# Effective Health Care

# Risks of Fluoroquinolone Antibiotics for Patients with Rheumatological Disorders Nomination Summary Document

## Results of Topic Selection Process & Next Steps

- The topic, *Risks of Fluoroquinolone Antibiotics for Patients with Rheumatological Disorders,* was addressed by existing Food and Drug Administration (FDA) warnings/labeling for fluoroquinolones. Given that the existing FDA warnings cover this nomination, no further activity will be undertaken on this topic.
  - Transcript for the November 5, 2015 Joint Meeting of the Antimicrobial Drugs Advisory Committee (AMDAC) and the Drug Safety and Risk Management Advisory Committee (DSaRM). Washington, DC: US Food and Drug Administration; November 5, 2015. http://www.fda.gov/downloads/AdvisoryCommittees/CommitteesMeetingMaterials/Drugs/Anti-InfectiveDrugsAdvisoryCommittee/UCM477657.pdf
  - FDA Drug Safety Communication: FDA requires label changes to warn of risk for possibly permanent nerve damage from antibacterial fluoroquinolone drugs taken by mouth or by injection. Washington, DC: US Food and Drug Administration; August 15, 2013. http://www.fda.gov/Drugs/DrugSafety/ucm365050.htm
  - FDA Requests Boxed Warnings on Fluoroquinolone Antimicrobial Drugs Seeks to Strengthen Warnings Concerning Increased Risk of Tendinitis and Tendon Rupture [FDA News Release]. Washington DC, US Food and Drug Administration; July 8, 2008. [ARCHIVED] http://www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/2008/ucm116919.htm

## Topic Description

**Nominator(s):** Individual

**Nomination Summary:** The nominator wants to know the risks of permanent connective tissue damage when fluoroquinolones are prescribed to adult patients with rheumatological disorders who are taking corticosteroids. This individual believes there is a need for the medical community to better understand the risks of prescribing fluoroquinolones to populations who are particularly vulnerable to adverse effects from this class of antibiotics. The nominator questions whether this increased risk is fully appreciated as symptoms may be attributed to the underlying rheumatologic disease rather than adverse effects from the fluoroquinolone. The individual is concerned that fluoroquinolones continue to be prescribed to patients with risk factors despite warnings by the US Food and Drug Administration (FDA).

**Staff-Generated PICO**

**Population(s):** Patients with arthritis or other chronic conditions taking corticosteroids

**Intervention(s):** Fluoroquinolone antibiotics

**Comparator(s):** Other antibiotic drug classes

**Outcome(s):** Nerve damage, tendinopathy, arthropathy, peripheral neuropathy,

connective tissue damage, disability

**Key Questions from Nominator:**

The nominator submitted the question: For adult patients with rheumatological disorders taking corticosteroids, what are the risks of permanent connective tissue damage causing pain and further disability when fluoroquinolone antibiotics are prescribed to them?

In consultation with our clinical reviewer, we revised the question to the following: What are the risks of fluoroquinolone adverse effects in patients who are at increased risk due to concurrent use of steroids, musculoskeletal conditions or other chronic illnesses?

## Considerations

- The topic meets EHC Program selection criteria. (For more information, see http://effectivehealthcare.ahrq.gov/index.cfm/submit-a-suggestion-for-research/how-are-research-topics-chosen/.)
- The Food and Drug Administration (FDA) has addressed the risks associated with the use of fluoroquinolones.
  - In 2008, the FDA called for a boxed warning concerning the increased risk of tendinitis and tendon rupture.
  - In 2013, the FDA required label changes to warn of risk for possibly permanent nerve damage from antibacterial fluoroquinolone drugs taken by mouth or by injection.
  - In 2015, the FDA called for additional warnings about the risks for serious adverse events, such as "fluoroquinolone-associated disability" to be added to the existing black box warning on fluoroquinolone labels.