EE351

Economic and Social Burden of Pulmonary Arterial Hypertension in Italy

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INTRODUCTION and OBJECTIVES

Pulmonary Arterial Hypertension (PAH) is a rare, chronic, and progressive disease with a significant clinical, social, and economic impact. Despite available therapies, none address the underlying cause but rather focus on symptom management. This study aims to estimate the economic and social burden of PAH in Italy, analyzing direct healthcare, direct non-healthcare and indirect costs related to productivity loss due to the disease.

METHODS

A bottom-up, prevalence-based Cost of Illness (COI) model was developed using epidemiological data and healthcare resource consumption obtained from national and international literature. The model was validated by panel of expert clinicians with extensive experience in the management of the condition across different regions of Italy . The analysis was conducted from the National Health Service (NHS) perspective and a societal perspective over a one-year horizon.

The study included direct healthcare costs (hospitalization, pharmaceuticals and specialist care), direct non-healthcare costs and indirect costs (productivity losses). Direct costs were estimated by multiplying resource consumption by the corresponding unit costs, based on national tariffs and ex-factory drug prices (net of mandatory discounts), while productivity loss due to the disease was evaluated using a Human Capital Approach.

RESULTS

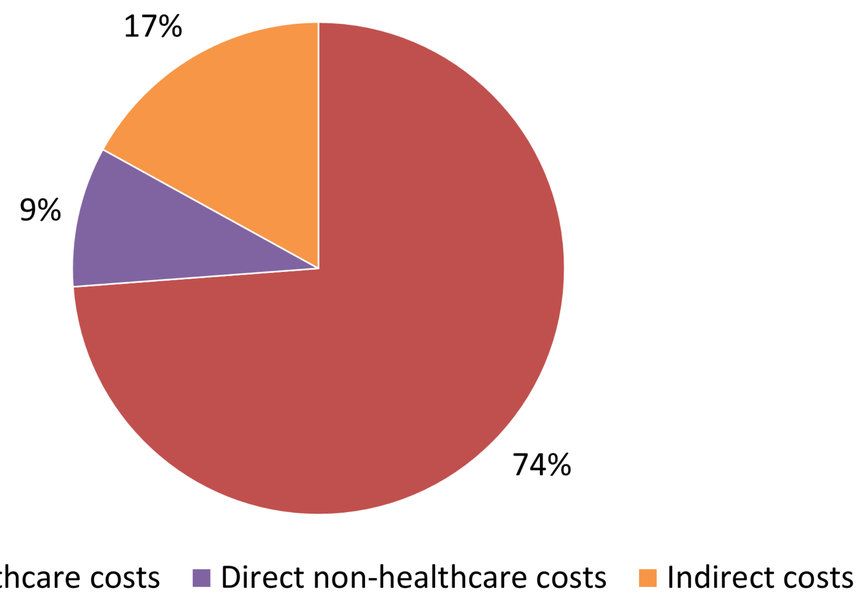
There would be approximately 3,500 patients with PAH in Italy, with 2-5% in functional class (FC) I, 28-31% in FC II, 53-57% in FC III, and 7-11% in FC IV.

Based on the average distribution per FC, the aggregate annual expenditure for the treatment and management of PAH patients was estimated at approximately €438 million (Table 1). This expenditure is composed of 74% direct healthcare costs, 9% direct non-healthcare costs and 17% indirect costs (Figure 1).

Table 1 – Annual costs of pulmonary arterial hypertension by functional class in Italy

Functional Class	Patients	Direct Healthcare Costs	Direct Non-Healthcare Costs	Indirect Costs	Total
I	105	4,861,807 €	0 €	0 €	**4,861,807 €**
II	1,015	59,430,071 €	6,656,370 €	18,306,128 €	**84,392,569 €**
III	1,995	177,250,711 €	27,415,290 €	46,988,055 €	**251,654,056 €**
IV	385	81,739,175 €	6,280,890 €	9,067,870 €	**97,087,936 €**
Total	**3,500**	**323,281,764 €**	**40,352,550 €**	**74,362,054 €**	**437,996,368 €**

Figure 1 - Distribution of costs by category



The mean annual cost per patient, approximately € 125,000, shows a direct correlation with the severity of the condition. In fact, costs increase progressively with disease progression, rising from € 46,303 for FC I to € 252,176 for FC IV (Figure 2).

In general, the primary driver of direct costs is related to drug expenses (Table 2).

