%: very high score; very good compliance.

ii) Between 75-50%: high score; good compliance.

iii) Between 50-25%: down score; down compliance.

iv) Less than 25%: very down score; very down compliance.

Even though AGREE II tool does not have got an established cut point to choose if a guideline is good or not, experts consensus suggest to be considered a good quality guideline should obtain a percentage higher than 60-70%, so that group decided take as cut point a 60%[19].

The data were processed with Microsoft Excel (version 15).

RESULTS

We obtained six guidelines which fulfilled the inclusion criteria in the study, and which were not approached by previous authors, and over which we applied the AGREE II method which we describe then. The six guidelines below: Quality Plan Guideline for the National Health System by the Spanish Ministry of Health[1]; by the Spanish Society of Family Medicine and the Spanish Society of Pneumology and Thoracic Surgery[13]; by the Mexican Institute of Social Security[14]; by the Work Group of GesEPOC[15]; by the Colombian Health Ministry and Social Protection[16]; and by Argentinian Health Ministry[17]. All of them specified in the table 1.

Table 1
Selected Guidelines.

Guidelines	Abbreviated Identifier
Grupo de trabajo de la Guía de Práctica Clínica para el Tratamiento de Pacientes con Enfermedad Pulmonar Obstructiva Crónica (EPOC). Guía de Práctica Clínica para el Tratamiento de Pacientes con Enfermedad Pulmonar Obstructiva Crónica (EPOC). Plan de Calidad para el Sistema Nacional de Salud (SNS) del Ministerio de Sanidad, Servicios Sociales e Igualdad. Unidad de Evaluación de Tecnologías Sanitarias de la Agencia Laín Entralgo; 2012. Guías de Práctica Clínica en el SNS: UETS Nº 2011/6.	SNS
Grupo de trabajo de la guía de práctica clínica sobre Atención Integral al paciente con Enfermedad Pulmonar Obstructiva Crónica (EPOC). Desde la Atención Primaria a la Especializada. Sociedad Española de Medicina de Familia (semFYC) y Sociedad Española de Neumología y Cirugía Torácica (SEPAR); 2010.	SEPAR
Diagnóstico y Tratamiento de la Enfermedad Pulmonar Obstructiva, México: Instituto Mexicano del Seguro Social; 2010.	Mexican or MEX
Grupo de Trabajo de GesEPOC. Guía de Práctica Clínica para el Diagnóstico y Tratamiento de Pacientes con Enfermedad Pulmonar Obstructiva Crónica (EPOC) - Guía Española de la EPOC (GesEPOC). Arch Bronconeumol. 2012;48 (Supl 1):2-58. (Más actualización posterior).	GesEPOC
Londoño D et al. Guía de práctica clínica basada en la evidencia para la prevención, diagnóstico, tratamiento y seguimiento de la enfermedad pulmonar obstructiva crónica (EPOC) en población adulta. Ministerio de Salud y Protección Social. Guía nº 28. Colciencias. Bogotá; 2014.	Colombian or COL
Videla AJ et al. Guía de práctica clínica nacional de diagnóstico y tratamiento de la enfermedad pulmonar obstructiva crónica. Buenos Aires; 2015.	Argentinean or ARG

First way, we can watch in the table 2 the valuations broken down into Domains each guideline, pointing the maximum individual Rank which every Domain can rate, the Rank rated by evaluators, the mean of the ratings assigned and the global summation of the ratings of the three guidelines. Second way, reflected in the table 3, showed up the mean per Domains and the total of each PCG. Third way, showed up in the table 4, it´s reflected its mean and Standard Deviation expressed in percentage. Fourth way, the next data depicted in the figure 1:

– For Domain 1 (scope and purpose of the guideline), every guidelines reached a high score in this parameter, highlighting Argentinean, Colombian and Mexican, followed by SEPAR, GesEPOC y SNS (values of 92,59%, 90,74%, 79,63%, 74,07%, 61,11% y 55,56%, respectively).

– As to Domain 2 (stakeholder involvement), tree of the guidelines obtained a high score: Argentinean, SNS and Colombian (values del 79,63%, 77,78% y 75,93%, respectively). Mexican achieved a high score (53,70%). At the opposite were SEPAR y GesEPOC guidelines (values of 44,44% and 37,04%, respectively) which suffered a low participation of the patients in the development of the texts.

Table 2
The obtained qualification for PCG by means of AGREE II tool (Outcomes Rounded).

