

INTRODUCTION

- Heart failure is a growing clinical and economic challenge in Europe and particularly in Italy, where an aging demographics increase disease prevalence.¹
- Mineralocorticoid receptor antagonists (MRAs) represent one of four evidence-based pillars of guideline-directed medical therapy (GDMT) for heart failure with reduced ejection fraction (HFrEF).² Among these, eplerenone, unlike other MRAs, has demonstrated clinical benefit in reducing hospitalizations and mortality within its approved indications.^{3,4,5}
- Expert opinion highlights a substantial evidence gap, while market data reveal that prescribing patterns are falling short of guideline recommendations, thereby potentially leading to suboptimal patient outcomes and increased healthcare resource utilization.

OBJECTIVES

The aim of this study is to evaluate the economic impact of increased use of eplerenone (Projected scenario) for the treatment of patients with HFrEF, compared with current clinical practice (Current scenario).

Figure 1. Budget impact model chart

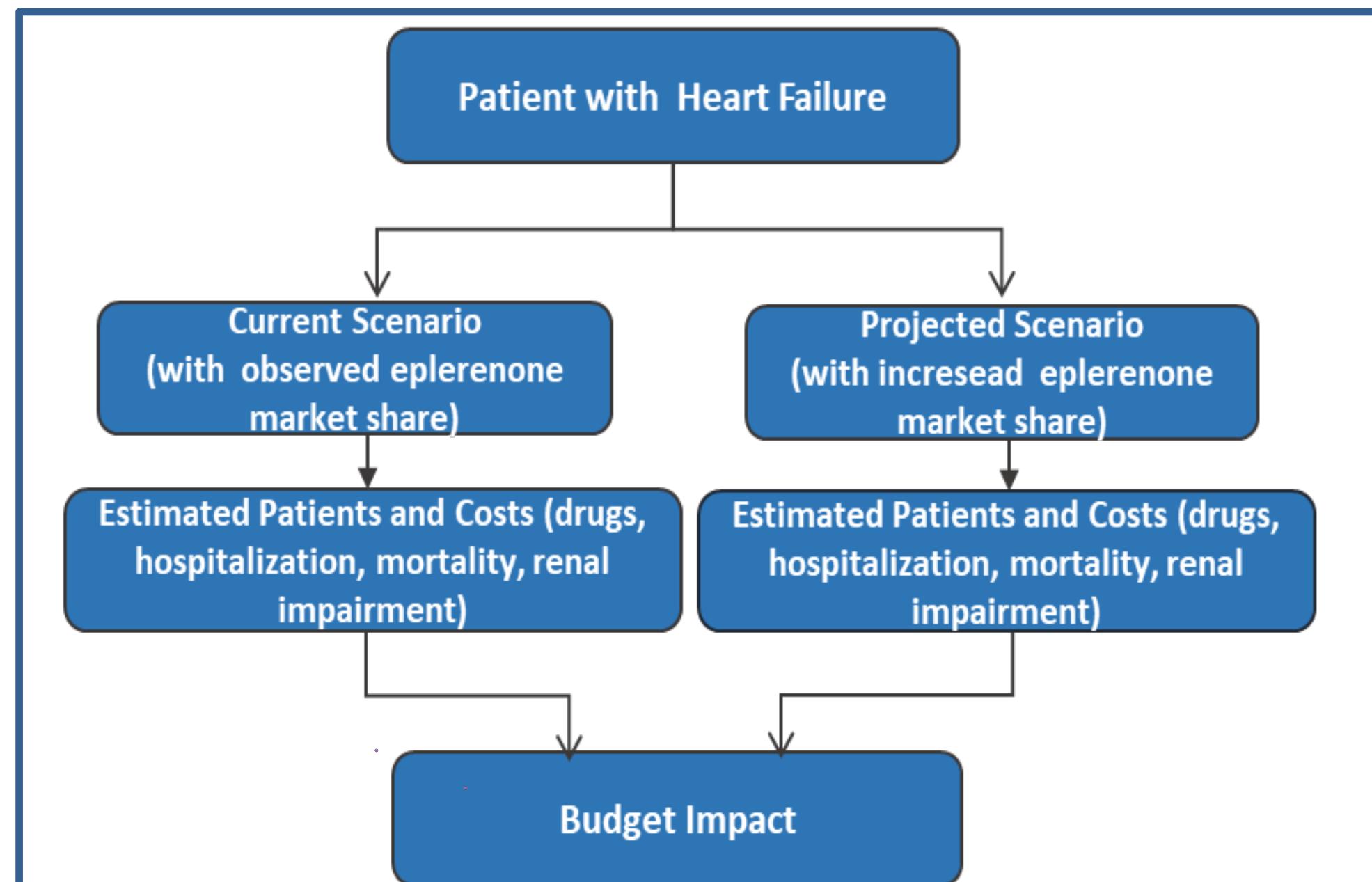
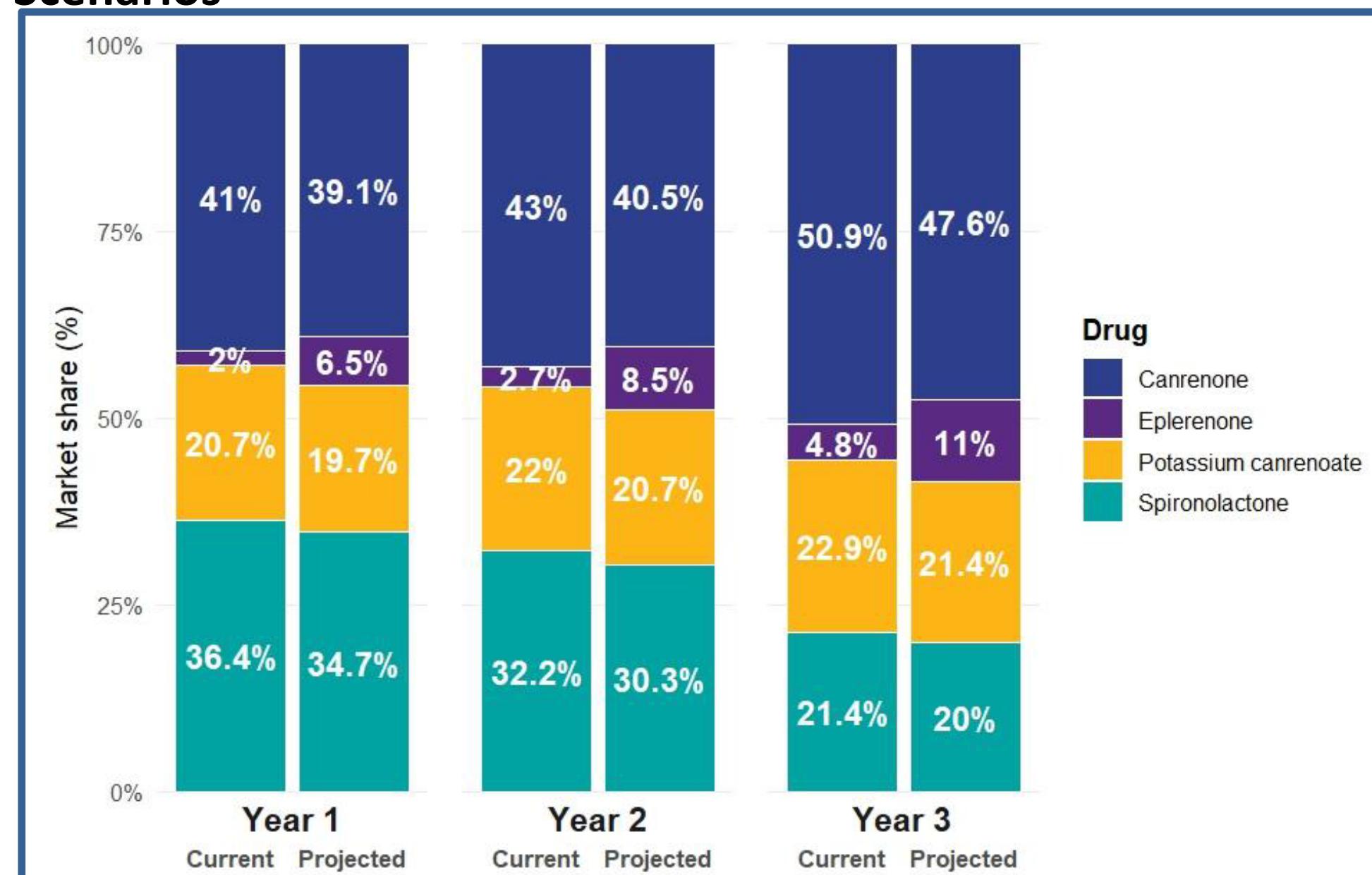


