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Cost-effectiveness of finerenone in chronic kidney disease associated with type 2 diabetes: impact of recent guideline implementation on results of the FINE-CKD Model

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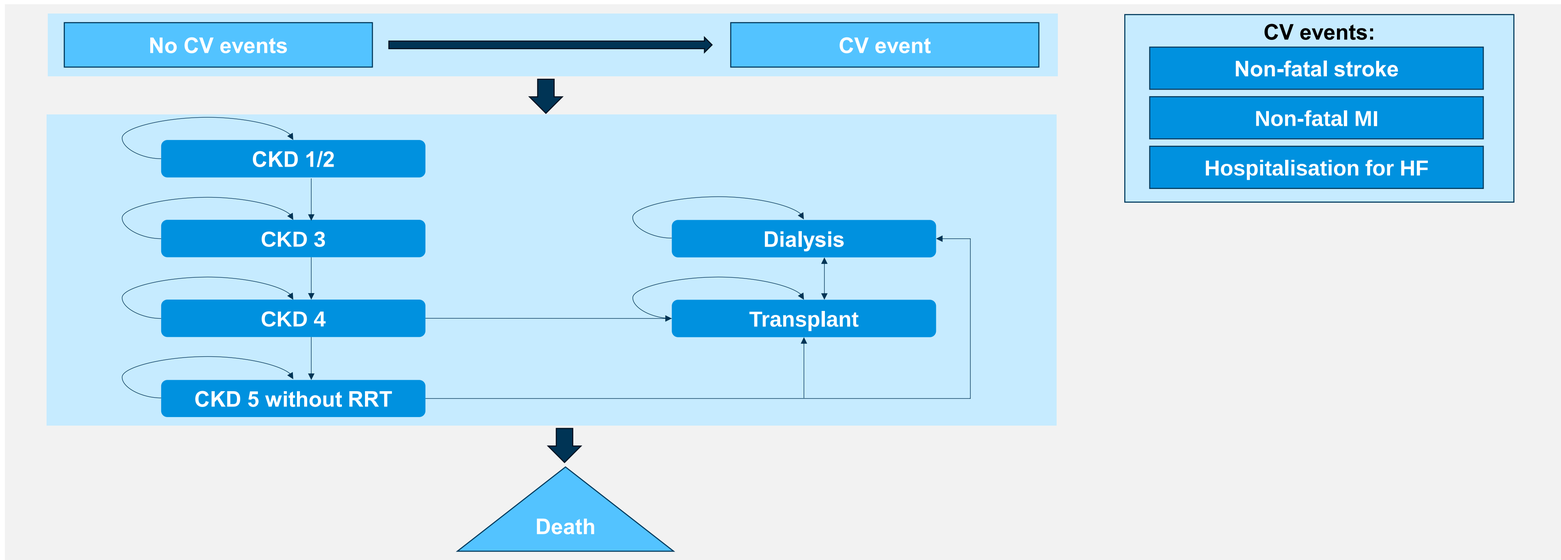
Introduction

- Chronic kidney disease (CKD) is a serious comorbidity of type 2 diabetes (T2D), associated with increased cardiovascular (CV) risk and at least 10-fold greater mortality, as compared to T2D alone.[1,2]
- Finerenone is a selective, nonsteroidal, mineralocorticoid receptor antagonist[3]. As an add-on therapy to standard of care (SoC), finerenone has shown benefits in reducing the risk of CV complications and the risk of kidney disease progression in the pivotal FIDELIO-DKD phase 3 trial (NCT02540993)[4-6].
- Following recent guideline updates[7] advocating for wider use of sodium-glucose co-transporter-2 (SGLT2) inhibitors, real-world data suggest their use has increased in this indication.[8]
- This study examines the impact of guideline updates on the cost-effectiveness of finerenone as an add-on to SoC in adults with CKD with T2D. The analysis adopted a UK National Health Service and Personal Services perspective, with a lifetime horizon.

Methods

- The previously described FINE-CKD[9,10] cost-utility model was adjusted based on recent guideline updates.[7] The FINE-CKD Markov model is based on outcomes of the FIDELIO-DKD trial and characterises key clinical dimensions of CKD and T2D: kidney disease progression and CV risk. Health states correspond to patients' CKD stage, initiation of renal replacement therapy (RRT) and CV event profiles. Moreover, a range of other clinically meaningful health events are included to account for additional impacts on patients' health-related quality of life (HRQoL) and total cost.
- FIDELIO-DKD was the main source of clinical inputs to the model, including baseline patient characteristics and transition probabilities, baseline risks of modelled events, and mortality. Hazard ratios (HRs), calculated from FIDELIO-DKD reflected the treatment effects of adding finerenone to SoC relative to SoC alone. The unit costs of drugs were based on the NHS dictionary of medicines and devices.[11]
- A range of commonly prescribed therapies for patients with CKD and T2D are considered as SoC in the model. To estimate costs of SoC, the most common drugs used in FIDELIO-DKD have been selected as representatives for each included group of medication.
- For simplicity, the SGLT2 inhibitors are considered as a class rather than independently in the model. In the present analysis, the efficacy HRs were based on canagliflozin due to the CREDENCE trial providing the most comparable data. These HRs are tested in both deterministic and probabilistic sensitivity analyses.

