

Improving Safe Use of Fluoroquinolone Antibiotics Through Development of an Innovative Education Program

Performer: WebMD Health Corp.

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Project Duration: 6/24/16 – 12/31/18

Regulatory Science Challenge

It is estimated that half of all antibiotics prescribed are either unnecessary or the wrong antibiotic for the diagnosis.¹ Specifically, antibiotics of the fluoroquinolone (FQ) class are often prescribed inappropriately and without full consideration of each drug's risks and benefits. A joint panel of the FDA's Antimicrobial Drugs Advisory Committee and the Drug Safety and Risk Management Advisory Committee met in November 2015 and voted that for patients who are able to take other antibacterial drugs the benefits of systemic fluoroquinolone antibacterial drugs do not outweigh the risks for treatment of acute bacterial sinusitis, mild acute bacterial exacerbation of chronic bronchitis in those with chronic obstructive pulmonary disease, and uncomplicated urinary tract infection. Thus, FDA determined that fluoroquinolones should be reserved for use in patients who have no other treatment options for these generally less severe infections.²

Project Description

This project proposes to increase the safety of post-approval FQ antibiotic use through a data-driven educational program targeted to high-decile FQ prescribers. Third-party provider prescription data will be used to identify frequent prescribers of FQs. Medscape, an online information and education platform, will be used to provide alerts, education, and feedback, with the goal of reducing preventable harm from FQs in conditions where the risks outweigh the benefits.

Project Goals

- Identify the top prescribers of fluoroquinolones and deliver information on fluoroquinolones to these prescribers via Medscape
- Measure the impact of the program through a fluoroquinolone prescription volume analysis of prescribers exposed to the various educational materials (drug safety information, individual-level prescribing information relative to same-specialty peers, or both) relative to a control group.
- Measure the impact of a Continuing Education (CE) program on prescribing of FQs.
- Analyze results by indication and specialty.

¹ CDC. Antibiotics Use in the United States, 2017: Progress and Opportunities. Atlanta, GA: U.S. Department of Health and Human Services, CDC; 2017.

² See <https://www.fda.gov/media/119537/download>

Project Results

The final report from the researchers to the FDA included the following results:

- Individual level prescribing data was used to match high-decile prescribers of fluoroquinolones (FQs) to Medscape subscribers.
- A total of 11,774 healthcare providers participated.
- Prescribers exposed to the educational materials reduced prescribing by 8.5% compared to controls. Those exposed to both the educational materials and the CE achieved a 21.7% reduction in prescribing FQs.
- The difference in FQ prescribing between providers who were sent individual prescribing data and those who were sent drug safety information was not significant.
- Compared to controls, participants wrote 85,484 fewer FQ prescriptions during the study period.

Publications

- A manuscript is in preparation.