Figure 2. Distribution of MRAs Use in Current and Projected Scenarios



METHODS

- A 3-year static budget impact model (BIM) was developed to estimate the cost differences between Current and Projected scenarios. (Figure 1) The model assessed costs from Italian National Health Service (INHS) and included the following key parameters:
 - Eligible HFrEF patient population: estimated from published literature at approximately 210,000 in Italy.⁶⁻¹⁰
 - Estimated proportion of patients treated with MRAs: based on market data and assumptions. (Figure 2)
 - Treatment costs: annual cost of eplerenone, spironolactone, potassium canrenoate, and canrenone were € 353.69, € 70.08 (74.10 for subsequent year), € 81.90m and 169.27 respectively. Costs were derived from the AIFA Transparency Lists¹¹, Farmadati database, and dosages assumptions based on SmPCs¹².

- Clinical outcomes: included all-cause mortality, hospitalizations, and renal complications. Event rates were sourced from published network meta-analysis¹³ and adjusted according to baseline risks estimated through meta-analyses.
- Costs associated with clinical outcomes: avoided deaths, relative to baseline mortality, and hospitalizations were valued at €5,910 and €3,702 per patient, respectively, based on published economic estimates. The cost of renal damage was estimated at €590 per event, according to DRG 316 from the Italian DRG system tariffs.^{14,15}
- The analysis was conducted both at the national level and at the regional level, applying identical epidemiological and economic assumptions to the adult population of each Italian region to derive region-specific budget impact estimates.
- A one-way deterministic sensitivity analysis (DSA) was performed, varying all model parameters by $\pm 20\%$ to test the robustness of results.

RESULTS

- Total spend falls slightly from €625.7M (Current) to €623.2M (Projected), yielding **cumulative savings of €2.5M** (-0.4%) over 3 years, with annual savings increasing from €0.19M in Year 1 to €1.74M in Year 3. (Table 1)
- Eplerenone was associated with an increase in total costs mainly attributable to higher drug acquisition and hospitalization expenses resulting from the expanded treated population. However, these additional expenses were more than offset by reductions in costs of managing renal impairment and hospitalizations associated with comparators of lower efficacy, as well as by savings from avoided deaths. (Figure 3)
- Key uncertainty: the DSA showed that the model is **most sensitive to the hospitalization hazard ratio for eplerenone** ($\pm €4.98M$ impact on net budget), followed by cost per renal failure event ($\pm €2.77M$). (Figure 4)
- Savings were observed across all Italian regions**, although with varying magnitudes. The largest budget impact was observed in Lombardia ($-€430,948.77$), followed by Lazio ($-€246,949.14$). (Figure 5)

Table 1. Estimated budget impact of the Projected scenario compared with the Current scenario

	Year 1	Year 2	Year 3	Total
Eplerenone	€ 8,848,985	€ 11,262,533	€ 12,089,592	€ 32,201,111
Spironolactone	-€ 1,646,539	-€ 1,871,917	-€ 1,362,267	-€ 4,880,725
Potassium canrenoate	-€ 2,385,478	-€ 3,251,665	-€ 3,717,936	-€ 9,355,079
Canrenone	-€ 5,009,578	-€ 6,751,285	-€ 8,752,989	-€ 20,513,852
Total Budget Impact	-€ 192,610	-€ 612,334	-€ 1,743,600	-€ 2,548,545

