EA-BPCO-2025

Predictive factors for 3-year survival of patients hospitalized for acute exacerbations (AE) of COPD in the pulmonology departments of general hospitals from 1/11/2025 to 31/10/2026

Promoter	**College of Pulmonologists of General Hospitals (CPHG)** House of Pulmonology, 68 boulevard Saint-Michel, 75006 Paris. Represented by: **Dr. Hugues MOREL** , President of the CPHG Tel: 02 38 61 32 23 E-mail: hmorel@ch-morlaix.fr
Investigator - coordinator	**Dr. Nicolas DELBERGHE** Eure-Seine Hospital Center – Évreux-Vernon Hospital Tel.: (+33) 2 32 33 80 66 Email: nicolas.delberghe@ch-eureseine.fr
Investigators	Within general hospitals (CH) in France, pulmonology departments will be contacted. All pulmonologists practicing in a pulmonology department will be invited to participate in this study by email.
Date of protocol	September 2025
Protocol version	2.0

Synopsis

Title of the study	**EA-BPCO-CPHG Study** ***Predictive factors for 3-year survival of patients hospitalized for acute exacerbations (AE) of COPD in the pulmonology departments of general hospitals from 1/11/2025 to 31/10/2026.***
Promoter	**College of Pulmonologists of General Hospitals (CPHG)** House of Pulmonology, 68 boulevard Saint-Michel, 75006 Paris. Represented by: **Dr. Hugues MOREL**, President of the CPHG Tel: 02 38 61 32 23 E-mail: hmorel@ch-morlaix.fr
Coordinating Investigator	**Dr. Nicolas DELBERGHE** Eure-Seine Hospital Center – Evreux-Vernon Hospital Tel.: (+33) 2 32 33 80 66 Email: nicolas.delberghe@ch-eureseine.fr

Steering Committee	**Investigator - coordinator:**
	• Dr. Nicolas Delberghe (Évreux)
	
	Other members:
	• **CHG Members**
	  • Dr. Marielle De Marchi - GHI Elbeuf
	  • Dr Marion Gory Bouilly - Guingamp Hospital
	  • Dr. François Goupil - CHR Le Mans
	  • Dr Hugues Morel – CH Morlaix
	  • Dr Cecilia Nocent - CH Bayonne
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	• **Academics**
	  • Professor Nicolas ROCHE - AP-HP Paris-Cochin
	  • Dr Maëva ZYSMAN - Bordeaux University Hospital
	  • Marina GUECAMBURU - CHU Bordeaux

Centers and Investigators	- The pulmonology departments of general hospitals (CH) in France will be contacted. All pulmonologists practicing in a pulmonology department will be invited to participate in this study by email. - Around 80 pulmonologist investigators are expected in 50 centers.

State of the question	**COPD is a public health problem with more than 3 million patients in France, its environment has changed in 15 years.** The rate of exacerbations in COPD patients varies from patient to patient and over time. The best predictor of exacerbations is a history of exacerbations (≥2 exacerbations/year). Worsening respiratory function is associated with an increased prevalence of exacerbations. The measurement of blood eosinophilia as a predictor of exacerbations is discussed. The implementation of a new observational, prospective, real-life study in conditions superimposable on those of the EA-BPCO study conducted in 2006 would make it possible, on the one hand, to describe the characteristics of COPD patients admitted to hospital for EA in 2025 and to study mortality at 3 months and 3 years and risk factors; on the other hand, to compare these data with those of the EA-BPCO study conducted in 2006.
Objectives of the study	**Main objective:** • To assess the 3-year survival and predictive factors of survival of patients admitted to hospital for acute exacerbation (AE) of COPD. **Secondary objectives:** • To assess the predictive factors for 3-month survival in patients admitted to hospital for acute exacerbation (AE) of COPD. • Explore the existence of subtypes ("phenotypes/endotypes") of exacerbations • To describe the characteristics of patients, COPD and its management prior to hospitalization, in patients with COPD admitted to hospital for EA; • Describe the hospitalization management of COPD EA (therapy, patient characteristics, follow-up, etc.) • Compare the evolution of patient characteristics, COPD and its management since 2006 • Assessing the seasonality of COPD EAs • To assess the impact of social deprivation on 3-year survival of patients admitted to hospital for EA

Population concerned	All patients hospitalized in a CH, in pulmonology for an EA linked to COPD (whether known or not) between 1/11/2025 and 31/11/2026 will be included, regardless of their mode of admission (emergency, consultation, direct admission, intensive care, other service) or associated pathologies (SAHOS, obesity/hypoventilation syndrome, active cancers, etc.) Also affected are: - patients with decompensation, initially admitted to pulmonology and subsequently transferred to intensive care. - patients already fitted with a device (OLD, NIV). All patients who have experienced EA related to known or unknown COPD, diagnosed between 01/11/2025 and 31/10/2026 at participating centers will be informed of the objectives and duration of the study. Each patient will be required to provide oral consent or non-opposition prior to inclusion in the EA-BPCO-CPHG study and follow-up. **Inclusion criteria** - Age ≥18 years old - All patients hospitalized in pulmonology for EA linked to COPD (whether known or not) , admitted between 1/11/2025 and 31/10/2026. Regardless of their mode of admission (emergency, consultation, direct admission, intensive care, other service) or the associated pathologies (SAHOS, obesity/hypoventilation syndrome, etc.) that they present. - Also affected are: o patients with decompensation, initially admitted to pulmonology and subsequently transferred to intensive care. o patients already fitted with a device (OLD, NIV) o Patients diagnosed with COPD following this EA. - Information note given and explained to the patient, oral agreement or non-opposition from the patient **Non-inclusion criteria** - Age < 18 years, - Previous inclusion in the study - Patient unable to perform an EFR, to collaborate with this protocol, unable to answer the questions asked. - Patient deprived of liberty following a judicial or administrative decision, - Patient unable to give consent.
Type of study and methodology	Prospective, observational, national, multicenter, non-interventional cohort study, not affecting patient care.

Data collected	**<u>At inclusion in the study</u>**
	1/ Patient demographic characteristics
	- Age, sex, municipality of residence
	- BMI
	- Smoking status, cannabis
	- Score SPICES
	2 / History: COPD comorbidities and treatment
	- History of COPD
	- Associated comorbidities
	- Latest spirometry
	- CAT score if available
	- Baseline Global Assessment of COPD – ABE score
	- Ongoing <u>COPD</u> management
	  o Drug Treatments
	  o Non-drug treatments
	- Vaccinations
	3/ Upon admission, characteristics of the EA
	- Admission mode
	- Etiologies or factors associated with EA-COPD of the current episode
	- Functional signs
	- Signs of severity including biology
	- EA Classification
	4/ EA support
	- Patient circuit
	- Treatments administered
	  o in critical care (if applicable)
	  o in pulmonology
	5/ Upon leaving pulmonology
	- Exit mode
	- COPD management at discharge
	  o Treatments
	  o Other support
	
	<u>After hospitalization</u>
	6/ Assessment between 3 and 9 months (as part of the patient's usual follow-up)
	- COPD Reassessment
	- Existence of obstructive ventilatory disorder (OVD)
	- Current treatments
	
