

CADTH RAPID RESPONSE REPORT: REFERENCE LIST Fidaxomicin Pulse Therapy for Clostridium difficile Infection: Clinical Effectiveness

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Research Question

What is the comparative clinical effectiveness of fidaxomicin pulse therapy versus twice daily dosing for the treatment of Clostridium difficile infections?

Key Findings

No relevant evidence was identified regarding the clinical effectiveness of fidaxomicin pulse therapy versus twice daily dosing for clostridium difficile infection.

Methods

A limited literature search was conducted on key resources including MEDLINE, Embase, the Cochrane Library, University of York Centre for Reviews and Dissemination (CRD) databases, Canadian and major international health technology agencies, as well as a focused Internet search. No filters were applied to limit retrieval by publication type. Where possible, retrieval was limited to the human population. The search was also limited to English language documents published between January 1, 2009 and February 19, 2019. Internet links were provided, where available.

Selection Criteria

One reviewer screened citations and selected studies based on the inclusion criteria presented in Table 1.

Population	Adult patients, in all settings, with a Clostridium difficile infection
Intervention	Fidaxomicin pulse therapy
Comparator	Fidaxomicin twice daily dosing
Outcomes	Clinical effectiveness (e.g., infection resolution, prevention of recurrence); safety (e.g., side effects, adverse events, mortality)
Study Designs	Health technology assessments, systematic reviews, meta-analyses, randomized controlled trials, non- randomized studies

Table 1: Selection Criteria

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Results

Rapid Response reports are organized so that the higher quality evidence is presented first. Therefore, health technology assessment reports, systematic reviews, and meta-analyses are presented first. These are followed by randomized controlled trials and non-randomized studies.

No relevant health technology assessments, systematic reviews, meta-analyses, randomized controlled trials, or non-randomized studies were identified regarding fidaxomicin pulse therapy versus twice daily dosing for clostridium difficile infection.

References of potential interest are provided in the appendix.

Health Technology Assessments

No literature identified.

Systematic Reviews and Meta-analyses

No literature identified.

Randomized Controlled Trials

No literature identified.

Non-Randomized Studies

No literature identified.



Appendix — Further Information

Randomized Controlled Trials - Alternative Comparator

 Guery B, Menichetti F, Anttila VJ, et al. Extended-pulsed fidaxomicin versus vancomycin for Clostridium difficile infection in patients 60 years and older (EXTEND): a randomised, controlled, open-label, phase 3b/4 trial. *Lancet Infect Dis.* 2018 03;18(3):296-307.
PubMed: PM29273269

Non-Randomized Studies

Alternative Dosing Schedule and Comparator

- Louie TJ, Miller MA, Mullane KM, et al. Fidaxomicin versus vancomycin for Clostridium difficile infection. N Engl J Med. 2011 Feb 03;364(5):422-431. <u>PubMed: PM21288078</u>
- In Vitro Model
- Chilton CH, Crowther GS, Todhunter SL, et al. Efficacy of alternative fidaxomicin dosing regimens for treatment of simulated Clostridium difficile infection in an in vitro human gut model. J Antimicrob Chemother. 2015 Sep;70(9):2598-2607. <u>PubMed: PM26078392</u>

Economic Evaluations

Alternative Comparator

 Cornely OA, Watt M, McCrea C, Goldenberg SD, De Nigris E. Extended-pulsed fidaxomicin versus vancomycin for Clostridium difficile infection in patients aged >=60 years (EXTEND): analysis of cost-effectiveness. *J Antimicrob Chemother*. 2018 Sep 01;73(9):2529-2539.
<u>PubMed: PM29800295</u>