Figure 3. Budget impact by cost components and active ingredients per year

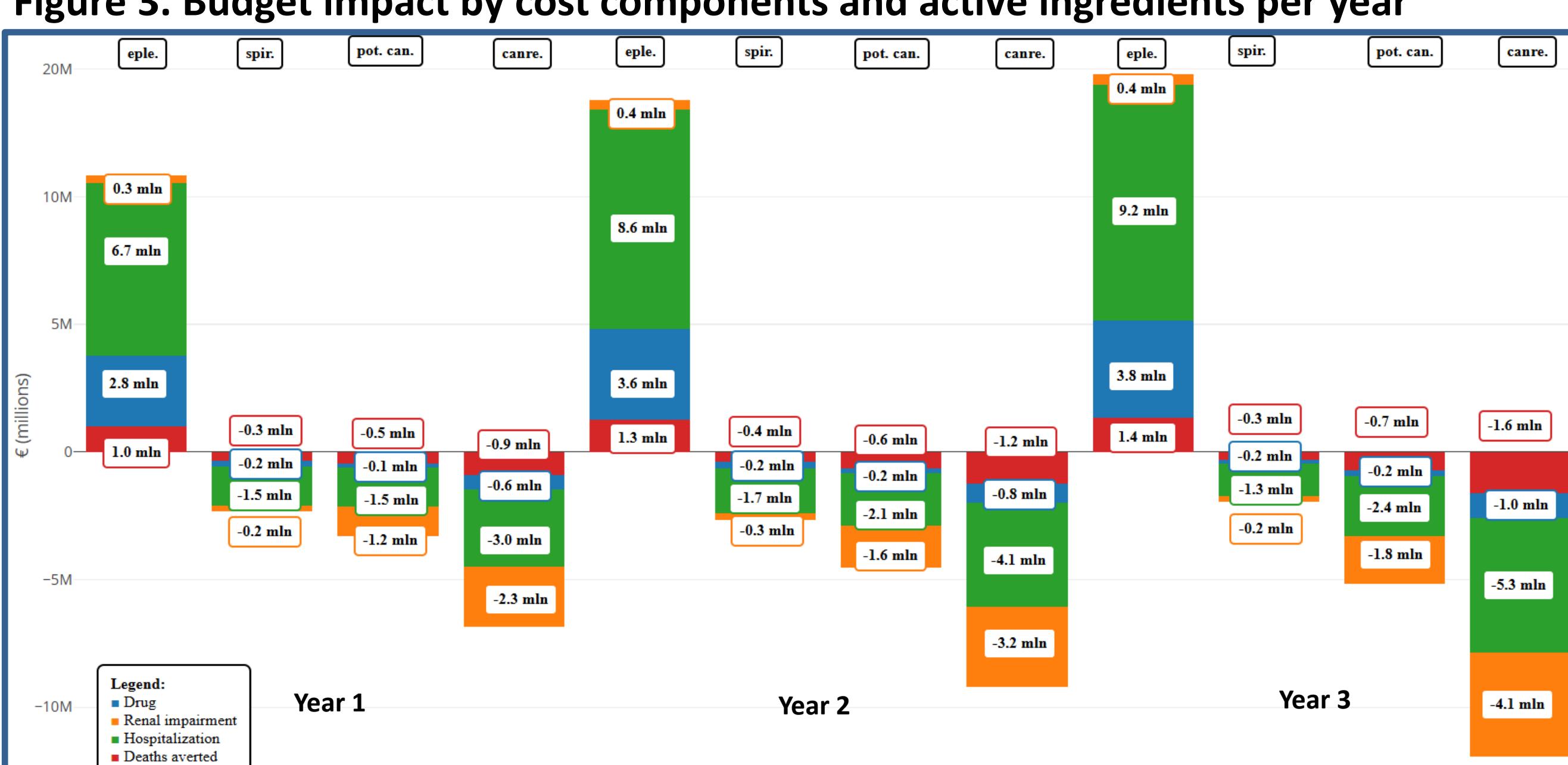


Figure 4. Deterministic sensitivity analysis

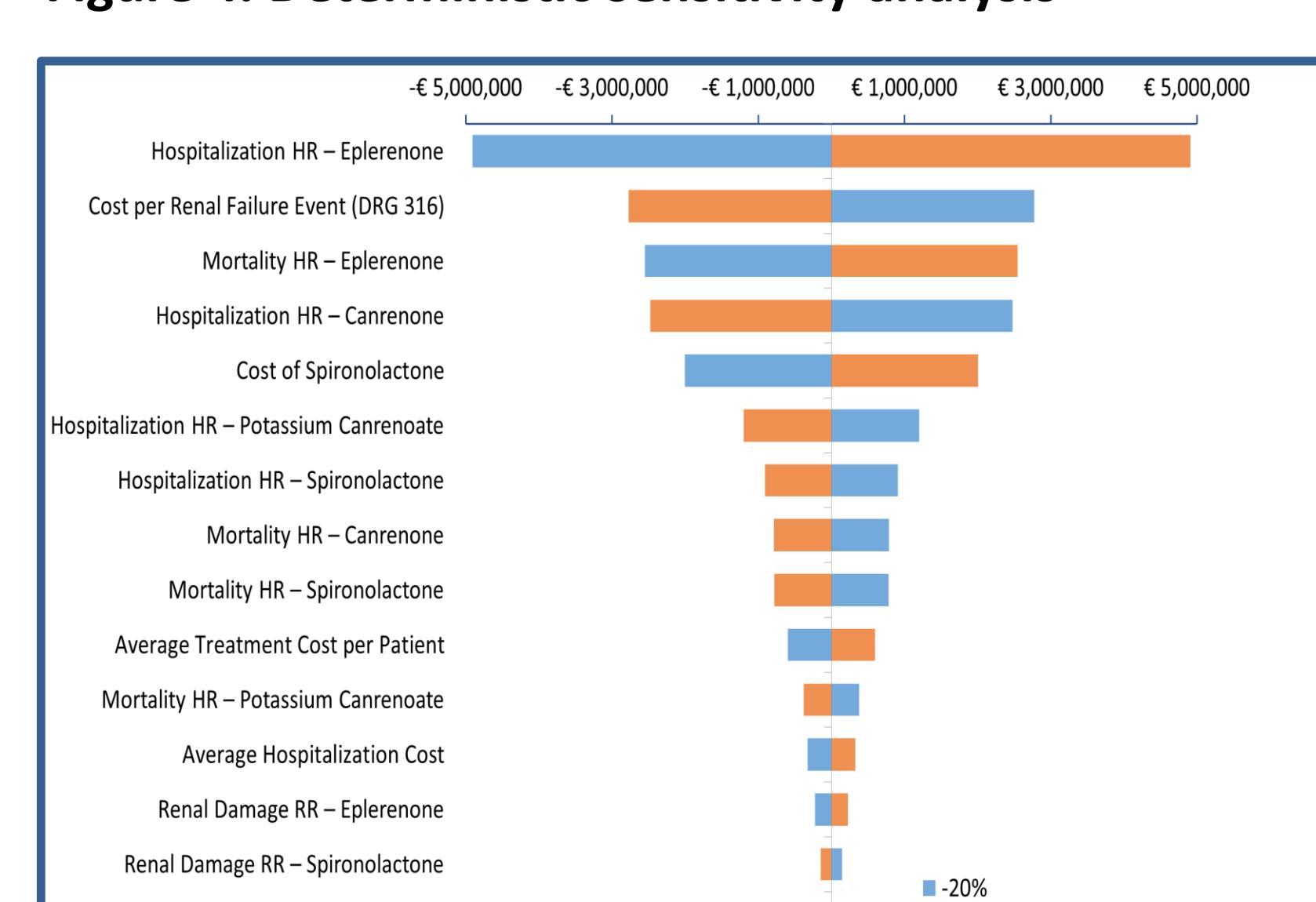
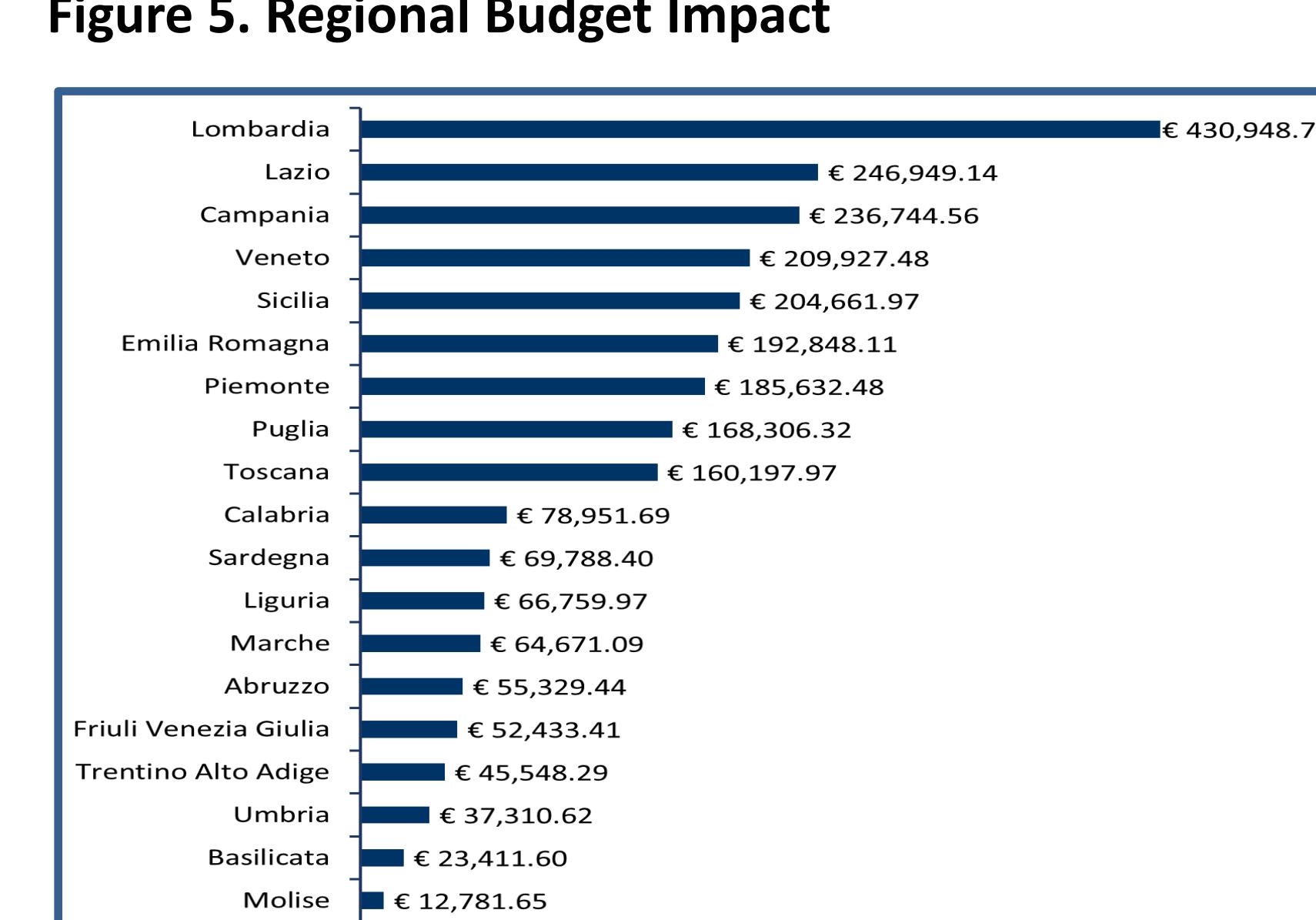


Figure 5. Regional Budget Impact



CONCLUSIONS

Eplerenone use in eligible HFrEF patients is well-supported by recent evidence and demonstrates **cost-saving potential for the Italian NHS**. The model underscores hospitalization prevention as a key cost driver and highlights the importance of regional planning when implementing value-based therapies in heart failure management.



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