	<u>At 3 years old</u>
	7 / Vital status at 3 years
	- Date
	- Cause of death
	
	** Items specific to intensive care were included in the questionnaire (intubation, length of stay in intensive care and invasive ventilation)*

Duration of the study	- Length of inclusion period: 1 year
	- Data collection for <u>each patient</u> :
	  o 1- At inclusion,
	  o 2- Between 3 and 9 months after inclusion,
	  o 3- At 3 years old
	- Total duration of the study: 4 years

Data analysis method	The analyses will be carried out using R software. The data collected will first be described: - Mean, standard deviation (SD), median, and quartiles, minimum, maximum for quantitative variables - Number and percentage for qualitative variables. Comparisons can be made using parametric and non-parametric tests: - Student test, or Wilcoxon-Mann-Whitney test, if 2 groups, ANOVA or Kruskal-Wallis test if more than 2 groups, for quantitative variables - Chi-square or Fisher test for qualitative variables To determine EA subtypes based on COPD characteristics, classification methods will be used. Survival is defined as the time from the date of admission for AECOPD to the date of death. 3-year survival rates will be calculated using the Kaplan-Meier method and presented with their 95% confidence interval (95% CI). Univariate and multivariate Cox analyses will be performed to study the predictive factors of survival. Considering the binary variable of death at 3 months (yes/no), logistic regressions will be performed to search for variables having a predictive role. Multivariate analyses may include socioeconomic factors (self-administered questionnaires) to study the impact of social deprivation on survival after EA COPD. To study the seasonality of EAs, time series analyses will be used.
Number of patients	With an estimated participation of 60 centers, approximately 80 to 100 pulmonologists and an inclusion period of 1 year, the cohort size is estimated at 3,000 to 5,000 patients. * *A center can represent several investigators*

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List of abbreviations

ALD: long-term illness
AMM: marketing authorization
ANSM: National Agency for the Safety of Medicines and Health Products
ARC: Clinical Research Associate
BD: bronchodilators
COPD: chronic obstructive pulmonary disease
CHG: General Hospital Center
CHR: Regional Hospital Center
CRF: Case Report Form (eCRF: electronic CRF)
CSI inhaled corticosteroid
CSO: oral corticosteroid
CV: vital / cardiovascular capacity
DEM: Mean expiratory flow
PEF: Peak expiratory flow
EA COPD: acute exacerbation of COPD
EFR: respiratory function test
ESPIC: Private health establishment of collective interest.
EPICES: Score Evaluation of precariousness and health inequalities in health examination centers
ETP: therapeutic patient education
EVA: Visual Analogue Scale
FC: heart rate
FFAAIR: French Federation of Associations and Friendly Societies for Respiratory Insufficiency Patients
FR: respiratory rate
HAS: High Authority for Health
IRC: chronic respiratory failure
IV: intravenous
LABA: long-acting bronchodilator
LAMA: long-acting antimuscarinic
MAR: anesthesiologist-resuscitator
MIR: intensive care physician
mMRC: The modified Medical Research Council (mMRC) Dyspnea Scale
MPR: physical and rehabilitation medicine
NICE: National Institute for Health and Care Excellence
OLD: long-term oxygen therapy
PaO2: arterial oxygen pressure
PMSI: Information Systems Medicalization Program
PO: per os
RR: respiratory rehabilitation
SABDs: Short-acting bronchodilators only
OSAS: obstructive sleep apnea syndrome
SpO2: pulse oxygen saturation of hemoglobin
SPLF: French-speaking pulmonology society
TEC: clinical trial technician
TVO: obstructive ventilatory disorder
USC: Continuing Care Unit
ICU: Intensive Care Unit
FEV1: forced expiratory volume in the first second
NIV: non-invasive ventilation

I. Background & Rationale of the study

COPD and exacerbations

Chronic obstructive pulmonary disease (COPD) is the third leading cause of death worldwide, resulting in 3.23 million deaths in 2019. Tobacco use accounts for more than 70% of COPD cases in high-income countries [1].

In France, its prevalence is difficult to estimate, at around 5 to 10% of adults over 45. In 2023, the number of inhabitants over 45 in France will represent 32 million inhabitants in 2024, representing a potential number of COPD patients of between 1.6 and 3 million. COPD has underestimated health, social and economic impacts; representatives of the medical community and patients have drafted recommendations in a white paper, calling on politicians to mobilize to provide effective responses to this health emergency [2]. In 2017, the number of hospitalizations for COPD was 105,723 stays, representing 76,938 patients. 77.5% were hospitalized once in 2017 and 22.5% were hospitalized at least twice (PMSI 2017 data).

In 2021, the French-speaking pneumology society (SPLF) updated [3] the recommendations for the drug management of stable COPD. Recommendations on the management of exacerbations were published in 2017 [4].
COPD was the first pathology to be selected in 2020 by the High Authority for Health (HAS) to develop quality indicators for the care pathway [5].

The definition of exacerbation

According to GOLD 2024 [6], an exacerbation is a worsening of dyspnea and/or cough lasting less than 14 days. Exacerbations are associated with increased local and systemic inflammation related to infection, pollution, or other pulmonary irritants. Symptoms are not specific to COPD.

The classification of exacerbations was formerly based on the therapeutic strategy: Mild: treated with short-acting bronchodilators (SABDs) only - Moderate: treated with SABDs and oral corticosteroids +/- antibiotics - Severe: patients requiring hospitalization or emergency department consultation. Severe exacerbation may be associated with acute respiratory failure, has been revised by several teams, including the ROME proposal [7].

GOLD 2024 Classification

Light	• Dyspnea EVA <5 • FR <24/ min • HR < 95bpm • Sat O2 ≥92% breathing room air (or in patients on O2) and change ≤3% • CRP < 10mg/l
Moderate	• Dyspnea EVA ≥5 • FR≥ 24/ min • HR ≥95bpm • Sat O2<92% breathing room air (or in patients on O2) and/or change >3% • CRP ≥10mg/l
Severe	• Dyspnea, RR, SatO2 and CRP same as moderate • Worsening blood gases and acidosis (PaCO2 >45 and pH <7.35)

Therapeutic management of exacerbations

Short-acting bronchodilators may be recommended in the initial phase, and maintenance therapy with long-acting bronchodilators should be initiated as soon as possible. In frequent exacerbators with blood eosinophilia, inhaled corticosteroids with LABA and LAMA are recommended.
In patients with severe exacerbations, systemic corticosteroids (lasting <5 days) can improve respiratory function and shorten hospital stay. Antibiotic therapy, if indicated, (lasting <5 days) shortens hospital stay and reduces the risk of relapse. NIV improves gas exchange, reduces hospital stay, and improves survival.
Healing time after an exacerbation varies from 4 to 6 weeks.

Risk factors for exacerbation

The rate of exacerbations in COPD patients varies from patient to patient and over time. The most important predictor of exacerbations is the history of exacerbations (≥2 exacerbations/year). Worsening of respiratory function is associated with the increased prevalence of exacerbations. The measurement of blood eosinophilia as a predictor of exacerbations is debated. Some studies have demonstrated this link [8- 9] . A high eosinophilia level is a predictor of response to inhaled corticosteroids and biotherapies.

