ORIGINAL ARTICLE

Clinical practice guideline for the medical care of patients with exacerbation of chronic obstructive pulmonary disease

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ABSTRACT

Introduction: the process of medical care for patients with COPD exacerbation in the province of Sancti Spíritus shows deficiencies in the uniformity of the use of the clinical method in a structured way based on the diagnosis and treatment of these patients.
Objective: to design a Clinical Practice Guideline for hospital emergency medical care for patients with COPD exacerbation.
Methods: an investigation was carried out that corresponds to the research-development typology, multistage, with a mixed approach, in the province of Sancti Spíritus from 2017 to 2019.
Results: methodological deficiencies were detected in the medical care process of patients with exacerbation of COPD. A clinical practice guideline was developed and executed that allowed the structuring of theoretical, clinical and investigative elements to evaluate this type of patients.
Conclusions: the clinical practice guideline proved to be relevant, feasible and effective; it made possible an approach to patients with exacerbation of COPD and allowed raising the level of knowledge of doctors about this condition.
Key word: pulmonary disease, chronic obstructive; symptom flare up; practice guideline

RESUMEN

Introducción: el proceso de atención médica de pacientes con exacerbación de la enfermedad pulmonar obstructiva crónica en la Provincia de Sancti Spíritus muestra carencias en la uniformidad de la utilización del método clínico de forma estructurada en función del diagnóstico y el tratamiento de estos pacientes.
Objetivo: diseñar una Guía de prácticas clínicas para la atención médica de urgencia hospitalaria de pacientes con exacerbación de la enfermedad pulmonar obstructiva crónica.

Métodos: se realizó una investigación que se corresponde con la tipología de investigación-desarrollo, multietápica, con enfoque mixto, en la Provincia de Sancti Spíritus, desde el 2017 al 2019.
Resultados: se detectaron carencias metodológicas en el proceso de atención médica de pacientes con exacerbación de la enfermedad pulmonar obstructiva crónica. Se elaboró y se ejecutó una Guía de prácticas clínicas que permitió la estructuración de elementos teóricos, clínicos e investigativos para evaluar a este tipo de pacientes.
Conclusiones: la Guía de prácticas clínicas demostró tener pertinencia, factibilidad y efectividad, posibilitó una aproximación a los pacientes con exacerbación de la enfermedad pulmonar obstructiva crónica y permitió elevar el nivel de conocimientos de los médicos sobre esa afección.
Palabras clave: enfermedad pulmonar obstructiva crónica; brote de los síntomas; guía de práctica clínica

INTRODUCTION

Chronic obstructive pulmonary disease (COPD) represents a great challenge for humanity; it is estimated to affect 384 million people worldwide and to cause the death of more than three million patients each year. It is currently considered the "epidemic of the 21st century" among chronic noncommunicable diseases.[1] In Cuba, it was reported, in 2019, as the sixth leading cause of death.[2]

The natural history of COPD is characterized by exacerbations, defined by the scientific community as acute events with worsening of respiratory symptoms, dyspnea, cough, and sputum production.[3]

In major medical publication databases and with the use of several search engines, meta search engines, directories and subject guides, few original published researches on the medical care of patients with COPD exacerbation were found.

The clinical practice guidelines[3,4,5,6,7,8,9,10,11,12,13] that were reviewed refer to the importance of timely diagnosis and treatment of patients with COPD. Most of them address, in less depth, aspects related to hospital emergency medical care in COPD, mainly in the application of the third stage of the clinical method, when formulating the hypothesis, for not using efficiently the method of prior probability or the prevalence of the condition because, sometimes, a diagnosis can be reached only with the information obtained in the first two stages without the need to perform confirmatory complementary tests, taking into account that these patients suffer from a disease that requires urgent diagnosis and treatment. Scientific evidence has shown that the application of these guidelines allows for uniformity of care, adequate treatment and reduction of mortality in this type of patients.[14]

In Cuba, and in the Province of Sancti Spíritus, there are no structured programs or guidelines and information on patients with COPD exacerbation is scarce. It has been objectified the absence of homogeneity in the use of the clinical method, specifically in the third stage, according to the urgent diagnosis and treatment of these patients.

