



Use of systemic fluoroquinolones in primary care and hospital settings in the UK: a population-level cohort study

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Background

- Fluoroquinolone antibiotics have been approved and widely used for decades
- Recently, they have been related to rare but severe adverse events
- This led to the MHRA issuing Risk Minimisation Measures (RMMs) in 2019
 - Avoid use for self-limiting, mild to moderate infections
 - Avoid use in patients with previous adverse reactions to quinolones or fluoroquinolones
 - Prescribe with special caution for patients aged ≥ 60 , patients with renal impairment or solid-organ transplant
 - Avoid concomitant use with corticosteroid

Fluoroquinolone antibiotics: new restrictions and precautions for use due to very rare reports of disabling and potentially long-lasting or irreversible side effects

Disabling, long-lasting or potentially irreversible adverse reactions affecting musculoskeletal and nervous systems have been reported very rarely with fluoroquinolone antibiotics. Fluoroquinolone treatment should be discontinued at the first signs of a serious adverse reaction, including tendon pain or inflammation.

From: [Medicines and Healthcare products Regulatory Agency](#)

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Study objectives

The study aimed to assess the impact of the RMMs by:

1. Monitoring the incidence rates (IRs) of fluoroquinolone use for the period 2012-2022.
2. Describing the patient characteristics and indications of use before and after the publication of RMMs.