This measure is justified at the time of initiation of these treatments. Retrospective cohorts of patients hospitalized for exacerbations have recently made it possible to study the link between the severity of COPD using the ROME criteria and mortality [10, 11]. The SPLF COPD working group has published its position on this new classification Regard et al [12]

In a French study conducted in 2003-2004, concerning 794 patients hospitalized for EA [13], a three-grade clinical severity index (no severity criteria, one or two severity criteria and at least three severity criteria) was constructed. Clinical signs of severity at admission (cyanosis, altered neurological status, lower limb edema, asterixis, use of inspiratory accessory muscles and expiratory use of abdominal muscles).

The EA-BPCO study in 2006

In 2006, the CPHG initiated a large observational, prospective study - EA-BPCO - with the creation of a cohort of patients consecutively hospitalized for EA in the pulmonology departments of the CHG [14]. This was part of a context of improving knowledge on acute exacerbations (EA) of COPD. This study had two components: the description of the management of hospitalized EA and their evolution at 3 months; the 3-year survival of this population.

- **Main objective:** to study 3-year survival and predictive factors of 3-year mortality (all causes and respiratory diseases)

- **Secondary objectives:** to study the predictive factors of the evolution of hospitalized COPD EA at 3 months in terms of long-term oxygen therapy (LTO) and/or non-invasive ventilation (NIV); to describe the characteristics of COPD prior to the EA episode; to describe the hospitalization management of COPD EA (therapeutics, patient characteristics, follow-up, etc.);

In 2007, 1849 patients were included between October 2006 and June 2007, by 68 investigating centers. The 4-year mortality rate after admission for EA was high 45%. Multivariate analysis showed that high age (60-80 years and > 80 vs < 60 years), low BMI (≤20 vs >25) , CV comorbidities, lung cancer, hospital admission for EA (> 4 vs 0), use of accessory respiratory muscles or lower limb edema at admission and long-term oxygen therapy at discharge were independent risk factors for death [15].

Problematic in 2024

COPD will affect between 1.6 and 3 million patients in France in 2024, and its environment has changed over the past 15 years. With an aging population, patient profiles have changed, with the presence of more

and more frequently associated comorbidities. Access to care has also changed since the 1980s, with the trend toward a reduction in the number of hospital beds, a number of partial hospitalization places, and increasing home hospitalization capacity.

Regarding the management of COPD, taking into account, among other things, the inflammatory component of the disease justifies the prescription of inhaled triple therapy (LABA-LAMA-CSI) and the development of biotherapies (anti IL-4/IL-13, anti-IL-5, anti IL-33, etc.). Beyond changes in the drug strategy, the widespread use of home oxygen therapy, respiratory rehabilitation, and therapeutic education have also shaken up the approach to COPD in recent years.

The implementation of a new observational, prospective, real-life study in conditions superimposable on those of the EA-BPCO study conducted in 2006 would make it possible, on the one hand, to describe in 2025, the characteristics of COPD patients admitted to hospital for EA, to explore possible subtypes of exacerbations and to study survival at 3 months and 3 years and risk factors for mortality; on the other hand, to compare these data with those of the EA-BPCO study conducted in 2006.

II. Objectives of the study

Main objective

- To assess the 3-year survival and predictive factors of survival of patients admitted to hospital for acute exacerbation (AE) of COPD.

Secondary objectives

- To evaluate the predictive factors of 3-month survival in patients with COPD admitted for acute exacerbation (AE) of COPD.
- Explore the existence of subtypes ("phenotypes/endotypes") of exacerbations according to
    - The phenotypic characteristics of the underlying COPD (chronic sputum, emphysema on imaging, history of exacerbations, associated asthma, etc.)
    - The inflammatory profile (blood eosinophil levels),
    - The presumed or documented etiology (microbiology),
- To describe the characteristics of patients, COPD (phenotype, inflammatory profile, presumed etiology) and its management prior to hospitalization, in patients with COPD admitted for hospitalization for EA;
- Describe the management (drug and non-drug) in hospitalization of COPD EA and in follow-up, according to age, comorbidities, etc.
- To compare the evolution since 2006 of the characteristics of patients with COPD admitted to hospital for EA and their management
- Assessing the seasonality of EAs in COPD
- To assess the impact of social deprivation on survival after EA in patients with COPD

III. Investigators and study organization

Study Sponsor

The sponsor of the study is the College of Pulmonologists of General Hospitals (La Maison de la Pneumologie, 68 boulevard Saint-Michel, 75006 Paris), represented by Doctor (Dr.) Hugues MOREL, pulmonologist (CHR de Morlaix), president of the CPHG.

Coordinating Investigator of the Study

The coordinating investigator of the study is Dr. Nicolas Delberghe, Pulmonologist at the Évreux Hospital Center, Rue Léon Schwartzenberg, 27000 Évreux

Scientific Committee of the study

The steering committee is made up of 11 members.

Investigator - coordinator:

- Dr. Nicolas Delberghe, Pulmonologist CH Évreux

Other members:

- **CHG Members**
  - Dr Marielle De Marchi — GHI Elbeuf
  - Dr Marion Gory Bouilly — CH de Guingamp
  - Dr François Goupil — CH R Le Mans
  - Dr Hugues Morel — CH Morlaix
  - Dr Cecilia Nocent — CH Bayonne
  - Dr Jacques Picquet — GHI Montfermeil
  - Dr. Laurent Portel — CH Libourne

- **Academics**
  - Professor Nicolas ROCHE — AP-HP Paris-Cochin
  - Dr Meava ZYSMAN — CHU Bordeaux
  - Marina GUECAMBURU — CHU Bordeaux

Centers and investigators

The study will take place in the pulmonology departments of hospitals in mainland France and in the overseas departments and regions and overseas communities (DROM-COM).

Center for Management and Statistical Analysis

The management of the study was entrusted by the CPHG to the company Margaux Orange (20 rue du mail, 75 002 Paris).
The collection of electronic data was entrusted to the company ClinInfo (Lyon).
Statistical analyses will be carried out by the company QualytiStat.

IV. Study outline

EA-BPCO-CPHG is a prospective, national, multicenter, observational cohort study of patients with acute exacerbation related to known or unknown COPD.

This study does not affect patient care in any way: no additional examinations will be carried out, nor any treatment administered, specifically within the framework of this study.
A post-hospitalization follow-up visit after a COPD exacerbation carried out between 3 and 9 months is part of follow-up according to good practices. Post-hospitalization follow-up by a pulmonologist of patients presenting a COPD exacerbation is one of the quality indicators of the care pathway recommended by the HAS [5].
3-year survival is sought without consultation required.

This study includes three periods:

- The constitution of the cohort, the collection of data at inclusion concerning the history of COPD, the description of the characteristics of the patients and the management of the EA episode.
- The visit between 3 and 9 months after inclusion in the study.
- Research into the vital status of patients at 3 years.

The following diagram summarizes the different stages of the EA-BPCO-CPHG study .

