

# Clinical characteristics, use and switch of drugs for obstructive airway diseases among patients with COPD experiencing an exacerbation: a retrospective analysis of Italian administrative healthcare data

**First published:** 12/06/2025

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Study

Finalised

## Administrative details

### EU PAS number

EUPAS1000000623

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### Study ID

1000000623

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### DARWIN EU® study

No

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### Study countries

☐ Italy

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## Study description

Background: In Italy, the pharmaceutical care of COPD patients is still ill-timed and inaccurate.

This study aimed to describe the treatment of COPD patients in Italy and possible switches following an exacerbation.

Methods: This observational retrospective analysis of Italian administrative healthcare data from the ReS database identified patients aged  $\geq 45$  years with COPD in 2019 and 2020. At least 6 years of look-back period and absence of concomitant asthma were required. COPD patients were categorized by treatment (SI-single/MI-multiple inhalers, TT-triple therapy, DT-dual therapy, other respiratory treatments, untreated) at index date (first dispensation during accrual period).

Occurrence of moderate/severe exacerbation during one-year preceding index date and treatments during one-year preceding the exacerbation (possible switch) were evaluated. Results From  $\sim 4.7$  million beneficiaries of the Italian National Health Service in 2019 and 2020, respectively, 105,828 and 103,729 (43 and 41  $\times 1,000$  inhabitants aged  $\geq 45$  years) were identified as having COPD. Of 2019/2020 patients: 3.4%/5.2% received SI-TT, 20.7%/17.5% MI-TT, 35.9%/38.1% DT, 33.0%/33.1% other treatments, and 7.0%/6.0% were untreated. Males were prevalent and median age was  $> 73$  years for all groups. Of 2019/2020 cohorts, heart failure and coronary artery disease affected 24/20%, 18/17%, and 11%/16% patients with SI-TT, MI-TT, DT, and other treatments, respectively.

A previous moderate/severe exacerbation (2019/2020 patients) occurred to 60.5%/56.6%, 39.9%/37.4%, 30.8%/29.2% and 31.9%/29.7% patients treated with SI-TT, MI-TT, DT, and other treatments, respectively. Of 2019/2020 patients experiencing moderate/severe exacerbation: 6.0%/7.0% receiving DT, 5.1%/7.0% receiving other treatments and 4.5%/10.0% untreated, switched to SI-TT; 23.7%/16.9% receiving DT, 21.4%/17.7% receiving other treatments and 15.4%/12.0% untreated, switched to MI-TT.

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## Study status

Finalised

## Research institutions and networks

### Institutions

Fondazione ReS (Ricerca e Salute), CINECA partner

☐ Italy

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Institution

Not-for-profit

ENCEPP partner

### Contact details

#### Study institution contact

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Study contact

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#### Primary lead investigator

Letizia Dondi

Primary lead investigator

### Study timelines

**Date when funding contract was signed**

Actual: 11/01/2023

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**Study start date**

Actual: 14/02/2023

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**Date of final study report**

Actual: 11/10/2023

## Sources of funding

- Pharmaceutical company and other private sector

## More details on funding

This report received unconditional funding from Astra Zeneca S.p.A. The financial support for this study was provided with a funding agreement ensuring maintenance of author independence in study design, data interpretation, writing, and decisions to publish.

## Regulatory

**Was the study required by a regulatory body?**

No

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**Is the study required by a Risk Management Plan (RMP)?**

Not applicable

## Methodological aspects

### Study type

### Study type list

**Study topic:**

Disease /health condition

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**Study type:**

Non-interventional study

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**Scope of the study:**

Disease epidemiology

Drug utilisation

**Data collection methods:**

Secondary use of data

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**Study design:**

Patients aged  $\geq 45$  years with COPD were identified in 2019 and in 2020.

A look-back (until 2014) was required. Different groups by dispensed treatment strategy for COPD were analysed in 1 year before index to assess exacerbations and in 1 year before exacerbation to assess eventual therapy switch

**Main study objective:**

This descriptive retrospective observational cohort study of Italian administrative healthcare data aimed to identify patients with COPD and describe them in terms of treatment approach in 2019 and 2020, and how treatment strategies changed following an acute exacerbation, in the light of the GOLD guidelines of the time and soon after the marketing and reimbursement in Italy of the SI-TT.

## Study Design

## **Non-interventional study design**

Cohort

## Study drug and medical condition

### **Medical condition to be studied**

Chronic obstructive pulmonary disease

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### **Additional medical condition(s)**

Exacerbations of chronic obstructive pulmonary disease

## Population studied

### **Short description of the study population**

From the ReS database, including Italian inhabitants and beneficiaries of the SSN, patients aged  $\geq 45$  years, variously distributed throughout northern, central and southern Italy, and with at least 6 years of look-back period (i.e., analysed until 2013) were identified.

The study population was categorized according to the first treatment strategy for COPD dispensed in the accrual periods into the following cohorts: patients treated with TT (SI or MI), DT (SI or MI), other treatment strategy with drugs for obstructive airway diseases.

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### **Age groups**

Adult and elderly population ( $\geq 18$  years)

Adults (18 to  $< 65$  years)

Adults (18 to  $< 46$  years)

Adults (46 to  $< 65$  years)

Elderly ( $\geq 65$  years)

Adults (65 to < 75 years)  
Adults (75 to < 85 years)  
Adults (85 years and over)

## Study design details

### Setting

Italian inhabitants and beneficiaries of the SSN which is a universal coverage health system. Two overall observation periods: 2014-2020 and 2014-2021. Patients with asthma during the accrual periods were excluded. Inhospital/local outpatient settings.

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### Summary results

From ~ 4.7 million beneficiaries of the Italian National Health Service in 2019 and 2020, respectively, 105,828

and 103,729 (43 and 41 × 1,000 inhabitants aged ≥ 45 years) were identified as having COPD. Of 2019/2020 patients: 3.4%/5.2% received SI-TT, 20.7%/17.5% MI-TT, 35.9%/38.1% DT, 33.0%/33.1% other treatments, and 7.0%/6.0% were untreated.

Males were prevalent and median age was > 73 years for all groups. Of 2019/2020 cohorts, heart failure and coronary artery disease affected 24/20%, 18/17%, and 11%/16% patients with SI-TT, MI-TT, DT, and other treatments, respectively. A previous moderate/severe exacerbation (2019/2020 patients) occurred to 60.5%/56.6%, 39.9%/37.4%, 30.8%/29.2% and 31.9%/29.7% patients treated with SI-TT, MI-TT, DT, and other treatments, respectively. Of 2019/2020 patients experiencing moderate/severe exacerbation: 6.0%/7.0% receiving DT, 5.1%/7.0% receiving other treatments and 4.5%/10.0% untreated, switched to SI-TT; 23.7%/16.9% receiving DT, 21.4%/17.7% receiving other treatments and 15.4%/12.0% untreated, switched to MI-TT.

## Documents

## Study publications

[L Dondi, G Ronconi, S Calabria, I Dell'Anno, L Dondi, C Piccinni, O Brignoli, G...](#)

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## Data management

### Data sources

#### Data source(s)

Database of Fondazione ReS

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#### Data sources (types)

[Administrative healthcare records \(e.g., claims\)](#)

### Use of a Common Data Model (CDM)

#### CDM mapping

No

### Data quality specifications

#### Check conformance

Yes

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#### Check completeness

Yes

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### **Check stability**

Yes

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### **Check logical consistency**

Yes

## **Data characterisation**

### **Data characterisation conducted**

Unknown