It was decided to carry out an investigation with the aim of designing a Clinical Practice Guideline (CPG) for hospital emergency medical care of patients with COPD.

METHODS

A research corresponding to the typology of research-development, multistage, with mixed approach (qualitative and quantitative) was conducted in the Internal Medicine Service of the "Camilo Cienfuegos" Provincial General Hospital in Sancti Spíritus city, from January 1, 2017 to December 31, 2019, which includes studies with varied scopes and research designs.

I. First stage. Diagnosis of the actual status of the hospital emergency medical care process for patients with COPD:

An exploratory study was conducted with a mixed quantitative-qualitative approach.

Sub-stages were established.

Sub-stage 1:

A case series study was conducted during 2017 and 2018 at the "Camilo Cienfuegos" Provincial General Hospital of Sancti Spíritus.

From a non-probabilistic purposive sampling, case types defined by all patients aged 19 years or older with a diagnosis of COPD were selected. The final sample consisted of 335 patients.

The variables selected were age, sex, risk factors, body mass index, associated chronic diseases, classification according to severity, place of treatment, pharmacological treatment, non-pharmacological treatment, complications, hospital stay and mortality.

Sub-stage 2:

An exploratory qualitative research was conducted with the aim of delving into aspects that characterized the process of hospital emergency medical care in patients with COPD exacerbation.

The study was developed in the context in which the care of patients with COPD was performed (Emergency Guard Corps, Conventional Ward, Progressive Care Units of the Provincial General Hospital "Camilo Cienfuegos" of Sancti Spíritus) during the years 2017 and 2018.

In this scenario, from the target population, a non-probabilistic sampling of intentional type was carried out that allowed selecting a homogeneous sample; it was considered as a selection criterion that the professionals were Specialists in Internal Medicine and Intensive Care.

The sample was made up of 35 physicians: 28 specialists in Internal Medicine and seven in Intensive Care; 29 of them worked all the time and six were administrative, assistants or teachers, with partial involvement in medical assistance.

The analysis of the situation was based on the search for documentary evidence on the process of hospital emergency medical care in patients with COPD and it was determined how well the physicians knew the theoretical aspects of this condition and the process of medical care for this type of patient.

With this intention, information gathering techniques and instruments were applied, including: analysis of documents (charge sheets, statistical records, individual clinical histories, operative reports and necropsy protocols), participant observation, in-depth interviews and nominal groups (three groups were formed: two with Internal Medicine Specialists [ten members] and one with Intensive Care Specialists [four members]).

II. Second stage. Design of a Clinical Practice Guide:

An analytical research aimed at the design of a clinical practice guideline for hospital emergency medical care in patients with COPD exacerbation was carried out.

In the methodology used, the following criteria and periodizations were taken into account.[15]

Phases of the guide

The chronogram and each phase of modeling of the guide for COPD patients are described; in some cases, the periods in which the types of studies are developed overlap.

1st. Preparation Phase (January 1, 2016 to January 31, 2017): this phase ended by having a defined structure and a sufficient body of knowledge about the health problem. Within this phase were included:

1. The choice of the problem based on the deficiencies detected, followed the prioritization criteria taken from traditional priority setting schemes in health planning that include relevance, magnitude, significance, vulnerability and feasibility.[16]
2. The type of guide was defined:
   - ✓ The level of attention involved: secondary care
   - ✓ Guideline activity: hospital emergency medical care.
   - ✓ Target professionals: physicians
3. The person responsible for its preparation was appointed: (Juana del Pilar Rodríguez Concepción).
4. A timeline was detailed and August 31, 2017 was set as the date for delivery of the draft guidance document.