Year	**2025**			**2026**			**2027**		**2028**		**2029**	
Month	**June**	**August**	**Nov.**	**Feb.**	**Oct.**	**Dec.**	**Feb.**	**Jul.**	**Oct.**	**Apr.**	**Oct.**	**Dec.**
Call for investigators	x	x										
Registration on the investigators' website	x	x										
Patient inclusion			x									
Data Collection - Inclusion			x									
Data collection - 3-9 month follow-up				x								
Data Collection - 3-Year Survival			x									
Data management					x							
Analyses							x					
Publications									x			

Cohort formation and data collection at inclusion

The EA-2020-CPHG study will take place over a **one- year period ,** from November **1 ' 2025 to October 31, 2026** .

In June 2025, all pulmonologists practicing in a pulmonology department of a CH and associated (ESPIC, Military Hospital, etc.) in metropolitan France and in the overseas departments and regions and overseas communities (DROM-COM), will be invited to participate in the EA-BPCO-CPHG study by email.

Before September 30, 2025, each physician agreeing to participate will register on the study site to indicate their participation in EA-BPCO-CPHG .

During the month of October, physicians who have agreed to participate (investigating physicians) will receive identifiers to connect to the e-CRF developed by the study's scientific committee. (Appendix 1).

From 01/11/2025 to 31/10/2026, investigators will exhaustively include all new patients admitted to the pulmonology hospital department for an acute exacerbation (AE), regardless of their mode of arrival (emergency, consultation, direct admission, intensive care, other department) or associated pathologies (OSA, obesity/hypoventilation syndrome, etc.). Patients in decompensation, initially admitted to pulmonology and subsequently transferred to intensive care, and patients already fitted with a device (OLD, NIV) are part of the population concerned.

A referring physician will be responsible for overseeing data collection at each center. Investigators, assisted by clinical research units where applicable, will complete an e-CRF for each patient included.

Investigating physicians who have agreed to participate in the study will have access to the corresponding questionnaire in the e-CRF. A request for access to the e-CRF may be made for people assisting investigators with its entry (clinical research nurse, TEC, ARC).

In all cases, the investigators will commit to an exhaustive collection of all new cases of patients admitted for EA and e-CRF data.

Follow-up between 3 and 9 months

An assessment of patients' COPD between 3 and 9 months is planned. Monitoring by a pulmonologist of patients with a COPD exacerbation is one of the quality indicators of the care pathway recommended by the HAS; a follow-up visit is also required as part of the renewal of the request for care for long-term oxygen therapy (LTO) and/or non-invasive ventilation (NIV). Thus, this assessment corresponds to a systematic practice for pulmonologists, carried out as part of the patient's usual monitoring and not as part of a study-specific consultation.

If this visit is carried out in another hospital or by a private pulmonologist, the investigator may contact them to collect information from this visit and enter it into the questionnaire.

3-year survival estimation

If the patient is deceased, the investigator will enter the date of death in the e-CRF.

If the center is not aware of the patient's death, the date of the last contact (consultation or other) will be specified in the e-CRF and will be updated to 3 years.

Various measures will be implemented to try to determine the patient's vital status at 3 years. The research center will try to contact the treating physician or the town hall where the patient was born, and will have contact with other medical institutions and public registers, including in the case of a patient who has been lost to follow-up.

V. Population concerned

Recruitment procedures

All patients who have experienced an EA related to known or unknown COPD, diagnosed between 01/11/2025 and 31/10/2026 at participating centers will be informed of the objectives and duration of the study. (See paragraph IV – Patient information).
Each patient will be required to provide oral consent or non-opposition prior to inclusion in the EA-BPCO-CPHG study and follow-up. The physician will note this information in the patient's medical file in accordance with good practice guidelines.

Number of patients

The EA-BPCO-CPHG study is expected to collect data from approximately 3,000 to 5,000 patients.
Compared to the 2006 Ea-COPD study, the study inclusion period is longer (12 months *vs*. 9 months); it is likely that in 2025 the number of hospitalizations for EA related to COPD will be similar to 2006 but the patient profile has changed due to aging and comorbidities.

Inclusion criteria

- Age ≥18 years old,
- All patients with COPD, known or not, hospitalized in pulmonology for EA, between 11/01/2025 and 10/31/2026 , regardless of their mode of arrival (emergency, consultation, direct admission, intensive care, other service) or the associated pathologies (SAOS, obesity/hypoventilation syndrome, etc.) that they present.
  Also affected are:
  - Patients with decompensation, initially admitted to pulmonology and subsequently transferred to intensive care.
  - Patients already fitted with a device (OLD, NIV)
- Patient's agreement or non-opposition to collaborate with this protocol, noted in their medical file.

Non-inclusion criteria

- Age < 18 years,
- Previous inclusion in the study;
- Patient unable to perform the EFR or to cooperate within the framework of this protocol;
- Patient deprived of liberty following a judicial or administrative decision,
- Patient unable to give consent, patients with cognitive impairment or difficulty understanding

In the event of inaugural EA and a diagnosis of COPD not retained* at the follow-up visit, the patient will be excluded from the main analysis but may be analyzed in a sub-cohort.
(*Normal or absent EFR / TVO not confirmed).

Previous and/or concomitant treatments

As the study is non-interventional, no treatment is prohibited.

VI. Data collection

The study is conducted using an electronic questionnaire (e-CRF). This questionnaire is composed of several parts (Appendix 1).
This questionnaire collects two data from self-questionnaires (simplified EPICES score – CAT score) which can be completed by the patient during the admission consultation or during their hospitalization (see specific paragraph) or with the investigator.

At inclusion

- Checking inclusion criteria

I - Collection of patient characteristics

- Patient identification data
    - first 2 letters of the name and first letter of the first name),
- The patient's sociodemographic characteristics:
    - Gender, age, postal code of the municipality of residence
    - Height, weight
    - Precarity: EPICES Score
- Smoking status, cannabis

II - Retrospective collection concerning the history of COPD, its comorbidities and its treatments

- History of COPD
    - Known or unknown COPD diagnosis, date of diagnosis, patient followed up
    - Number of EA* during the past year
- Associated comorbidities:

  Asthma, alpha antitrypsin deficiency (associated questions), history of *Pseudomonas Aeruginosa,* respiratory allergies, bronchiectasis, emphysema, gastroesophageal reflux, stroke, dyslipidemia, ischemic heart disease, PAD, heart failure, rhythm disorders, hypertension, osteoporosis, sleep apnea syndrome, diabetes, anxiety/depression, bronchial cancer
- Data from the most recent spirometry within 3 years
- Overall assessment of COPD:
    - Symptoms (cough and sputum for more than 3 months/year)
    - mMRC and combined ABE score
    - CAT score (if available in the patient's file)
- (Current) drug treatments for COPD
- Non-drug (ongoing) treatments for COPD
- Nebulized bronchodilator
- Vaccinations

** EA defined as increased dyspnea, cough or sputum production of less than or equal to 14 days caused by infection, pollution or another irritant which may be accompanied by tachypnea and tachycardia and which is frequently associated with increased local and systemic inflammatory syndrome.*

Upon admission

III- Characterization of the current episode of EA - Description of EA on admission

The results of biological (excluding blood gas) and spirometric examinations are those of the examinations carried out within 24 hours following admission for EA in intensive care or in the pulmonology department.