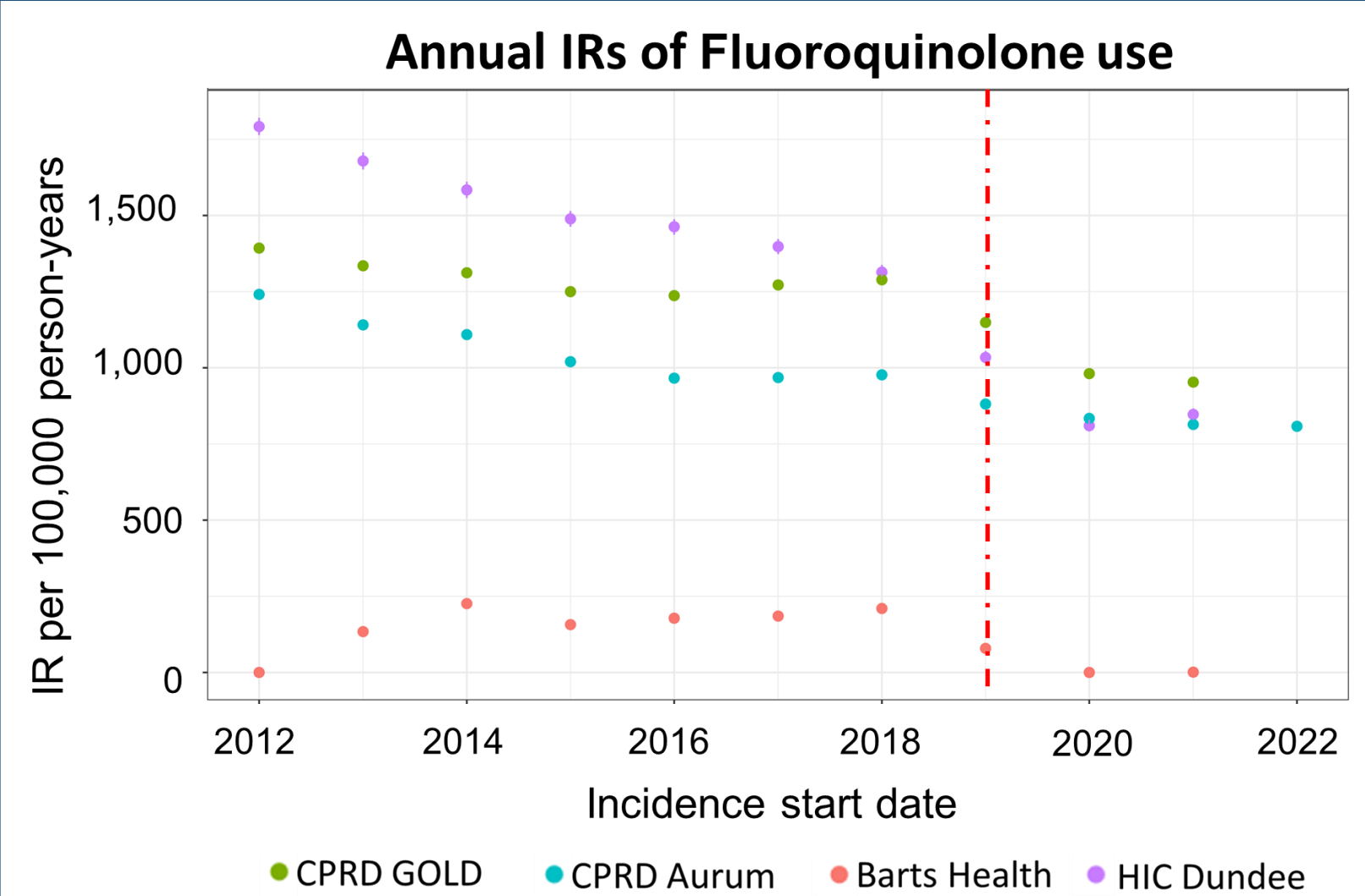
Methods

- Data sources
 - Primary care: CPRD GOLD, CPRD AURUM
 - Secondary care: Barts Health, Lancashire Teaching Hospital (LTHR)
 - Primary and secondary care: HIC Dundee
- Study population
 - All adults included in any database between 2012 to 2022
 - At least 30 days of previous database visibility
- Index date
 - Date of first fluoroquinolone use with no prior use in previous 30 days
- Statistical analysis
 - Annual incidence rates (IRs) of fluoroquinolone use per 100,000 person-years
 - Compare IRs before vs. after RMM, stratified by age 18-59 vs. ≥ 60 years
 - New user characterisation
 - Potential indications: conditions recorded 7 days prior to index date