Guidelines	Scope MIR: 3–21 Range */average** Global***		Involvement MIR: 3– 21 Range */average** Global***		Rigor MIR: 8 – 56 Range */average** Global***		Clarity MIR: 3 – 21 Range */average** Global***		Applicability MIR: 4 – 28 Range */average** Global***		Independence MIR: 2 – 14 Range */average** Global***		Global Evaluation. 7: very high 1: very low recommendations
SNS	9-18	13	16-19	17	38-45	41	21-21	21	8-15	12	2-9	5	4
	56		78		69		100		35		25		Yes, w/ mod
SEPAR	14-18	16	8-13	11	35-51	42	19-21	20	4-13	10	4-10	6	4
	74		44		71		94		24		33		No
GESEPOC	11-16	14	6-13	10	18-25	22	17-21	19	5-6	5	2-6	3	2
	61		37		30		91		6		11		No
ARG	19-21	20	13-20	17	46-52	49	19-21	20	15-25	18	12-14	13	6
	93		80		85		94		60		94		Sí
COL	18-20	19	13-19	17	28-43	37	19-21	20	7-26	19	2-3	3	4
	91		76		60		96		64		6		Yes, w/ mod
MEX	17-18	17	12-13	13	31-38	35	18-21	19	5-9	7	4-9	7	3
	80		54		56		91		11		44		No

* Rating range obtained by each guide in each domain; ** Average score obtained by each guide in each domain;
*** Percentage of the overall score obtained in each domain.MIR: maximum individual range for each AGREE II domain.

Table previously used by Parra-Anguita, L et al[16] and Navarro Puerto, MA et al[22].
SNS: PCG of the Quality Plan Guideline for the National Health System by the Spanish Ministry of Health[1]; SEPAR: PCG of Spanish Society of Family Medicine and the Spanish Society of Pneumology and Thoracic Surgery[13]; MEX: PCG of Mexican Institute of Social Security[14]; PCG of Work Group of GesEPOC[15]; COL: PCG of Colombian Health Ministry and Social Protection[16]; y ARG: PCG of Argentinian Health Ministry[17].

Table 3
Application of the formula AGREE II (%) in Domains.

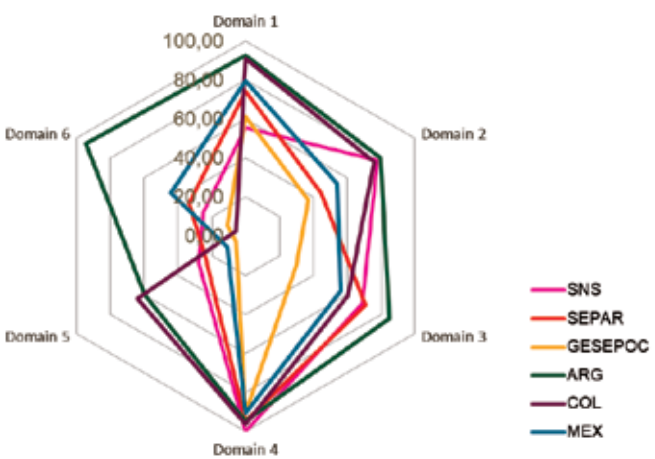
Domains	SNS	SEPAR	GESEPOC	ARG	COL	MEX
Domain 1	55.56	74.07	61.11	92.59	90.74	79.63
Domain 2	77.78	44.44	37.04	79.63	75.93	53.70
Domain 3	68.75	70.83	29.86	84.72	60.42	56.25
Domain 4	100	94.44	90.74	94.44	96.30	90.74
Domain 5	27.78	23.61	5.56	59.72	63.89	11.11
Domain 6	25.00	33.33	11.11	94.44	5.56	44.44
Total	61.35	59.42	36.96	82.85	66.91	54.59

SNS: PCG of the Quality Plan Guideline for the National Health System by the Spanish Ministry of Health[1]; SEPAR: PCG of Spanish Society of Family Medicine and the Spanish Society of Pneumology and Thoracic Surgery[13]; MEX: PCG of Mexican Institute of Social Security[14]; PCG of Work Group of GesEPOC[15]; COL: PCG of Colombian Health Ministry and Social Protection[16]; y ARG: PCG of Argentinian Health Ministry[17].

Table 4
Mean and Standard Desviation (%).

Domains	Mean	S.D.
Domain 1	75.62	15.15
Domain 2	61.42	18.72
Domain 3	61.81	18.48
Domain 4	94.44	3.51
Domain 5	33.10	24.46
Domain 6	35.65	32.13

Figure 1
Graphic representation of the Domains' compliance of each guideline.