- **The admission method**
  - Date of admission to hospital (all departments)
  - Date of admission to pulmonology
  - Mode of entry into the pulmonology department
- **Etiologies or factors associated with EA-COPD of the current episode**
  - Infectious causes suspected or documented
  - Cardiac decompensation
  - Pulmonary embolism
  - Pneumothorax
  - Thoraco-abdominal "traumas" (trauma, postoperative period, vertebral compression)
  - Iatrogeny
  - Failure to treat (insufficient, inappropriate, not taken)
  - Other
- **Functional signs**
  - Increased dyspnea
  - EVA dyspnea (hospitalization time)
  - Increased cough
  - Change in expectoration
- **Looking for signs of severity**
  - SaO2 on arrival (before oxygen), in ambient air if available
  - Existence of clinical signs of respiratory failure
  - Existence of a respiratory rate ≥ 24 /min
  - Existence of a heart rate ≥ 95 min
  - *De novo* rhythm disorder
  - Existence of signs of hemodynamic failure
  - Existence of signs of neurological failure (agitation / confusion / coma)
- **Biology on admission (within the first 24 hours) if available**
  - Hemoglobin
  - CRP
  - Blood eosinophilia level
- **Blood gases on admission:**
  - Measurement methods
  - pO2, pCO2, pH, HCO3-
  - EA management upon admission.
- **EA classification ,** *according to the GOLD 2024 definition (Mild / Moderate / Severe)*

IV - EA support

- **Patient circuit**
  - Need for critical care (intensive care, intensive care unit, non-respiratory intensive care unit)
  - Admission and discharge dates
  - Time between hospital admission and transfer to critical care
- **EA management in critical care**
  - Use of invasive ventilation, if yes, duration
  - Use of non-invasive ventilation (NIV)

- High flow oxygen therapy (HFOT), if yes, duration

- **Management of EA in the pulmonology department**
  - Oxygen
  - NIV
  - OHD
  - Antibiotic therapy
  - Nebulized bronchodilators
  - General corticosteroid therapy (PO or IV)

Upon discharge from hospital

V- Leaving the hospital

- **Exit arrangements**
  - Release date
  - Total length of hospital stay, stay in pulmonology
  - Return home
    - If no, the type of facility to which the patient was transferred
    - If yes, discharge arrangements: simple, PRADO, home care, care network
  - Death, if yes, cause and date
    - If death, within the framework of a limitation of care
- **Therapeutic support upon discharge**
  - **Medicinal**
    - Inhaled therapeutics (trade names)
    - Nebulized bronchodilators
    - Oral corticosteroids
    - Oxygen
    - Biotherapy (trade names)
    - Antibiotic therapy
  - **Non-medicinal**
    - Non-invasive ventilation
    - Physiotherapy
    - Scheduled respiratory rehabilitation
    - Implementation of smoking cessation

Follow-up visit

VI- Assessment between 3 and 9 months after admission

The follow-up consultation is within the interval of 3 to 9 months after the EA that led to admission to the hospital.

The data collected concern the reassessment of COPD at 3 months and its management.
In the absence of a visit to the hospital, a telephone call (to another hospital or to a private pulmonologist who is treating the patient) can provide certain data.

- Date of consultation or phone call

<u>COPD Reassessment:</u>

- Number of EA* within 3 months of hospital discharge
- Cardiovascular event within 3 months of hospital discharge
- Stage of dyspnea on the day of consultation
- Smoking cessation
- Up-to-date vaccinations

- Spirometry
- Weight
- Blood gas

In patients for whom the diagnosis of COPD was not known at inclusion:

- Existence of a confirmed TVO? If not, has an alternative diagnosis been made?
- CAT score

Processing in progress

- Drug treatments on the day of the consultation
- Drug treatment following the consultation
- Non-drug treatments
- Rehabilitation carried out since leaving the hospital: if yes, date; if no, is it a refusal

Vital status

VII 3-year survival data

- Death

  In case of death

  • Date of death

  • Cause of death
    - Respiratory
    - Cardiovascular
    - Unknown
    - Other
- Patient lost to follow-up

Each center maintains an inclusion register for all patients who agree to participate and meet the eligibility criteria. This register, which will not be computerized, will remain within the department and may be used to collect vital status as part of the survival assessment.

A test phase of the questionnaire was carried out in the services of the members of the scientific council. This test demonstrated the feasibility of the study.

Self-questionnaires

The Simplified EPICES score [16] (appendix 4)

This score is an indicator of precariousness; it makes it possible to identify situations of social vulnerability.
Deprivation is a predictor of emergency department visits and hospitalizations for COPD exacerbations. Its assessment is carried out as part of the routine management of patients with COPD.
This questionnaire of 11 closed questions (binary answer: Yes/No) can be completed by the patient or an assistant and takes less than 5 minutes. It is important to ensure confidentiality is respected when collecting the score .

The CAT (COPD Assessment TestTM) score [17] (appendix 5)

The CAT is a validated questionnaire used in routine medical practice; it measures the impact of COPD on the patient's well-being and daily life. This questionnaire reflects the patient's baseline condition; it will not be collected in the context of an exacerbation, but to measure the impact of the disease upstream. As part of this protocol, the result of this questionnaire will be reported in the e-CRF Part 2 – *COPD History* when available in the patient's file.
It is also requested at the assessment between 3 and 6 months (Part 6) for all patients. This questionnaire includes 8 items to be scored on a scale of 0 to 5. It is easy for the patient with COPD to complete, it takes less than 5 minutes.

Personal data

The description of patient characteristics is one of the secondary objectives of the study in order to determine predictive factors of disease severity. Age and sex are among these factors.

In order to determine the impact of social deprivation on the occurrence of COPD exacerbations, in addition to the EPICES score, the postal code of the municipality of residence is collected. The social disadvantage index, the FDep (*French Deprivation index*), makes it possible to characterize the socio-economic environment based on the municipality of residence.
The postal code of the municipality of residence may secondarily allow certain pollution factors to be linked to the COPD exacerbation episode.

VII. Study Procedure

Recruitment of pulmonologists and patients

This is a prospective, observational, national, multicenter cohort study, not affecting patient care.
The study will be conducted on a voluntary basis in the pulmonology departments of the CHs and associated hospitals, with the sole sponsor being the CPHG. This choice ensures a national distribution of inclusions and homogeneity of data, as demonstrated by the EA-BPCO-CPHG study in 2006.

All patients who have presented an EA related to known or unknown COPD, diagnosed between 01/11/2025 and 31/10/2026 at participating centers will be informed of the objectives and duration of the study. *(See paragraph V. - Patient information and recruitment procedures)*.
Only patients who have been informed and have given their verbal consent to participate in EA-BPCO-CPHG, as well as deceased patients who have not expressed non-opposition, will be included. The investigating physicians will record in the patient's file their consent or non-opposition to participate in this study.

