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Communication

The Decline of Fluoroquinolones Use in Clinics: 2015–2024 Data from an Italian Tertiary-Care Hospital

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Abstract: This study examines the trends in fluoroquinolone use in a tertiary-care hospital in Italy from 2015 to 2024, with a focus on the impact of European Medicines Agency (EMA) regulatory measures introduced in 2019. Analysing antimicrobial consumption data, the research found a significant overall reduction of 58% in fluoroquinolone use over the decade, with a marked decline of approximately 54.5% between 2019 and 2024 following EMA warnings and restrictions. Linear regression analysis demonstrated a strong downward trend in prescribing, likely influenced by hospital-level interventions such as personalized prescription protocols and electronic prescribing tools. Additionally, resistance rates among key pathogens, including *E. coli* and *K. pneumoniae*, decreased significantly during this period. These findings suggest that regulatory actions, combined with targeted hospital strategies, effectively reduced fluoroquinolone consumption, potentially contributing to improved antimicrobial stewardship and resistance patterns. Further research is warranted to assess how the observed decline in fluoroquinolone use translates to patient outcomes and whether replacement therapies are being used judiciously.

Keywords: quinolones; antimicrobial consumption; fluoroquinolones; regulatory interventions; EMA; European medicines agency; hospital prescribing trends

1. Introduction

Fluoroquinolones belong to a class of broad-spectrum antibiotics extensively used in both outpatient and inpatient settings, particularly valued for their potent bactericidal activity, high tissue penetration, and oral bioavailability. In hospital environments, fluoroquinolones have played a significant role in the treatment of severe infections such as hospital-acquired pneumonia, complicated urinary tract infections, intra-abdominal infections, and as prophylaxis in immunocompromised patients [1].

However, over the past decade, increasing concerns have emerged regarding the safety profile of these antibiotics. Reports of serious, disabling, and potentially irreversible adverse effects—such as tendonitis and tendon rupture, peripheral neuropathy, and central nervous system disturbances—have prompted regulatory agencies to re-evaluate their benefit-risk balance [2]. In 2018, the European Medicines Agency (EMA), through its Pharmacovigilance Risk Assessment Committee (PRAC), concluded a major safety review, conducted under Article 31 of Directive 2001/83/EC, which led to the suspension of several quinolones and the restriction of fluoroquinolone use [3]. These recommendations were officially adopted and implemented across EU member states starting in 2019.

In 2023, a second EMA communication reiterated the importance of adhering to these guidelines and emphasized the need for national health authorities to monitor prescribing behaviour and ensure compliance. These

communications were particularly relevant for hospital settings, where empirical and broad-spectrum antibiotic use is common but must be carefully justified considering evolving safety data [4].

Despite these regulatory efforts, real-world evidence suggests that their impact may have been limited, at least in the primary care setting. A recent multicentre retrospective study analysing prescribing trends in six European countries in primary care found that although fluoroquinolone use declined modestly, these reductions were inconsistent across regions and not clearly attributable to the EMA interventions. Moreover, the study did not find substantial changes in early discontinuation rates or the use of alternative antibiotics following the 2019 label changes [5].

Italian most recent consumption data (2023) showed a decrease of fluoroquinolones consumption. In the outpatient setting, their use declined by 1%, representing 9.7% of total antibiotic consumption—still above the European average of 6.9%. In hospital setting, fluoroquinolones consumption dropped by 26% compared to 2019, moving towards the national target (PNCAR 2022–2025) of a 10% reduction by 2025 [6].

Moreover, data from the EARS-Net surveillance in Italy highlight some noteworthy changes in fluoroquinolones resistance between 2019 and 2023. For *Escherichia coli*, the proportion of invasive isolates resistant to fluoroquinolones dropped from 40.6% in 2019 to 34.1% in 2023. A similar trend was observed for *Klebsiella pneumoniae*, with resistance decreasing from 54.7% to 50.1% over the same period. In the case of *Pseudomonas aeruginosa*, resistance levels declined from 21.7% in 2019 to 16.0% in 2023. Also, *Acinetobacter* spp. showed a reduction, albeit more modest, going from 82.5% to 76.9%. All these trends were statistically significant [7].