2nd. Document development phase (February 1 to August 31, 2017): consisted of writing a document with all the data and knowledge collected in the previous phase, which ended with the provisional writing of the guide document. Four key parts were included in this phase:

1. An informed approach to the topic that included several aspects: formulation of the problem, identification and assessment of the scientific evidence. The strength of the evidence (the key areas of scientific uncertainty and theoretical discussion were considered), the relative importance of the benefits, the expected risks and the priority of the intervention.
2. General recommendations for the design were taken into account, including those related to the brevity of the document, which were designed and adapted to hospital care. A theoretical-conceptual document was prepared to justify its development and an operational document that included the algorithm.
3. The AGREE II instrument was used to prepare the guide.[17]
4. An algorithm was constructed to summarize the guide processes and decision analysis techniques were used. The recommendations of Adán Gil[18] were followed in relation to its construction, in which the approved symbols were used.

The algorithm was developed based on the review, analysis and integration of scientific evidence on the clinical and diagnostic evaluation of patients with COPD exacerbation published in peer-reviewed specialized medical journals;[19]

in addition, the inadequacies found in the process of in-hospital emergency medical care of these patients were taken into account.
The algorithm was approved by the Hospital's Scientific Council and was designed in compliance with the clauses of the Declaration of Helsinki[20].
3rd. Review and critique phase (September 1 to March 31, 2018): consisted of submitting the structure designed and the wording obtained in the previous phases to the discussion and critique of the professionals included in the nominal groups previously created and involved in its implementation. After collecting the corresponding suggestions and modifications, the final text of the guide was drafted and submitted for expert consultation.
4th. Dissemination phase (April 1 to December 31, 2017): the implementation consisted of disseminating the guide to all personnel involved. At that time, the date for implementation was set (January 1, 2018).
5th. Evaluation phase (every three months during 2019): compliance was monitored on a quarterly basis during 2019; the compliance and effectiveness of the guide was commented and analyzed. The AGREE II instrument was also used during this phase.[17]

Analysis of the information in the first stage:
In the first sub-stage, descriptive statistics were used: by hundreds and frequencies.
In the second sub-stage, a qualitative analysis was carried out in which the information obtained was organized into categories. Once the saturation of the information was reached, a reduction and transformation of the data were carried out, which were codified in the following themes or explanatory planes: cognitive, structural and results. Subsequently, the themes were related and the data were triangulated, which made it possible to generate hypotheses.
These results obtained in the diagnosis of the actual state of the hospital emergency medical care process in patients with COPD allowed the design of a clinical practice guide taking into account the context in which the process takes place.
The authors chose the use of the guide as a scientific result in their research because it is based on a planning process that allows the projection of the transformation process of the emergency medical care process for these patients from an actual state to a desired state through intervention actions elaborated in a conscious and intentional manner.
Analysis of the information in the second stage:
A qualitative analysis was performed to design the guideline through the results obtained in the diagnosis of the actual state of the hospital emergency medical care process in patients with COPD exacerbation.

III. Third stage. Evaluation of the Clinical Practice Guideline:
Analytical research was conducted for the evaluation of relevance and feasibility in the period from January 1, 2017 to December 31, 2017.

Methodology for the evaluation of relevance and feasibility through expert criteria:
It corresponds to the evaluation of its relevance. The research used expert criteria to evaluate the relevance, feasibility and acceptance of the Clinical

