

Indications for systemic fluoroquinolone prescribing in Europe: a descriptive population based study

Study protocol

Data sources

Article 57 database

The European Medicines Agency (EMA) Article 57 database will be used to identify fluoroquinolone products across the EEA and perform a descriptive analysis of their indications identified by searching disease descriptions for each fluoroquinolone product.

Clinical Databases

IMS® Disease Analyzer France and Germany and the UK THIN database will be used to describe systemic fluoroquinolone prescribing in primary care. Diagnoses will be identified by searching for International Classification of Disease (ICD) codes (France and Germany) and Read codes (UK). The study period will be 01.01.2000 to 31.12.2015.

Populations

Patients will be included from the IMS® Disease Analyzer France and Germany with a minimum period of 1 year follow-up defined according to their consultation and prescribing observability. All patients with a consultation during the year will be used as population denominator. For THIN, all patients will be required to have a minimum of 1 years follow-up defined by the date of registration with a general practice.

Exposures

In the IMS® Disease Analyzer France and Germany databases, prescriptions for incident fluoroquinolones will be identified by EphMRA ATC codes J01G1 (non-topical fluoroquinolone administration) and by gemscript codes in the UK THIN database. Incident fluoroquinolone prescription episodes will be evaluated, and will be defined as a prescription for a systemic fluoroquinolone with no prescription in the previous 30 days.

Fluoroquinolone indications

Clinical indications will be identified in electronic medical records by identifying ICD10 and Read codes recorded in people recently prescribed a systemic fluoroquinolone antibiotic. Disease descriptions and codes will be broadly categorised into the following pre-specified groups: upper respiratory tract infections (URTI); lower respiratory tract infections (LRTI); urinary tract infections (UTI); ear infections; gastrointestinal infections (including hepatobiliary infections); genital infections (excluding testicular and prostatic infections considered separately); testicular infections; prostatic infections; skin and soft tissue infections; bone infections; and other indications. Codes will be screened by two reviewers, with a third reviewer used to reach consensus if needed.

For upper respiratory tract infections (URTI), lower respiratory tract infections (LRTI) and urinary tract infections (UTI), indications will be categorised into acute sinusitis, acute bronchitis and uncomplicated UTIs.

Analysis

The prevalence of incident systemic fluoroquinolone prescribing in France, Germany and the UK will be calculated for each indication category as a percentage of the total number of incident fluoroquinolone prescriptions identified with a systemic route of administration. The descriptive analysis of indications recorded in the Article 57 database will then be compared to clinical indications through routine electronic prescribing for France, Germany and the UK with yearly trends in the prevalence of fluoroquinolone prescribing plotted.