Empagliflozin for the treatment of adult patients with symptomatic chronic heart failure with reduced ejection fraction (HFrEF): a cost-effectiveness analysis from the Italian NHS perspective

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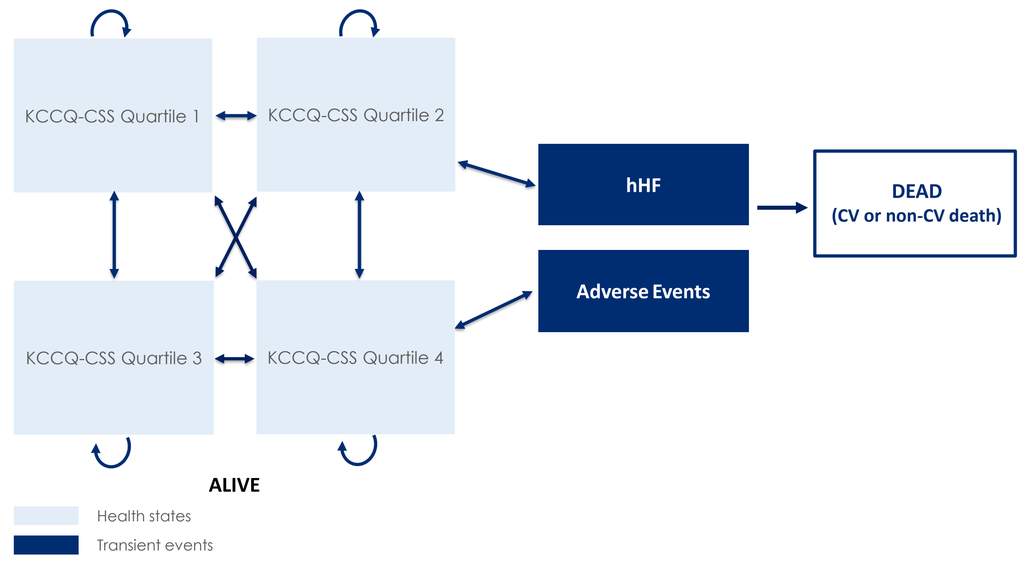
PURPOSE

- Empagliflozin is recently reimbursed in Italy for the treatment of adult patients with symptomatic chronic heart failure with reduced ejection fraction. Hence, a cost-effectiveness analysis was developed to confirm the economic value empagliflozin in Italy.

METHODS

- A Microsoft Excel® based Markov model was developed from the perspective of the Italian NHS with a lifetime time horizon.
- The model estimated the cost-effectiveness of empagliflozin in addition to standard of care (SoC), compared to SoC alone, based on clinical efficacy and safety outcomes collected in the EMPEROR-Reduced clinical trial, and assessing health-related quality of life, as well as key cost elements for the treatment of patients with HFrEF. (1)
- The model was developed to simulate patients' progression through health states based on KCCQ-CSS (Clinical Summary Score) quartiles over time (Figure 1).
- Costs included direct medical costs for treatment acquisition (ex-factory gross price), costs for the management of clinical events, adverse events (AE) and disease management.
- All costs were extrapolated from the Italian national tariffs. (2,3)
- Utilities were accrued based on time spent in each KCCQ-CSS quartile, adjusted for disutilities associated to HF-related hospitalisations and AEs. (1, 4)
- A 3% annual discount rate was applied to costs and health outcomes.
- Deterministic and probabilistic sensitivity analyses were run to assess the robustness of results.

Figure 1. Model structure



Abbreviations: CV: cardiovascular; hHF: hospitalization for heart failure; KCCQ-CSS: Kansas City Cardiomyopathy Questionnaire clinical summary score.

RESULTS

- Over the lifetime horizon, patients treated with empagliflozin as an add on to SoC experienced lower rates of hHF (hospitalization Hearth Failure) and CV (cardiovascular) death compared to SoC alone. This leads to an improvement in the patient's quality of life (increase of 0.22 total QALYs), with a slight increase in costs (increase of €1,462 total cost) (Table 1, 2).
- Considering total incremental costs and QALYs, an incremental cost effectiveness ratio (ICER) of €6,689 per QALY was calculated (Table 3).
- This ICER is significantly below the willingness-to-pay threshold of €30,000 - €60,000, defined acceptable for the evaluation of the cost effectiveness in Italy. (5,6)
- The robustness of results was confirmed by deterministic and probabilistic sensitivity analyses (Figure 2,3).