Practice Guideline for hospital emergency medical care for patients with COPD in order to improve it and try to reduce errors before its application.[19,21]
It was carried out using the expert judgment method in the peer comparison modality.[19,21] The dynamics of the procedures are described in more detail below:
(a) Determination of experts.[19,21]
Initially, 35 potential experts were identified, from which 30 were chosen to constitute the final panel of experts. This selection took into account practical experience and expertise in aspects related to hospital emergency medical care of patients with COPD exacerbation, as well as professional prestige and a competence coefficient equal to or greater than 0.8.
The self-assessment test was applied to each selected expert to calculate the competence coefficient, in which first the argumentation coefficient (Ka) and the knowledge coefficient (Kc) were calculated and, subsequently, the competence coefficient (K) was calculated by obtaining the average of the Kc and Ka coefficients. The K coefficient is calculated by the expression: K=(Kc+Ka)/2.
b) Analysis of the experts' criteria[19,21]
Subsequently, a questionnaire with open-ended and weighting questions, as well as a synthesis of the guide, was prepared for the experts' consideration. Direct delivery was the selected method of consultation.
The questionnaire was sent to each expert with the guidelines for analyzing the guide, as well as the indicators that enabled them to make their judgment. Five evaluative categories were considered with their corresponding rationale. The evaluations given were statistically processed through the steps established by the pairwise comparison procedure.
Each aspect included in the guide was evaluated independently by each expert with the following categories (in descending order): very adequate (VA), quite adequate (VA), adequate (A), not very adequate (VA) and inadequate (I).
A quasi-experimental analytical research was conducted for the evaluation of the effectiveness of the designed Clinical Practice Guideline through ascertainment in clinical practice in the period from January 1, 2019 to December 31, 2019.

Methodology for effectiveness evaluation

A non-probabilistic purposive sampling was performed to define a sample of 161 patients with COPD diagnosed in the period from January 1, 2019 to December 31, 2019, who formed the study group. For the purpose of evaluating effectiveness, all the participants in the first stage of the study were assumed as the historical control group.

Criteria and indicators of effectiveness of the Clinical Practice Guidelines:

1. Indicator: adherence to the Clinical Practice Guideline.
   - Type of indicator: process. Dimension: effectiveness
   - Definition: actions performed during the medical care of patients with COPD exacerbation according to the applied guideline.
   - Calculation: number of actions performed on COPD patients/total number of actions planned for COPD patients according to the guideline.

- Rationale: this indicator aims to identify the number of actions performed in accordance with the guidelines according to the medical records of patients with COPD during emergency medical care.
- Data to be collected and sources: number of actions performed in correspondence with the guideline according to clinical records. Purpose: 70%.

2. Indicator: complicated patients
   - Type of indicator: outcome. Dimension: effectiveness
   - Definition: the presence of complications according to those considered in the theoretical framework of the thesis.
   - Calculation: number of complicated patients with diagnosis of COPD/number of patients with diagnosis of exacerbation of COPDx100
   - Rationale: this indicator aims to identify the complications presented during the admission of patients with COPD.
   - Data to be collected and sources: type of complications and number of complications according to clinical history from admission to hospital discharge.
   - Available standards: 75.2% (taken from the outcome of the historical control group). Purpose: 60%.
3. Indicator: hospital stay
   - Type of indicator: outcome. Dimension: effectiveness
   - Definition: days that patients with COPD exacerbation stayed in hospital.
   - Calculation: total number of days of stay of patients diagnosed with COPD/number of patients diagnosed with COPD.
   - Rationale: this indicator aims to identify the time elapsed between admission and discharge in patients with COPD during hospital emergency medical care
   - Data to be collected and sources: time elapsed in days according to medical records from admission to hospital discharge.
   - Available standards: more than seven days (taken from historical control group outcome). Purpose: less than seven days.
4. Indicator: mortality
   - Type of indicator: outcome. Dimension: effectiveness
   - Definition: patients who died with a diagnosis of COPD exacerbation.
   - Calculation: number of patients who died with a diagnosis of COPD exacerbation/number of patients with a diagnosis of COPD exacerbation.
   - Rationale: this indicator aims to identify patients who died with a diagnosis of COPD exacerbation during emergency medical care.
   - Available standards: 49.5% (taken from historical control group outcome)
   - Target: 45%.
   - Indicator population: patients admitted with a diagnosis of COPD.

RESULTS

I. First stage. Main diagnostic results.

Sub-stage 1:

During 2017 and 2018, 335 patients were discharged with the diagnosis of COPD exacerbation. It was identified that 75.2% of patients presented

complications, hospital stay was more than seven days in 79.7% and 166 (49.5%) patients died.

Sub-stage 2:

In the documental review, evidence of emergency behavior in patients with COPD was detected, as well as the clinical manifestations at the time of admission, the medical investigations performed, the unit of admission, complications and hospital stay.