Data collection

EA-BPCO-CPHG study protocol and access codes to the e-CRF.
Investigators will receive information (explanations) for the correct completion of the e-CRF and can contact the CRO Margaux Orange by email and/or telephone (BPCO-CPHG@margauxorange.com / 01 42 21 15 25).
All questions in the e-CRF must be completed by the investigating physicians.
Physicians are committed to comprehensive data collection for each patient.

Communication of results

Dissemination of study results or publication

It is contrary to the collective interest that the results obtained are never available or cannot be taken into account, in particular by public decision-makers or authorized representatives of the community where the study was carried out. Withholding information or refusing to disclose results can only be justified in exceptional circumstances; for example, when methodological problems encountered during the study deprive the results obtained of any meaning.
Where it is not possible to present or publish the full results or conclusions of an epidemiological study for reasons of either limited space or insufficient time to allow for such presentation or publication, the study manager must ensure that all persons who may be interested in the full results or conclusions will have access to them upon request.
The main results must be shared with those who participated in the study or their representatives, as well as with other members of the community where the study was conducted. As such, the scientific committee undertakes to transmit the results of the studies to all the investigating physicians who participated in them.

Interim results

Interim results must always be presented explicitly as such. Interim results, as well as raw or processed data or data, results, analyses or conclusions that could be derived from these interim results, may not be transmitted to third parties or used in other studies unless such transmission or use is expressly provided for in the protocol and is expressly approved by the study manager.
In the event that the study is discontinued for any reason, the presentation or publication of any preliminary or partial results or conclusions resulting from the study may take place subject to compliance with prior validation procedures. Data or results from the discontinued study must be identified as such in subsequent publications and presentations.

Publication rules

Obligation to publish

All results of a study, whether funded by public or private sources, are the scientific responsibility of the physician responsible for the study, not the funder, and the results must always be made public if they have sufficient scientific validity.

Any request to conceal results, change or mitigate the content of a report, or delay the publication of results will be categorically rejected.

Obligation to evaluate publications

The general rule is to submit the results of a study to a journal with independent peer review before making them public or submitting them to the media.

Impartiality of publications

Publications should honestly and fairly describe all aspects of the study without taking into account other interests, particularly non-scientific ones. Members of the scientific committee should not exaggerate the results of the study in order to increase their chances of obtaining more funding for future research or to make their articles more attractive to the editor of a journal. A certain bias consisting of selecting the results that agree with the point of view of the doctor in charge of the study and omitting those that contradict it, should be avoided.

Authors of epidemiological articles must comply with the rules of quality journals in which possible conflicts of interest are disclosed. The definition and order of authors must respect the practices in scientific publication. As part of this study, the list of investigating physicians will be systematically associated with all publications.

CPHG Study Publication Rules

Once the study is completed, the final report will be published by the Scientific Advisory Board Coordinator and the study statistician. The Coordinating Investigator will sign the final version and thus approve the final analysis, results, and conclusions.

The key participants in the clinical study will be the investigators, members of the Scientific Council, CRO employees and statisticians who will all have collaborated at different levels in the development and writing of the protocol, as well as in the writing of the final report.

A rotation of signatories according to the number of inclusions will be carried out on the basis of the list of inclusions by investigator and by center. This list will also be used to apply the rules below by group, if applicable, for abstracts / communications and articles / publications separately.

VIII. Statistical analysis

Statistical analyses will be performed using R software, as well as any additional R packages required for the analyses, in their most up-to-date version at the time the analyses are performed.

The study population will include all patients with a completed electronic questionnaire on time.

Sample size

The previous EA-COPD study conducted with the CPHG included 1,849 patients from 68 research centers over a 9-month inclusion period, between October 2006 and June 2007. With an estimated participation of between 80 and 100 pulmonologists and an extended inclusion period of 12 months, the cohort size could be 3,000 to 5,000 patients.

Descriptive statistical methods

For descriptions of patients, the EA episode and its management:

- Continuous variables will be summarized using the number of available data, mean, standard deviation (SD), median, first quartile (Q1), third quartile (Q3), minimum, maximum, and number of missing values.
- Categorical variables will be summarized using the number and proportion (based on non-missing values) of each category as well as the number of missing values. Confidence intervals may be included if statistically relevant.

It should be noted that some continuous variables may be presented in class to be analyzed as qualitative variables, if relevant.

The EA-COPD 2025 cohort may be compared with the EA-COPD 2006 cohort using the Student t-test or analysis of variance for quantitative variables and the Chi-square test for qualitative variables. Other non-parametric tests may be performed if necessary.

Characterization of EA

Classification methods will be used to identify possible homogeneous subgroups of EA (“phenotypes/endotypes”) .

Survival analyses

Survival is defined as the time from the date of admission for AECOPD to the date of death. 3-year survival rates will be calculated using the Kaplan-Meier method and presented with their 95% confidence interval (95% CI).

Survival curves will be plotted, with number at risk, overall and in different subgroups of interest.

Univariate and multivariate Cox analyses will be performed to study predictive factors of survival and calculate hazard ratios (HR). The assumptions of the Cox model will be verified (R packages survival, survminer).

Considering the binary variable of death at 3 months (yes/no), logistic regressions will be carried out to search for variables having a predictive role.

Multivariate analyses may include socioeconomic factors (self-administered questionnaires) to study the impact of social deprivation on survival after EA of patients admitted to hospital for EA-COPD.

Seasonality of EA

To study the seasonality of EAs, time series analyses will be used.

Managing missing data

Data will be processed initially only on complete data.

The number of missing data will be indicated. No imputation will be performed.

IX. Legal and ethical considerations

Ethical considerations

This study falls within the framework of research not involving human subjects (RNIPH), non-interventional and a reference methodology MR 0004. (https://www.cnil.fr/fr/declaration/methodologie-de-reference-04-recherches-nimpliquant-pas-la-personne-humaine-etudes-et-evaluations-dans-le-domaine-de-la-sante)
In this context and to follow regulatory procedures, the following procedures will be carried out:
1- Registering the search on the ANSM website and obtaining the RCB ID number
2- Commitment to compliance with the CNIL
3- Registration of the search with the Health Data Hub

Patient information

All patients meeting the study inclusion criteria will be informed orally and in writing of the objectives and duration of the study (Appendix 2-Patient Information Note).
An information note will be given by the investigator to the patient upon admission to the pulmonology department. After briefly explaining the study orally to the patient, the investigator will give the patient the information note so that they can read it together and the investigator can answer the patient's questions. Before the study begins, a website dedicated to patients will be launched. Patients will be informed that a website dedicated to them will be available, containing all information relating to the study (objectives, duration of the study, methodology, etc.) and will be updated regularly.

Pulmonology departments and healthcare establishments will also have to update the means at their disposal and according to their practices (welcome booklet, website, written note, scrolling banner, etc.) to inform the patient that, within the framework of clinical research carried out in the establishment, their pseudonymised data may be collected (in accordance with the regulations) and that they have the possibility of opposing this use by informing the investigator.