Figure 2 – Average annual cost per patient by costs category and functional class

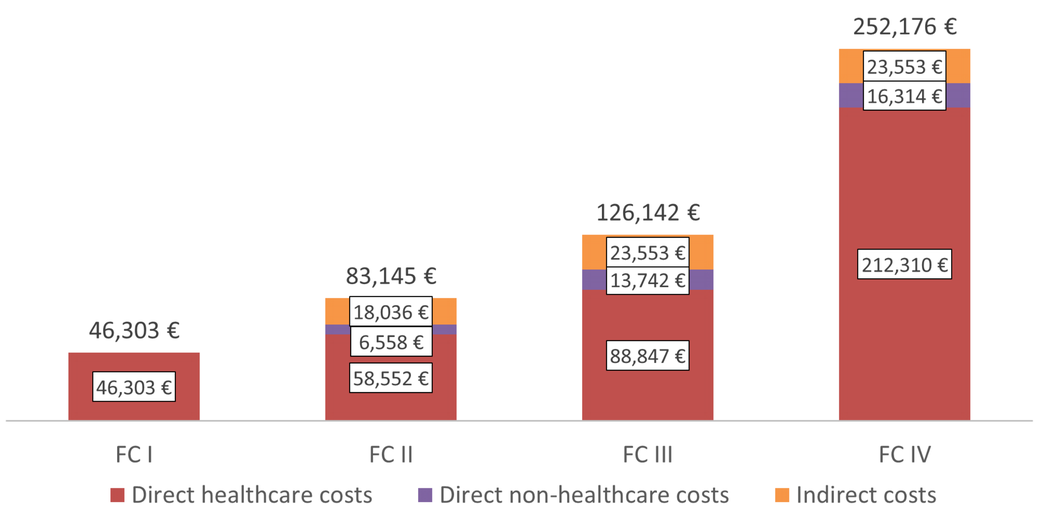
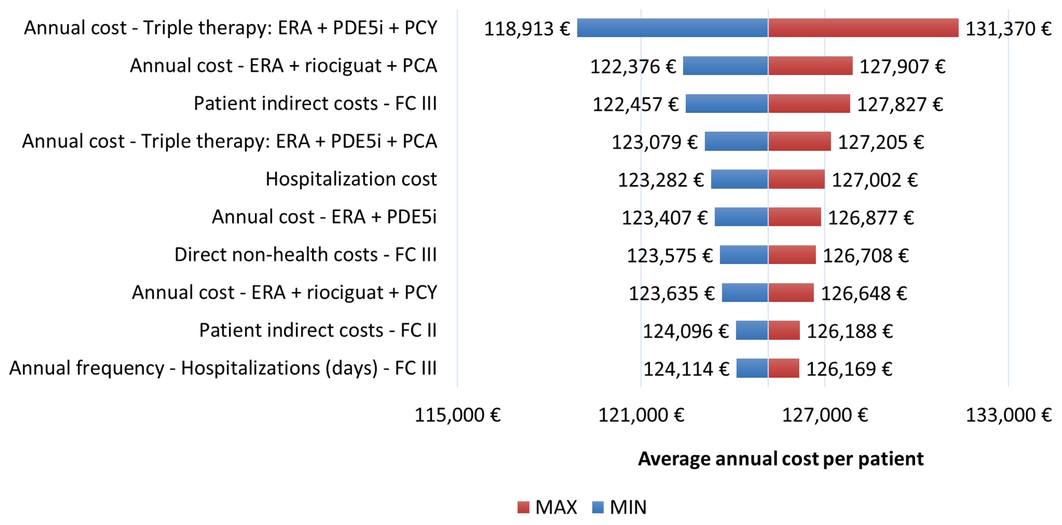


Table 2 - Average annual direct healthcare costs per patient by functional class

Functional Class	Drugs	Outpatients	Hospitalizations and Transplant	Total
I	41,745 €	3,774 €	784 €	46,303 €
II	47,071 €	4,422 €	7,059 €	58,552 €
III	72,408 €	7,296 €	9,143 €	88,847 €
IV	183,777 €	8,735 €	19,798 €	212,310 €
Total	**76,391 €**	**6,515 €**	**9,460 €**	92,366 €

To verify the uncertainty of the model, a deterministic sensitivity analysis (DSA) was performed, considering a 20% variability of all inputs. The sensitivity analysis highlights that the variable with the greatest impact on the average annual cost per patient is the annual treatment cost of triple therapy ERA + PDE5i + PCY, as shown in the tornado graph in Figure 3.

Figure 3 - Tornado diagram: variation in average annual cost per patient



CONCLUSIONS

Our study underscores the substantial disease burden of pulmonary arterial hypertension (PAH), despite its rarity, and highlights the need for further investigation into the direct and indirect costs borne by this patient population. There is a clear need for new treatments to reduce disease burden, because—despite currently approved therapies—many patients continue to progress to more severe stages, reflecting a high unmet need that significantly impairs quality of life and increases management costs. Strategies that promote early diagnosis, timely intervention, and stronger adherence to treatment guidelines may slow disease progression, improve patients' quality of life, and yield positive impacts for patients, the NHS, and society.

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