A review of the autopsy protocols revealed the causes of death. The results obtained through the techniques of approximation and identification of the problems were organized according to the categories of the participating groups.

Once the saturation of the information was reached, the data were reduced and transformed and codified into the following themes or explanatory, cognitive, structural and outcome levels. After relating all the themes, the data were triangulated (Figure 1), which made it possible to generate the following hypotheses:

- There was a need for learning about COPD
- Difficulties in the interpretation of times related to hospital stay
- Lack of multidisciplinary management from admission
- Variability in in-hospital treatment
- Lack of individualization of therapeutic actions
- Lack of CPG, protocols and action algorithms that would allow an organized flow in the emergency medical care process.

II. Second stage. Design of the Clinical Practice Guideline for the hospital emergency medical care process for patients with COPD exacerbation.

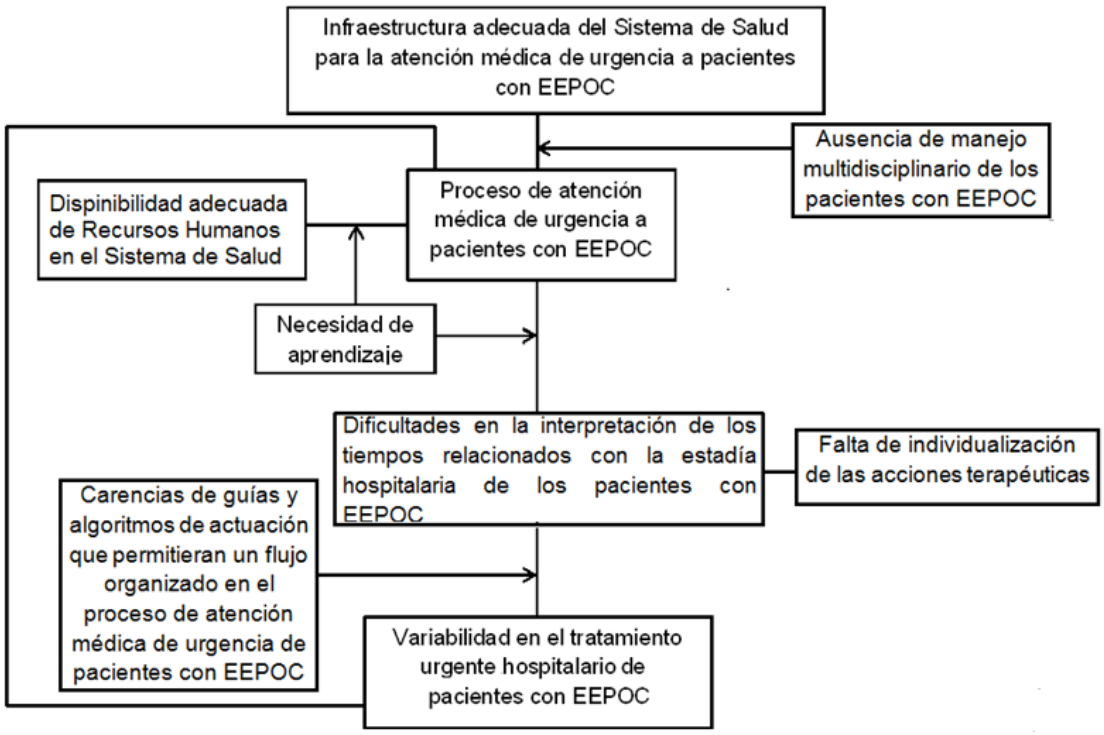

Figure 1. Set diagram. Factors related to the process of medical care for patients with COPD exacerbation

From the results obtained in the diagnosis of the actual state of the process of hospital emergency medical care of patients with COPD, it was derived that the fundamental ideas that should be developed in a clinical practice guide to modify the problems identified should be: actions to raise the level of knowledge of physicians about COPD exacerbation, actions that allow multidisciplinary interrelation for the care of patients with this condition and actions to organize the process of clinical, diagnostic and therapeutic evaluation of these patients.