Figure 1. FINE-CKD model structure



CKD – Chronic kidney disease, CV – Cardiovascular, HF – Heart failure, MI – myocardial infarction, RRT – Renal replacement therapy

- Since 2021, in light of growing evidence of the beneficial effects of SGLT2 inhibitors, various organisations have published new guidelines for the use of these drugs in patients with CKD and T2D, recommending wider use of SGLT2 inhibitors.[7,12,13]
- According to real-world data, the proportion of UK patients treated with SGLT2 inhibitors has increased to 22% vs. the 6.2% observed in the FIDELIO-DKD trial.[8] To account for this change and to investigate the impact on cost-effectiveness of finerenone added to SoC, the rate of SGLT2 inhibitor use has been adjusted in the model.
- Three scenarios based on the proportion of patients using SGLT2 inhibitors were analysed for the purpose of this study:

BASE CASE	SCENARIO 1	SCENARIO 2
6.2% as in FIDELIO-DKD	22% based on real-world data	100% (extreme assumption)

- As part of SoC, SGLT2 inhibitor use is assumed equal in both arms of the model, impacting both costs and health outcomes. Increased usage reduces the baseline risk of CKD progression and CV events among patients with CKD and T2D.
- The relative treatment effects of finerenone in combination with SGLT2 inhibitors remained constant, consistent with existing literature.[14]

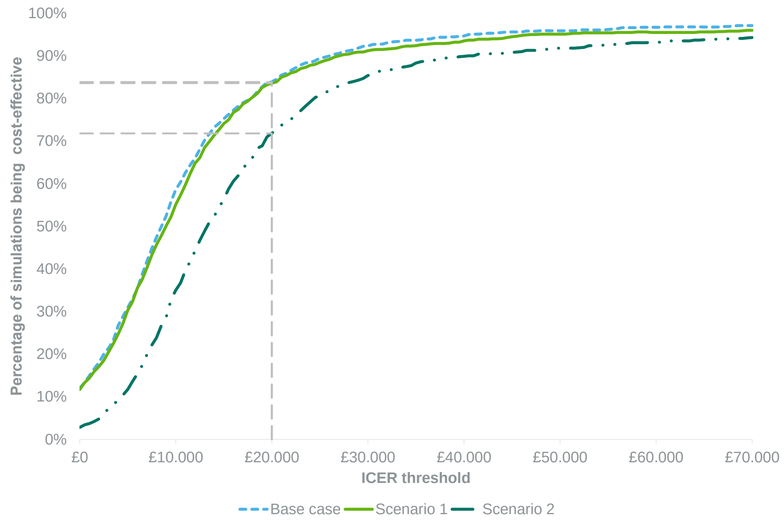
Table 1. Deterministic results

Scenario	FIN + SoC vs SoC Incremental costs		Incremental QALY		Incremental cost / QALY gained	
	Undiscounted	Discounted	Undiscounted	Discounted	Undiscounted	Discounted
Base case 6.2% SGLT2 usage	£1,488	£1,224	0.20	0.139	£7,530	£8,808
Scenario 1 22% SGLT2 usage	£1,563	£1,288	0.19	0.136	£8,071	£9,490
Scenario 2 100% SGLT2 usage	£1,989	£1,650	0.17	0.116	£11,826	£14,212

Results

- Increasing the SGLT2 inhibitor usage in line with the published real-world data, marginally decreased the improvement in quality-adjusted life years (QALYs) gained, from 0.139 to 0.136 QALY per patient. Incremental costs increased from £1,224 to £1,288.
- The incremental cost-effectiveness ratio (ICER) increased from £8,808 to £9,490 per QALY gained, demonstrating the high value of finerenone added to SoC.
- In an unlikely scenario analysis considering 100% SGLT2 inhibitor utilization, the ICER remained below the UK cost-effectiveness threshold, at £14,212 per QALY gained.

Figure 2. Cost-effectiveness acceptability curve



- In Scenario 1, the key drivers of the modelled cost-effectiveness remained similar to those in the base case. However, in Scenario 2, inputs relating to the efficacy of SGLT2 inhibitors became the most influential, replacing the health state utilities and the probability of CV death following dialysis.
- Based on a probabilistic sensitivity analysis of 1,000 simulations, there was an 84% likelihood that finerenone combined with SoC would be cost-effective compared to SoC alone both in the base case and in Scenario 1 when a willingness-to-pay threshold of £20,000 per QALY was applied. For Scenario 2, the probability was estimated as 72%.

Conclusion

- **Finerenone is a cost-effective treatment option when added to SoC for CKD in T2D, even as SGLT2 inhibitor use has increased following changes in guidelines.**
- **This would be expected to remain true even if SoC included SGLT2 inhibitors for all patients, thereby demonstrating the consistent value of finerenone across different treatment scenarios.**

Disclosures

Dr Cherney has received honoraria from Boehringer Ingelheim-Lilly, Merck, AstraZeneca, Sanofi, Mitsubishi-Tanabe, AbbVie, Janssen, Bayer, Prometic, BMS, Maze, Gilead, CSL-Behring, Otsuka, Novartis, Youngene, Lexicon, Inversago, and Novo-Nordisk and has received operational funding for clinical trials from Boehringer Ingelheim-Lilly, Merck, Janssen, Sanofi, AstraZeneca, CSL Behring, and Novo Nordisk.
Dr. Roy-Chaudhury reports personal fees from WL Gore, Medtronic, BD, Cormedix, Akebia, Bayer, Target RWE, Humacyte, Astra Zeneca, Alexion. He is a part owner and Chief Scientific Officer of Inovasc LLC.
Dr Levy and Dr Morris report personal fees from Bayer AG, during the conduct of the study.
Dr Sullivan reports personal fees from Bayer AG, outside the submitted work.
Mernagh and Folkerts report personal fees from Bayer AG, outside the submitted work; and Employee of Bayer AG, funder of the publication.
Dr Millier reports other from Clever-Access, during the conduct of the study.
Dr Pochopień reports other from Clever-Access, during the conduct of the study.
Medical Writing support was provided by Clever-Access.

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