**INTRODUCTION**

C. difficile is a debilitating condition associated with mortality, substantial morbidity and hospitalization.1–3 The most commonly recommended treatment options for C. difficile are vancomycin and metronidazole. However, C. difficile has developed resistance to these regimens, which requires clinicians to utilize new treatment options, such as fidaxomicin, to improve patient outcomes.4–6

Fidaxomicin is the first in a new class of macrocyclic antibiotics licensed to treat C. difficile. It was developed to improve therapy by decreasing recurrence and complications.7–9

In two phase III trials, fidaxomicin was non-inferior to vancomycin in terms of clinical cure and produced significantly lower recurrence rates (p<0.005) and significantly higher sustained cure rates (p<0.001).3,10

**OBJECTIVE**

To evaluate the cost-effectiveness and budget impact in Germany of fidaxomicin compared with vancomycin in the first-line treatment of patient subgroups with C. difficile at increased risk of recurrence.

**METHODS**

**Model overview**

A Markov model was developed in MS Excel to simulate the therapeutic management and disease course in patients with C. difficile.

The cycle length was 10 days—corresponding to the duration of a course of treatment in clinical practice—and the time horizon was either 45 days (hospital perspective) or one year (payer perspective) to account for multiple recurrences.

The structure of the model is illustrated in Figure 1. It was applied to the following patient subgroups, who are more susceptible to recurrence:6–9

- Patients with cancer
- Age ≥65 years
- Those aged ≥65 years, and those receiving concomitant antibiotics.

**Models**

The ‘initial CDI episode’ is shown in Table 1. This is a new-onset infection; CEA, cost-effectiveness analysis; ICER, incremental cost-effectiveness ratio.

**Cost-Effectiveness analyses**

Table 1. Clinical efficacy inputs for the model.

<table>
<thead>
<tr>
<th>Treatment</th>
<th>Recurrence rate (%)</th>
<th>Efficacy factor (likelihood of cure)</th>
<th>Cost per bed-day in hospital (€)</th>
<th>Cost per QAL Y gained (€)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Fidaxomicin</td>
<td>0.56</td>
<td>1.24</td>
<td>33,403</td>
<td>84.5</td>
</tr>
<tr>
<td>Vancomycin</td>
<td>1.00</td>
<td>1.00</td>
<td>31,349</td>
<td>82.5</td>
</tr>
</tbody>
</table>

**Cost-effectiveness of fidaxomicin vs. vancomycin**

- Fidaxomicin is more effective, with a lower recurrence rate, compared to vancomycin.
- The cost per QAL Y gained with fidaxomicin is lower than with vancomycin.
- Sensitivity analysis showed one of the key drivers of cost-effectiveness was the mortality rate.

**Budget impact**

Table 3 shows the budget impact of fidaxomicin vs. vancomycin in 100 patients treated with fidaxomicin vs. vancomycin in all patient subgroups.

**CONCLUSIONS**

- Compared with vancomycin, fidaxomicin is associated with a lower recurrence rate and substantially higher sustained cure rates in all patient subgroups; this resulted in a reduction in hospital re-admission rates and the overall number of bed-days of fidaxomicin.

- Replacement of vancomycin with fidaxomicin on the formulary has been shown to be cost-saving in patients with cancer over a 1-year time horizon, despite the higher drug cost of fidaxomicin. This is due to savings being made due to reduced hospital readmissions as more recurrences are prevented with fidaxomicin.

- First-line fidaxomicin is likely to be a cost-effective treatment option in patients at higher risk of recurrence, compared to vancomycin at a willingness-to-pay threshold of €50,000 per QAL Y gained. These results are highly relevant given the emphasis on reducing hospital admissions and the overall length of stay in EU healthcare systems.

**REFERENCES**

3. May 2015 DIF/15/0001/EUb
4. International Meeting May 16 – 20, 2015 Philadelphia PA
5. 20th Annual ISPOR