The guidelines were modeled according to the methodology proposed by Alva Diaz,[15] which includes theoretical considerations by way of introduction, scope and objectives, clinical questions, synthesis of essential knowledge on COPD and 17 recommendations on diagnosis and treatment with their respective levels of evidence and degree of recommendation. It also includes an algorithm that, by way of synthesis, made it possible to graph the sequence of steps corresponding to the diagnosis and treatment process (Figure 2).

III. Third stage. Evaluation of the Clinical Practice Guideline.

Evaluation of the relevance and feasibility of the proposed clinical practice guideline by means of expert criteria.

In order to obtain an initial evaluation of the relevance of the guide, the expert criteria was used as a method, characterized by its potential to show consensus opinions regarding the proposal, based on the judgment issued by people who have a high level of knowledge in the subject under investigation.

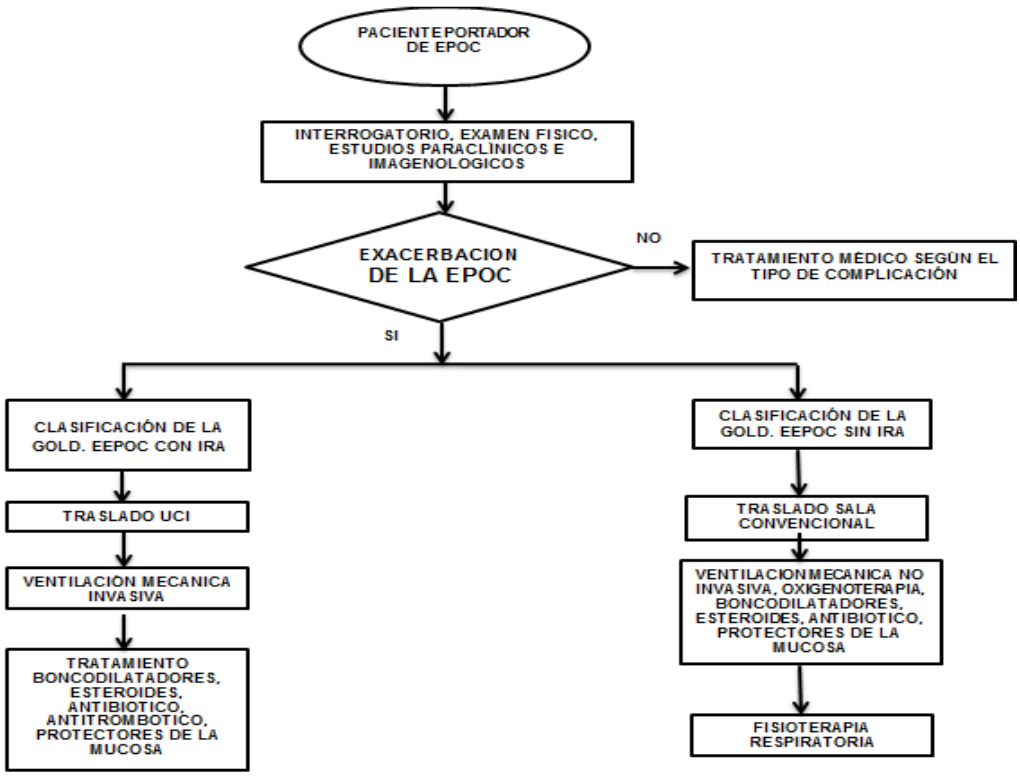

Figure 2. Diagnostic-therapeutic algorithm for patients with COPD exacerbation

The experts carried out the analysis of the guide through the indicators that allowed them to make their judgment and, when statistically processing the

evaluations given through the steps established by the peer comparison procedure, the indicators to be evaluated reached the category of "very adequate", which allowed affirming that the guide was considered pertinent by the experts consulted.
The proposed guide was positively evaluated by the experts, according to the results obtained, for its contribution to therapeutic decision-making according to the different situations presented, the individualized actions proposed and the multidisciplinary approach to patient behavior.