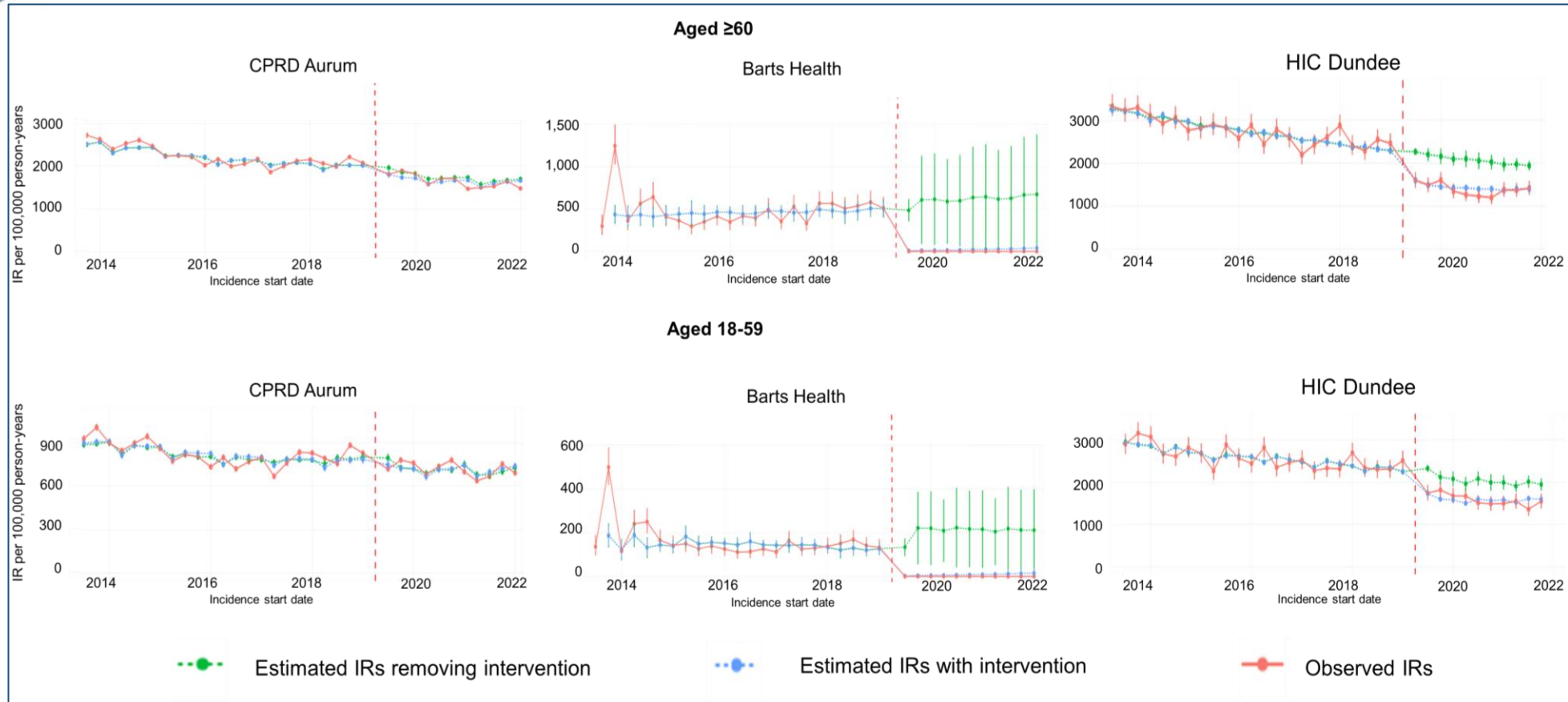


Results – IRs before vs. after 2019





Results – Segmented regression analysis



Significant step changes after RMMs in CPRD Aurum, Barts Health and HIC Dundee



Results – New users characteristics

	Before RMM					After RMM				
	CPRD GOLD	CPRD Aurum	Barts Health	LTHTR	HIC Dundee	CPRD GOLD	CPRD Aurum	Barts Health	LTHTR	HIC Dundee
Total numbers										
Subjects (N)	324,570	726,249	6,878	113	56,683	80,670	391,454	176	2,186	15,393
Fluoroquinolone records (N)	496,192	1,091,008	8,500	120	92,778	110,491	530,098	180	2,407	20,962
Characteristics										
Age (median [IQR])	59 [42, 73]	59 [41, 74]	57 [37, 71]	64 [49.5, 74]	58 [41, 72]	57 [38, 72]	56 [36, 72]	57 [37.5, 69]	71 [55, 80]	57 [39, 71]
Antibiotics use 30 days prior (n (%))	170,597 (34.4%)	355,258 (32.6%)	2,485 (29.2%)	NA	NA	35,032 (31.7%)	157,557 (29.7%)	43 (23.8%)	NA	NA
Chronic kidney disease diagnosis (n (%))	62,950 (12.7%)	137,142 (12.6%)	1,582 (18.6%)	NA	NA	10,498 (9.5%)	53,802 (10.1%)	50 (27.8%)	NA	NA
Prior glucocorticoid use (n (%))	84,817 (17.1%)	184,495 (16.9%)	0 (0)	NA	NA	15,803 (14.3%)	72,250 (13.6%)	0 (0)	NA	NA
Indications										
Respiratory infection (n (%))	30,211 (6.4%)	72,327 (7.0%)	2,035 (26.3%)	29 (24.4%)	201 (0.2%)	2,482 (2.4%)	21,076 (4.3%)	39 (23.8%)	857 (35.8%)	33 (0.2%)
Urinary tract infection (n (%))	45,041 (9.5%)	185,072 (17.9%)	1,370 (17.7%)	8 (6.7%)	67 (0.1%)	5,995 (5.8%)	67,961 (13.9%)	30 (18.3%)	77 (3.2%)	10 (0.1%)



Conclusion

- Results suggest that RMMs introduction contributed to lower Fluoroquinolone prescriptions
- A third of new users received different antibiotic the immediate time before fluoroquinolone prescription -> “second-line” use
- Proportion of prescriptions for UTIs and respiratory tract infections decreased after RMMs relative to the time before



Press release

MHRA introduces new restrictions for fluoroquinolone antibiotics

Following a review of the effectiveness of current measures to reduce the risk of potentially long-term or irreversible side effects associated with fluoroquinolone antibiotics, the MHRA has introduced further restrictions to limit their use.

From: [Medicines and Healthcare products Regulatory Agency](#)

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