The Use of Oral Fluoroquinolones in Canada: Drug Utilization Study Update

First published: 24/10/2023

Last updated: 08/07/2026

Study Finalised

Administrative details

EU PAS number

EUPAS107333

Study ID

108049

DARWIN EU® study

No

Study countries

Canada

Study description

In January 2017, Health Canada issued a risk communication to restrict the use of fluoroquinolone antibiotics due their disabling and potentially persistent side effects. The labelling of all systemic fluoroquinolones available in Canada were

updated accordingly.
There is a need to determine if fluoroquinolone utilization patterns have changed since these regulatory actions were implemented.
The main objectives of this study are to update our previous study to describe fluoroquinolone utilization trends from 2008 to 20022 and to assess the impact of the risk minimization measures introduced in 2017.
We will conduct a retrospective cohort study using administrative health databases from 6 provinces (Alberta, British Columbia, Manitoba, Nova Scotia, Ontario, and Saskatchewan) between January 1, 2008 and December 31, 2022.
Similar methods to the previous CNODES drug utilization study will be used.
We will assess utilization patterns and indications of systemic oral fluoroquinolones available in Canada from 2008 to present. In addition, we will assess the impact of the 2017 risk minimization measures (risk communication, updates to the labels) on the use of fluoroquinolones through a time series analysis.
These findings will provide important insight on the current trends of fluoroquinolones use in Canada.
The study will only include prescriptions for the oral formulation of fluoroquinolones and will not include fluoroquinolone prescriptions dispensed in hospital.

Study status

Finalised

Research institutions and networks

Institutions

Lady Davis Institute

First published: 01/02/2024

Last updated: 01/02/2024

Institution

Networks

Canadian Network for Observational Drug Effect Studies (CNODES)

Canada

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Network

Contact details

Study institution contact

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Primary lead investigator

Pierre Ernst

Primary lead investigator

Study timelines

Date when funding contract was signed
Actual: 06/10/2023

Study start date
Planned: 01/02/2024

Actual: 23/10/2023

Data analysis start date
Planned: 01/02/2024

Actual: 01/12/2023

Date of interim report, if expected
Planned: 01/03/2024

Actual: 01/03/2024

Date of final study report
Planned: 30/04/2024

Actual: 30/04/2024

Sources of funding

- Other

More details on funding

CNODES is a collaborating core network partner of CoLab, which is funded for query-related activity by Canada’s Drug Agency (CDA-AMC, grant number C222 360).

Regulatory

Was the study required by a regulatory body?

Yes

Is the study required by a Risk Management Plan (RMP)?

Not applicable

Methodological aspects

Study type

Study type list

Study topic:

Human medicinal product

Study type:

Non-interventional study

Scope of the study:

Assessment of risk minimisation measure implementation or effectiveness

Drug utilisation

Data collection methods:

Secondary use of data

Study design:

This is a multicentre retrospective cohort study describing fluoroquinolone utilization trends from 2008 to 2022 and assessing the impact of the risk minimization measures introduced by Health Canada in 2017

Main study objective:

The main objective of this study are to update our previous study to describe fluoroquinolone utilization trends from 2008 to 20022 and to assess the impact of the risk minimization measures introduced in 2017.

Study Design

Non-interventional study design

Cohort

Study drug and medical condition

Anatomical Therapeutic Chemical (ATC) code

(J01MA02) ciprofloxacin

ciprofloxacin

(J01MA06) norfloxacin

norfloxacin

(J01MA12) levofloxacin

levofloxacin

(J01MA14) moxifloxacin

moxifloxacin

Population studied

Short description of the study population

The study population consisted of individuals registered in the provincial administrative databases in 6 provinces (Alberta, British Columbia, Manitoba, Nova Scotia, Ontario, and Saskatchewan) between January 1, 2008, and December 31, 2022 (last year of data available).

Age groups

- Preterm newborn infants (0 – 27 days)
- Term newborn infants (0 – 27 days)
- Infants and toddlers (28 days – 23 months)
- Children (2 to < 12 years)
- Adolescents (12 to < 18 years)
- Adults (18 to < 46 years)
- Adults (46 to < 65 years)
- Adults (65 to < 75 years)
- Adults (75 to < 85 years)
- Adults (85 years and over)

Estimated number of subjects

4850000

Study design details

Setting

Administrative health databases from the provinces of Alberta, British Columbia, Manitoba, Nova Scotia, Ontario, and Saskatchewan.

Data analysis plan

We will first assess utilization patterns and indications for oral fluroquinolones available in Canada from 2008 to 2022. We will estimate the yearly fluoroquinolone dispensation rates (per 1,000 population) overall and by molecule. We will describe fluoroquinolone use by dosage and duration of use, by prescriber group or specialty, and frequent indications associated with their use. For 3 indications of interest (see section 7), we will determine the rate and percentage of prescriptions for fluoroquinolones vs. other antibiotics, for adults with uncomplicated disease. In addition, we will assess the impact of the regulatory actions on fluoroquinolone use over time. A segmented regression model will be used to compare the rate of fluoroquinolone dispensations before and after 2017, and the rates of fluoroquinolone vs. other antibiotics for the 3 indications of interest. Results will be reported by provinces, pooled, and by age group and sex.

Summary results

Fluoroquinolone Utilization

Main Take-Aways

• Overall dispensation rates of the 4 oral fluoroquinolones of interest decreased by approximately 50% across provinces, sexes, and age groups between 2008 and 2022 (from 107 to 45 dispensations per 1,000 population).

• Fluoroquinolone use decreased for the treatment of adults with acute bacterial sinusitis, acute exacerbations of COPD (patients aged ≥ 66 years only), and uncomplicated UTIs (females only).

• Interprovincial variation in the use of fluoroquinolones was noted.

Impact Assessment Analysis

Main Take-Aways

• The reduction in the rates of fluoroquinolone dispensations was 50% from January 1, 2017, to February 29, 2020 (segment 2) and 62% from March 1, 2020, to December 31, 2022 (segment 3) relative to segment 1 (January 1,

2008, to December 31, 2016; before introduction of risk minimization measures).

• Similarly, reductions in the percentages of antibiotic dispensations for fluoroquinolones were observed for the 3 selected conditions: uncomplicated UTIs (females only), acute exacerbations of COPD (patients aged ≥ 66 years only), and acute bacterial sinusitis.

• There were variations across provinces in the magnitude of the reductions in the rates of fluoroquinolone dispensations and the percentage of antibiotic dispensations that were fluoroquinolones

Documents

Report

Link to project page on CNODES website

Study publications

Impact of risk mitigation measures on oral fluoroquinolone prescribing: a multi...

Data management

ENCePP Seal

The use of the ENCePP Seal has been discontinued since February 2025. The ENCePP Seal fields are retained in the display mode for transparency but are no longer maintained.

Data sources

Data source(s), other

Provincial administrative health databases Canada

Data sources (types)

Administrative healthcare records (e.g., claims)

Use of a Common Data Model (CDM)

CDM mapping

No

Data quality specifications

Check conformance

Unknown

Check completeness

Unknown

Check stability

Unknown

Check logical consistency

Unknown

Data characterisation

Data characterisation conducted

No