Evaluation of the effectiveness of the Clinical Practice Guideline for hospital emergency medical care of patients with COPD.
To evaluate the effectiveness of the designed guideline, a quasi-experimental investigation was conducted during the time period from January 1 to December 31, 2019.
For the purposes of the quasi-experiment, we worked with two groups: a historical control group, made up of the participants in the diagnosis made during the first stage (335 patients), and a study group, prospectively composed of 161 patients with COPD exacerbation, that is, all of those seen in the period of 2019.
The results of the evaluation of effectiveness according to compliance with the assumed indicators are shown in Table 1. A summary was made showing the purpose figures and comparing the results of each indicator between the historical control group and the group of patients who were treated with the guideline.

Table 1. Results of the evaluation of the effectiveness of the CPGs

Indicator	Previous	Purpose	Real	CP
Adherence to CPG	-	70%	74.6%	Yes
Complications	75.2%	60%	37.2%	Yes
Hospital stay	> 7 days	< 7 days	< 7 days	Yes
Mortality	49.5%	45%	40.3%	Yes

CP: compliance with the purpose

More than 70% adherence to the actions described in the CPG was achieved, while the number of patients with complications was reduced to below the target figure. In addition, the hospital stay was reduced and mortality was reduced.
Compliance with the indicators shows that the CPG for hospital emergency medical care for patients with COPD exacerbation was effective.

DISCUSSION

The medical care process is defined as a set of actions to be performed by the physician in order to intervene in an active and determinant way on the health-disease process that occurs in an individual, the family and the community to reach a specific result; it is one of the dimensions of quality in the medical care of patients with COPD.[22]
This process should include a set of actions to convert the structure (institutions, supplies and personnel in charge of patient care) into outcomes

(identification, assessment, diagnosis, treatment and follow-up of patients with COPD exacerbation) and to add value to the service provided to these patients.[22]

It was possible to diagnose the actual state of the hospital emergency medical care process for patients with COPD prior to the design of the clinical practice guidelines, which showed inadequacies, both in the identification of patients and in the organization of their diagnosis and treatment.

Through the triangulation of the data, a set diagram of the factors related to the medical care process for patients with COPD exacerbation was developed.

The Clinical Practice Guideline was designed and implemented with the intention of perfecting the process of hospital emergency medical care for patients with COPD, and a flow algorithm was created.

The implementation of the Clinical Practice Guide allows for a resizing and restructuring of the elements involved in the process of care for patients with this condition and establishes the necessary conditions for its improvement based on the integration of the system's components.

The feasibility and relevance of the proposed Clinical Practice Guide were validated based on the criteria and assessment of 30 experts, as well as its effectiveness through the application of quality criteria and indicators.

When the process of hospital emergency medical care was developed, according to the proposed guide, a first approach to patients with COPD could be made, which allowed describing clinical and epidemiological aspects that characterized them.

Comparisons with other studies were not made because there are no reports on the scientific results of applying published clinical practice guidelines for patients with COPD exacerbation.

CONCLUSIONS

From the methodological deficiencies detected in the process of hospital emergency medical care in patients with COPD, a Clinical Practice Guide was designed with the aim of improving this process. The guide was based on two fundamental aspects: the first consisted of the integration of epidemiological, clinical and investigative theoretical elements of the disease under study, as well as its organization and structuring to evaluate and investigate these patients. After its application, the relevance, feasibility and effectiveness of the Clinical Practice Guideline were verified.

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CONFLICT OF INTEREST

The authors declare that they have no conflict of interest in this research.

CONTRIBUTION OF THE AUTHORS

JPRC: conceptualización, análisis formal, metodología, curación de datos, investigación, recursos, validación, visualización, investigación, redacción del borrador original, redacción (revisión y edición).
GAOM: curación de datos, investigación, recursos, validación, redacción (revisión y edición).
BDCF: metodología, investigación, visualización, redacción (revisión y edición).
MFVR y AMVR: visualización, redacción (revisión y edición).