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Cost-effectiveness of extended-pulse fidaxomicin (EPFX) versus standard vancomycin (SV) in older patients with Clostridium difficile infection in England

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Background: In a Phase IIIb/IV, randomised clinical trial (EXTEND; Clinicaltrials.gov: NCT02254967), sustained cure rates were evaluated following EPFX (200 mg twice daily on Days 1–5, then every alternate day from Days 6–25) versus SV (125 mg four times daily for 10 days) in older patients (≥60 years) with *Clostridium difficile* infection (CDI). This dosing regimen uses the same number of fidaxomicin tablets as the standard licensed dosage and thus incurs the same acquisition costs, but the cost-effectiveness of EPFX has not yet been studied. The primary results of the study demonstrated superior sustained clinical cure of CDI for EPFX compared with SV and a significant reduction in recurrence rates was also observed at days 40, 55 and 90.

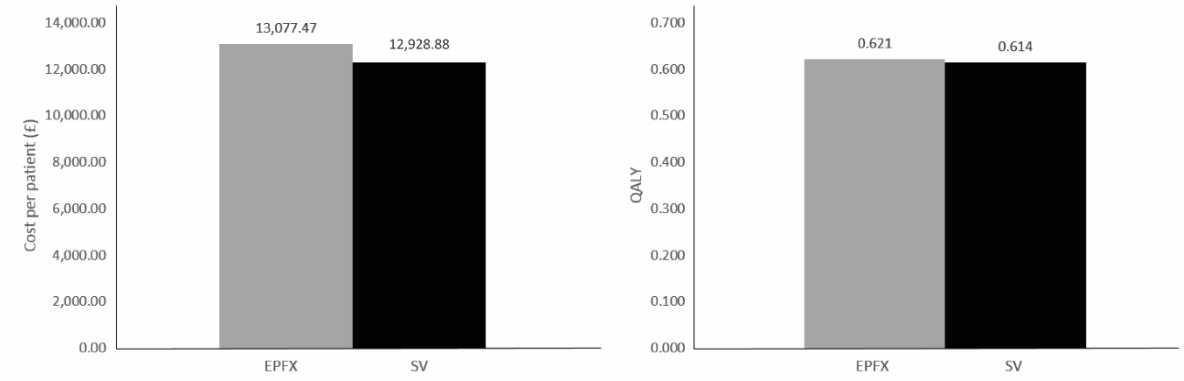
Material/methods: A semi-Markov model was developed to estimate the costs and outcomes of first-line treatment with EPFX compared with SV based on clinical data from the EXTEND trial. The cohort was followed for up to three lines of therapy and up to two recurrent CDI episodes. Independent of initial first-line therapy, vancomycin was used as second-line treatment. Third-line rescue treatment was assumed to have a 100% clinical cure rate and 0% recurrence rate. Recurrence was treated with vancomycin regardless of initial first-line therapy. Costs and outcomes were analysed over a 365-day time horizon from an English National Health Service perspective. The inputs included: clinical cure at 2 days post-treatment, CDI recurrence at Days 40, 55 and 90, mortality rates and adverse event rates (all derived from EXTEND); drug acquisition costs (sourced from the British National Formulary); and costs associated with hospitalisation, health state utilities and utility decrements, which were sourced from the literature. Treatment effectiveness was measured in quality-adjusted life years (QALYs),

number of recurrent episodes, and number of sustained clinical cures. Deterministic and probabilistic sensitivity analyses were conducted.

Results: Substitution of EPFX in place of SV in first-line CDI treatment was associated with an incremental cost (£149) and QALY gain (0.007 QALYs) (Figure). Cost-effectiveness was driven by a reduction in hospitalisation costs attributed to the reduction in recurrence with fidaxomicin. Sensitivity analyses demonstrated that the incremental cost per QALY was most sensitive to clinical cure and recurrence rates for first-line treatments, the utility value ascribed to the sustained clinical cure health state and the need for rescue treatment and hospitalisation costs. EPFX first-line therapy had a 52% probability of being cost-effective at a £30,000 per QALY willingness-to-pay threshold.

Conclusions: EPFX was the cost-effective treatment strategy compared with SV (cost per QALY: £21,500). The economic model results resonate with the clinical outcomes reported in the EXTEND trial, demonstrating the potential clinical and financial benefits of this extended-duration fidaxomicin regimen as a first-line CDI treatment in older patients in England.

Figure: Total cost per patient (left) and QALY gain (right) for EPFX versus SV



EPFX, extended-pulsed fidaxomicin; QALY, quality-adjusted life-years; SV, standard vancomycin