Each patient will give their oral consent or non-opposition prior to their inclusion in the EA-BPCO-CPHG study and their follow-up. The physician will note this information in the patient's medical file in accordance with good practice rules.
In the event that the patient dies before having consented to inclusion in the study, the data concerning him/her may be used without the agreement of the trusted person, if the patient did not object during his/her lifetime to the use of his/her data, to the extent that the above provisions were made to inform the patient of this study. This non-opposition will also be noted in the medical file, so as to be able to verify that the patient has been informed of these provisions.

Pharmacovigilance

In accordance with the Jardé law, pharmacovigilance reports of serious adverse events (SAEs) concerning drugs will not be collected during the study, nor transmitted to the pharmaceutical laboratories concerned.
Adverse events and SAEs will be managed by investigators according to their usual practices.

Amendment to the protocol

Any modification to the protocol must be discussed and approved by the steering committee and will be subject to amendment.

Minor changes (formal corrections to improve understanding, spelling corrections, administrative changes, etc.) will result in an increase in the number after the period in the version number: version 1.1 instead of version 1.0.
Major changes will result in an increase in the number before the period in the version number: version 2.0 instead of version 1.0.
Major changes will be notified to the relevant authorities.

Archiving

The retention of data in the active database will last until December 31, 2036; i.e. for 11 years.
Data archiving will then last for 15 years, until December 31, 2050. The study management center will keep all documentation related to the study until that date.
Then all the documents will be returned to the study sponsor.

Appendix 1 : E-CRF

Appendix 2: Information note – patients

ÉTUDE

Ea-BPCO-2025

Étude non interventionnelle, analysant les caractéristiques des patients hospitalisés en France pour des exacerbations aiguës (EA) de BPCO et les facteurs prédisant l'évolution de la maladie

Madame, Monsieur,

Vous avez été hospitalisé(e) pour une exacerbation aiguë de bronchopneumopathie chronique obstructive (BPCO) connue ou nouvellement diagnostiquée.
Dans le contexte de cette hospitalisation, le Collège des Pneumologues des Hôpitaux Généraux (CPHG) mène actuellement une étude visant à améliorer les connaissances sur la BPCO et sur les facteurs influençant le devenir des patients hospitalisés pour une exacerbation aiguë.
Nous vous proposons de participer à une étude de recherche non interventionnelle, ce qui signifie qu'elle n'entraînera aucun changement dans votre prise en charge ou dans les soins que vous recevez (ni visite, ni examen supplémentaire par rapport à votre prise en charge habituelle). Elle se base uniquement sur des informations collectées dans votre dossier médical et des données cliniques déjà disponibles.

Objectif de l'étude
L'objectif principal de cette étude est d'identifier les facteurs prédisant l'évolution de la maladie à 3 ans des patients hospitalisés pour exacerbation aiguë de BPCO.
Les informations recueillies permettront de mieux comprendre cette maladie et, à terme, de perfectionner les stratégies de prise en charge de la BPCO.

Déroulement de l'étude
Votre participation ne modifie en rien votre prise en charge médicale. Dans un premier temps, les informations déjà présentes dans votre dossier médical seront recueillies lors de votre arrivée dans le service de pneumologie (entre le 1er novembre 2025 et le 31 octobre 2026), ces informations concernent :

- vos antécédents médicaux,
- les traitements que vous avez reçus dans le cadre de la BPCO,
- les résultats d'examens cliniques dans le cadre de la BPCO,
- et des données de suivi.

L'étude prévoit un suivi de votre dossier médical à différentes étapes : entre 3 et 9 mois après votre hospitalisation pour l'évaluation de l'évolution clinique et à 3 ans. Ce suivi est inclus dans le cadre de vos soins habituels.

Les informations seront collectées de manière confidentielle et seront traitées de façon à garantir le respect de votre vie privée. Certaines informations relatives à la BPCO pourront être recherchée dans votre dossier médical.
Les données seront recueillies, avec votre accord et à l'aide d'un questionnaire électronique qui sera rempli soit directement par votre médecin, soit par un technicien d'étude clinique (TEC) dûment habilité et astreint au secret professionnel.

Votre participation
Votre participation est volontaire. Vous êtes libre de refuser de participer ou de retirer votre consentement à tout moment, sans justification, en informant simplement votre médecin. Ce choix n'aura aucune conséquence sur la qualité des soins que vous recevrez ou sur votre suivi médical. Conformément à la loi, vous avez le droit d'accéder à vos données, de les rectifier, ou de vous opposer à leur utilisation dans cette étude.

Site internet
Le site internet https://www.ea-bpco-cphg.com est à votre disposition pour vous partager ces informations sur l'étude et pour vous apporter des informations complémentaires.

Protection de vos données personnelles
Toutes les informations collectées dans le cadre de cette étude sont strictement confidentielles et seront pseudonymisées afin de garantir votre confidentialité. Cela signifie qu'aucune information ne permettra de vous identifier directement.
La collecte et le traitement de vos données personnelles seront réalisés par le CPHG et à des fins de recherche scientifique (art. 9 du « RGPD ») et par les personnes ou sociétés agissant pour son compte en France.
Aucune donnée individuelle ne sera communiquée aux partenaires de l'étude, seuls des rapports de données agrées pourront être communiqués.

CPHG

1 – V2.0 Septembre 2025

ÉTUDE

Ea-BPCO-2025

Dans le cadre de l'étude EA-BPCO-2025, vous disposez de droits sur vos données personnelles conformément au Règlement Général sur la Protection des Données (RGPD). Vous pouvez notamment accéder à vos données, demander leur correction si elles sont inexactes, demander leur suppression dans certains cas, ou en limiter temporairement le traitement. Ces droits peuvent toutefois être encadrés si leur exercice compromet les objectifs de la recherche.
Vous pouvez accéder directement ou par l'intermédiaire d'un médecin de votre choix à l'ensemble de vos données médicales (article L. 1111-7 du code de la santé publique). Ces droits s'exercent auprès du médecin qui vous suit dans le cadre de la recherche et qui connaît votre identité. Le droit d'accès peut être exercé à tout moment, soit directement auprès de l'investigateur (votre médecin), soit auprès de l'investigateur par l'intermédiaire d'un médecin désigné à cet effet par l'intéressé.
Le CPHG auquel sont transmises de telles demandes s'engage à y donner suite dans les meilleurs délais ou dans un délai maximum d'un mois (article 12.3 du RGPD).

En vertu de l'article 13 du Règlement (UE) n° 679/2016 du Parlement européen et du Conseil du 27 avril 2016 (RGPD), nous vous informons que vos données seront traitées conformément au Règlement et selon les règles de confidentialité auxquelles le CPHG attache une particulièrement importance.

Vos droits pourront s'exercer auprès du Délégué à la Protection des Données (DPO) :

Dr François GOUPIL
Centre Hospitalier du Mans - 194 avenue Rubillard 72037 Le Mans
Tel: 02 43 43 24 50
fgoupil@ch-lemans.fr

Vous disposez également du droit d'introduire une réclamation auprès d'une autorité de contrôle.

Conformément aux lois et règlements en vigueur, le traitement de vos données respecte le Règlement Général sur la Protection des Données (RGPD) et a été soumis aux autorités compétentes.