Table 1. Quality-adjusted life years (QALYs) QALYs per patient

QALYs per patient	Empagliflozin + SoC	SoC	Incremental
KCCQ-CSS 1st Quartile	0.46	0.50	-0.04
KCCQ-CSS 2nd Quartile	0.76	0.73	0.03
KCCQ-CSS 3rd Quartile	1.13	1.14	-0.01
KCCQ-CSS 4th Quartile	1.78	1.59	0.19
Loss due to hHF	-0.217	-0.258	0.04
Loss due to AEs	-0.007	-0.007	0.00
Total QALYs	**3.91**	**3.69**	**0.22**

Table 2. Cost outcomes per patient

Cost outcomes per patient	Empagliflozin + SoC	SoC	Incremental
Drug Acquisition Cost	€ 5,368	€ 3,357	€2,011
Clinical Event Management Cost	€ 5,285	€ 5,895	-€610
Adverse events Management Cost	€ 2,305	€ 2,348	-€43
Disease Management Cost	€ 2,876	€ 2,773	€103
Total Cost	**€ 15,834**	**€ 14,373**	**€ 1,462**

Table 3. Cost outcomes per patient

Final outcomes per patient	Empagliflozin + SoC	SoC	Incremental	ICER
Total Cost	€ 15,834	€ 14,373	€ 1,462	**€ 6,689**
Total QALYs	3,91	3,69	0,22	

Figure 2. Deterministic sensitivity analysis results: tornado diagram (ICER)

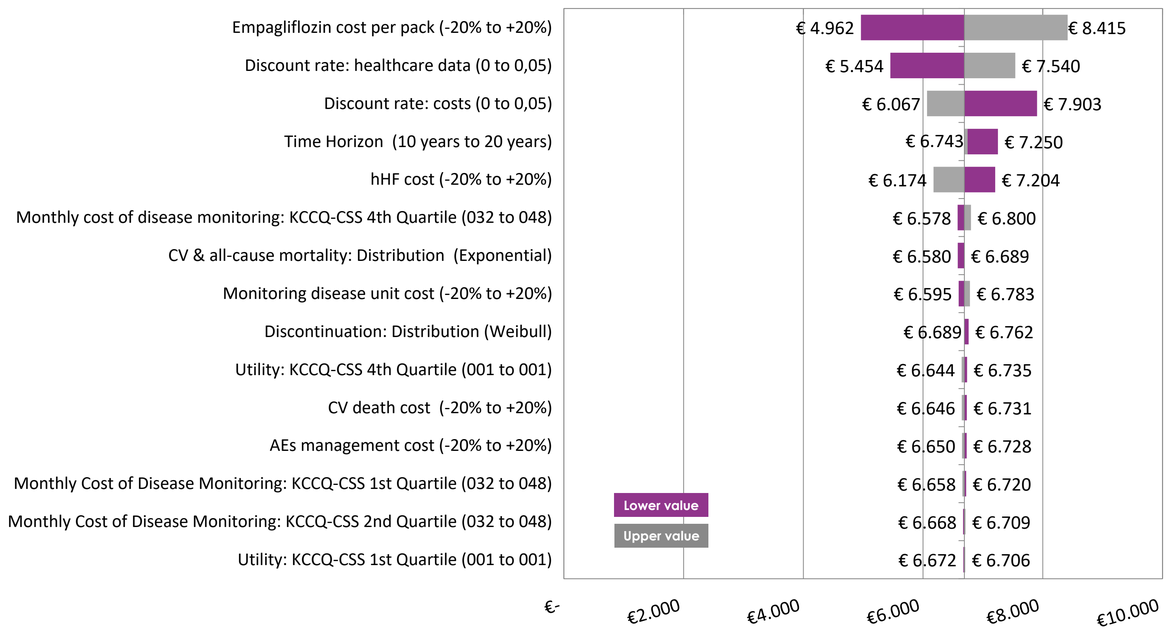
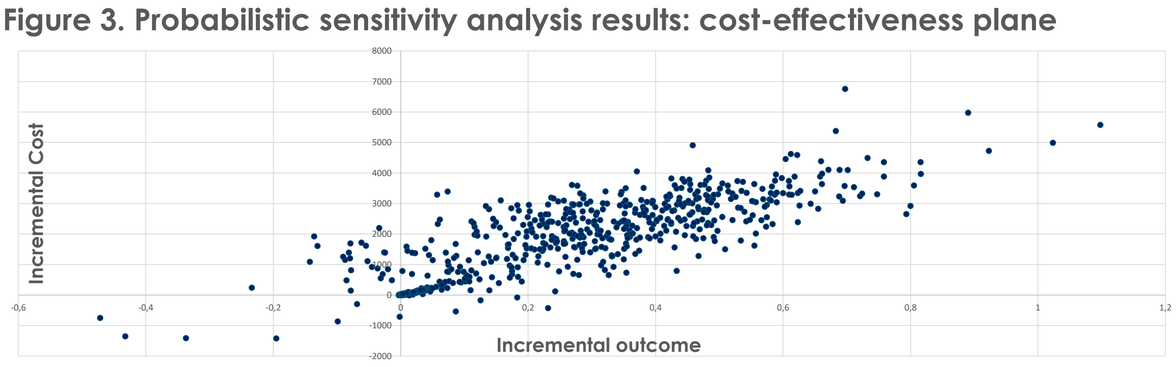


Figure 3. Probabilistic sensitivity analysis results: cost-effectiveness plane



CONCLUSION

- The results have shown an ICER significantly below the willingness-to-pay threshold in Italy (€6,689), clearly indicating that empagliflozin is a new cost-effective therapeutic option for the Italian NHS in the treatment of HFrEF patients on top of standard therapy.

Declaration of interest
Boehringer Ingelheim provided funding for this study.

Poster presented at ISPOR Europe 2022 conference, November 6-9, 2022, Vienna, Austria

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