– Regarding Domain 3 (rigor of development), continued highlighting Argentinean Guideline (84,72%), following SEPAR, SNS, Colombian y Mexican (values of 70,83%, 68,75%, 60,42% y 56,25%, respectively) which achieved a high score. In the opposite was GesEPOC, with a low score (29,86%).

– For Domain 4 (clarity of presentation), every consulted guidelines achieved a very high score. By order: SNS, Colombian, SEPAR, Argentinean, GesEPOC and Mexican (values del 100%, 96,30%, 94,44%, 94,44%, 90,74% and 90,74%, respectively).

– As to Domain 5 (applicability of the guideline), most of the guidelines achieved a low score, excluding Colombian and Argentinean (values of 63,89% and 59,72%, respectively) which, even though, did not achieved an outstanding outcome, at least obtained a high score, followed by SNS, SEPAR, Mexican and GesEPOC (values of 27,78%, 23,61%, 11,11% and 5,56%, respectively).

– Last one, in Domain 6 (editorial independence), only Argentinean guideline described explicitly a suitable editorial independence (94,44%), others did not pass half of the requirement posed by AGREE II evaluation: Mexican (44,44%), SEPAR (33,33%), SNS (25%), GesEPOC (11,11%) and Colombian (5,56%).

DISCUSSION

The obtained results served us to categorize and Rank which guidelines achieved the higher quality. Argentinean guideline is the only with very high score / very good compliance; followed by SNS, SEPAR, Colombian and Mexican with high score / good compliance; and, finally, GesEPOC with down score / down compliance.

Nowadays there is a great inconsistency in how "developers of clinic guidelines" of all the world sort out quality of the available and strength of recommendations[20], even though the most researchers are adapting GRADE system when they prepare manuscript about clinic guidelines[20]. Although the analysis of GRADE system[21] was not the objective of this study, seems reasonable reaching this point to describe this one.

Four of the six guidelines consulted in this study expressly mentioned using GRADE system to endorse quality of evidence found, as well as the grade of its recommendations. Four guidelines which use GRADE are Argentinean, SNS, SEPAR and Colombian. In other way, GesEPOC and Mexican guidelines do not expressly allude to the method used to achieve the evidence grade.

Seems reasonable to think that using GRADE system is a good strategy to save the quality of the guidelines because of, if we take the obtained data in our study, authors that establish the evidence with GRADE obtained a higher score before evaluation with AGREE II, both in the rigor of development domain and the global score.

In the other way, three of the looked at guidelines reference the using AGREE II method and the application of its recommendations during developing. These are: Argentinean, Colombian and SEPAR.

In one hand, we can derive that the better score Domains were the 4th (clarity of presentation) and 1st (scope and purpose of the guideline), being too which have less standard deviation and coincide with very high score category. These results are similar of the obtained by Parra-Anguita[10] and Uzeloto[11] as to the valoration of the Domains 1 and 4. Even

though with Parra-Anguita[10] in categories they do not match, but there is a trend. This high score show a good management of the objectives development, choice of the target population, clarity and the limited o null ambiguity of the recommendations issued by guidelines.

In the other hand, we reflect low score achieved in Domains 5 (applicability of the guideline) and 6 (editorial independence) by the most guidelines (except Argentinean), which achieved a standard deviation between 20-30%, with a score mean with the low compliance category. Mean and deviation of Domain 5 are similar to the outcomes of Uzeloto[11] and Acevedo[12] (this one, specially, deviation higher than our study). Again, with Parra-Anguita[10] outcomes do not match, but there is a trend; and both being the lowest score. This evidence the necessity of improve aspects related to implementation in practice of the guidelines, audit of PCGs, conflict of interests between professionals and independence with entities which help funding these studies.

After valuing results, we observed the most differences between guidelines affect, to a larger extent, in methodology and, lesser degree, to quality recommendations that provide.

We find interesting to mention that two guidelines with better score in Domain 5 (implementation), more than double, have used during developing a Guideline Implementability Appraisal (GLIA) tool to identify intrinsic barriers of PCGs reference to recommendations implementation.

The limitations we found in our study emerge in difficulty to obtain PCGs with search methods described in Methods, as well as limitation around language point due to limited number of evaluators used in this study. These factors excluded the evaluations of other guidelines like used by Uzeloto[11].

Finally, we want to bring out that is not our purpose disparage and disqualify using any evaluated PCGs, but show up aspects of developing of these which, in our judgment and backed by the AGREE II tool, should correct to increase quality and continuing developing these so valuable instruments for sanitary professionals.

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