Publications
Les données recueillies lors de cette étude seront publiées dans des revues scientifiques et médicales par le comité scientifique de l'étude et seront conservées jusqu'au 31 décembre 2045.
Vous pourrez être informé des résultats de cette étude, dès qu'ils seront disponibles, par l'intermédiaire du médecin investigateur du service dans lequel vous êtes pris en charge.

Contact
Si vous avez des questions ou souhaitez obtenir plus d'informations, vous pouvez contacter l'équipe de recherche ou votre médecin traitant.
Vous trouverez ci-dessous les coordonnées de la personne responsable de l'étude :

Dr Nicolas Delberghe
Centre Hospitalier Eure-Seine – Hôpital d'Évreux-Vernon
Tél. : 02 32 33 80 66
Courriel : nicolas.delberghe@ch-eureseine.fr

Nous vous remercions pour l'attention portée à cette note et pour votre contribution à l'avancée des connaissances sur la BPCO.

Bien cordialement,
Dr. Hugues Morel - Président du CPHG
Dr Nicolas Delberghe - Coordinateur de l'étude

*Comité scientifique de l'étude

Coordinateur : Dr Nicolas Delberghe - CH Evreux
Membres des CHG : Dr Marielle De Marchi - CH Elbeuf, Dr Marion Gory Bouilly - CH Guigamp, Dr François Goupil - CH Le Mans, Dr Hugues Morel - CH Morlaix, Dr Cecilia Nocent - CH Bayonne, Dr Laurent Portel - CH Libourne, Dr Jacques Picquet - CH Montfermeil
Universitaires : Dr Marina Guecamburu – CHU Bordeaux, Pr Nicolas ROCHE - CHU Paris-Cochin, Dr Maeva ZYSMAN - CHU Bordeaux

Appendix 3: mMRC

The modified Medical Research Council (mMRC) Dyspnea Scale is a subjective classification of dyspnea severity in patients with chronic obstructive pulmonary disease (COPD).

The higher the stage, the more severe the dyspnea. This helps assess the risk of COPD exacerbation.

Stade	Symptômes	Description
0	rares	Pas de dyspnée, sauf en cas d'effort physique important.
1	légers	Dyspnée lors de la marche rapide à plat ou en pente légère.
2	modérés	Dyspnée lors de la marche sur terrain plat en suivant quelqu'un de son âge ou obligeant à s'arrêter pour reprendre son souffle en marchant sur terrain plat à son propre rythme.
3	sévères	Dyspnée obligeant à s'arrêter pour reprendre son souffle après quelques minutes ou une centaine de mètres sur terrain plat.
4	très sévères	Dyspnée ne permettant plus de quitter le domicile, dyspnée lors de l'habillage ou du déshabillage.

Mahler DA, Wells CK. Evaluation of clinical methods for rating dyspnea. Chest 1988; 93:580-586

Appendix 4 : SPICES Score

N°	Questions	Oui	Non
1	Rencontrez-vous parfois un travailleur social (assistante sociale, éducateur) ?	1	0
2	Y-a-t-il des périodes dans le mois où vous rencontrez de réelles difficultés financières à faire face à vos besoins (alimentation, loyer, EDF…) ?	1	0
3	Bénéficiez-vous d'une assurance maladie complémentaire (mutuelle) ?	0	1
4	Vivez-vous en couple ?	0	1
5	Etes-vous propriétaire de votre logement (ou accédant à la propriété) ?	0	1
6	Vous est-il arrivé de faire du sport au cours des 12 derniers mois ?	0	1
7	Etes-vous allé au spectacle (cinéma, théâtre…) au cours des 12 derniers mois ?	0	1
8	Etes-vous parti en vacances au cours des 12 derniers mois ?	0	1
9	Au cours des 6 derniers mois, avez-vous eu des contacts avec des membres de votre famille autres que vos parents ou vos enfants	0	1
10	En cas de difficultés (financières, familiales, de santé…) y-a-t-il dans votre entourage des personnes sur qui vous puissiez compter pour vous héberger quelques jours en cas de besoin ?	0	1
11	En cas de difficultés (financières, familiales, de santé…), y-a-t-il dans votre entourage des personnes sur qui vous puissiez compter pour vous apporter une aide matérielle (y compris un prêt) ?	0	1

≥ 4 réponses précaires/défavorables (codées 1) = Situation de vulnérabilité sociale

* Cette méthode simplifiée, utile pour un repérage en première intention, ne constitue pas la méthode à retenir pour l'évaluation de la fragilité selon Epices mesurée a postériori dans les CES (mesure retenue pour les indicateurs remontés à la Cnamts).

Appendix 5- CAT Score

Nom :_____

Date :_____

Quel est l'état de votre BPCO ? Répondez au questionnaire CAT (COPD Assessment Test™) pour évaluer votre BPCO.
Ce questionnaire vous aidera, ainsi que votre médecin, à mesurer l'impact de la BPCO sur votre bien-être et votre vie au quotidien. Vous pourrez, ainsi que votre médecin, utiliser les réponses et scores du questionnaire pour mieux prendre soin de votre BPCO et obtenir le meilleur bénéfice de votre traitement.

Pour chaque élément ci-dessous, veuillez indiquer d'un X la case qui correspond le mieux à votre état actuel. Prenez soin de ne sélectionner qu'une seule réponse par question.

Exemple : Je suis très heureux (heureuse) | 0 | **X** | 2 | 3 | 4 | 5 | Je suis très triste

			SCORE
Je ne tousse jamais	0 1 2 3 4 5	Je tousse tout le temps	☐
Je n'ai pas du tout de glaire (mucus) dans les poumons	0 1 2 3 4 5	J'ai les poumons entièrement encombrés de glaire (mucus)	☐
Je n'ai pas du tout la poitrine oppressée	0 1 2 3 4 5	J'ai la poitrine très oppressée	☐
Quand je monte une côte ou une volée de marches, je ne suis pas essoufflé(e)	0 1 2 3 4 5	Quand je monte une côte ou une volée de marches, je suis très essoufflé(e)	☐
Je ne suis pas limité(e) dans mes activités chez moi	0 1 2 3 4 5	Je suis très limité(e) dans mes activités chez moi	☐
Je ne suis pas inquièt(e) quand je quitte la maison, en dépit de mes problèmes pulmonaires	0 1 2 3 4 5	Je suis très inquièt(e) quand je quitte la maison, en raison de mes problèmes pulmonaires	☐
Je dors bien	0 1 2 3 4 5	Je dors mal à cause de mes problèmes pulmonaires	☐
Je suis plein(e) d'énergie	0 1 2 3 4 5	Je n'ai pas d'énergie du tout	☐
		SCORE TOTAL	☐☐

Le Test d'évaluation COPD a été développé par un groupe pluridisciplinaire d'experts internationaux spécialisés dans la COPD, soutenu par GSK. Les activités de GSK en rapport avec le Test d'évaluation COPD sont supervisées par un Conseil de gouvernance composé d'experts externes indépendants, dont l'un d'eux préside le Conseil.

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