



Topic Brief: Comparative Safety and Effectiveness of Newer Antimicrobials

Date: 8/24/2022

Nomination Number: 1012

Purpose: This document summarizes the information addressing a nomination submitted on June 3, 2022, through the Effective Health Care Website. This information was used to inform the Evidence-based Practice Center (EPC) Program decisions about whether to produce an evidence report on the topic, and if so, what type of evidence report would be most suitable.

Issue: The nominator is interested in a review on all antimicrobials FDA-approved from 2013 on compared to antimicrobials approved before 2010. They plan to use an evidence review to inform dissemination efforts to patients.

Findings: Concerns about comparative effectiveness of antimicrobial treatment is important. We identified around 50 new antimicrobials FDA-approved from 2013 on. The nomination is too broad for further consideration.

Background

An antimicrobial agent is defined as a natural or synthetic substance that kills or inhibits the growth of microorganisms such as bacteria, parasites, viruses and fungi. Antimicrobials save lives, but any time antimicrobials are used they can cause side effects and can contribute to the development of antimicrobial resistance¹.

Many new drugs are new versions of existing drugs that offer modest change. Among new U.S. drugs where effectiveness was also evaluated by a regulatory authority in another country, when compared to existing treatment there was consistent agreement in 37% of cases that the drug was better than existing products. However there was agreement that new drugs had no health advantages over existing products for 43% of cases. Of these, many were costly^{2,3}.

Summary

We identified close to 50 antimicrobials FDA-approved since 2013⁴⁻¹⁴. These are used for a variety of infections including inhalational anthrax, Ebola, COVID, pneumonia, and HIV. This nomination is too broad due to the number of interventions, potential comparators, and diversity of conditions. We reached out for input from the nominator. Due to the limited response, the program will not consider this nomination further.

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Conflict of Interest: None of the investigators have any affiliations or financial involvement that conflicts with the material presented in this report.

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