To assess the effectiveness of the EMA's regulatory measures in real-world settings, up-to-date data are essential. Currently, updated 2024 data on antimicrobial consumption and resistance in Italy have yet to be released.

This report focuses on fluoroquinolone use in a public tertiary hospital in Italy, analysing prescribing patterns from 2015 to 2024, with projection for 2025 where applicable. It aims to evaluate the influence of the EMA's 2019 regulatory interventions on local prescribing behaviour in inpatient care.

2. Materials and Methods

We retrospectively reviewed data on Antimicrobial Consumption (AMC) from a tertiary-care University Hospital in Italy, with 600 beds and approximately 27,000 admissions per year, during the study period from January 2015 to December 2024.

The consumption of Fluoroquinolones (ATC J01MA) and expenditure dataset covering 2015–2024, with projection for 2025 where applicable. It was extrapolated from IT management system (AMC Areas®). The exposure index to antibiotics was expressed in line with WHO methodology in DDD/100 Patient-Days (DGDs) [8]. All molecules (levofloxacin, moxifloxacin, and ciprofloxacin) are subject to a justified and personalized physician prescription (RMP), with the aim of improving prescribing appropriateness. Descriptive analysis of the data was carried out using median values, with interquartile range for quantitative variables and percentage values for qualitative ones. Normality of variables was assessed using the Shapiro-Wilk test, and values of skewness and kurtosis were compared to their standard error. Changes in the DGDs during the 2019–2024 period were calculated as percentages and assessed through linear regressions following the same method as reported in ECDC reports [7]. We performed linear regression to identify trends in fluoroquinolone consumption. A p-value of <0.05 was considered statistically significant. All analyses were performed using the SPSS statistical software [9].

3. Results and Discussion

The analysis revealed a significant decline in fluoroquinolones consumption at the studied tertiary-care hospital over the period from 2015 to 2024. Total quinolone use decreased from 13.41 DGDs in 2015 to 5.63 DGDs in 2024, representing a 58.02% reduction (Table 1).

Focusing on the period between 2019 and 2024, following EMA's warning on fluoroquinolone use, a pronounced decrease in quinolone consumption was observed. Ciprofloxacin usage declined from 3.16 to 1.27 DGDs, a 59.8% reduction, while levofloxacin decreased from 9.18 to 4.33 DGDs, marking a 52.8% reduction. The overall fluoroquinolones consumption dropped from 12.37 to 5.63 DGDs, amounting to a 54.5% decrease during this period.

Statistical analysis using linear regression demonstrated a strong negative correlation in fluoroquinolones consumption from 2019 to 2024 [$y = 2027.544 - 0.710(x)$; $r = -0.981$; $p = 0.001$], indicating a highly significant downward trend, with a forecast for 2025 projecting a consumption level of 3.58 DGD (Figure 1). This suggests that the EMA's regulatory interventions, including the suspension (cinoxacin, flumequine, nalidixic acid, and pipemidic acid) and restriction of other fluoroquinolones due to safety concerns, could have had a substantial

impact on prescribing practices within the hospital. In our hospital setting, during the reference period (2019–2014), we collected one report of an adverse drug reaction (ADR). In the previous available period (2012–2018), six reports were collected. The reactions were mainly allergic in nature: lip edema, skin rashes, and urticaria.

The findings align with broader Italian trends, where regulatory actions have led to reductions in fluoroquinolone prescribing [6]. However, the extent of the decline observed in this hospital setting appears more pronounced, potentially reflecting effective local implementation of personalized physician prescription (RMPs) and heightened awareness among prescribers regarding the risks associated with fluoroquinolone use. The implementation of Electronic Personalised Prescription Software within our institution may have contributed to supporting clinicians and pharmacists in facilitating this reduction, by improving prescription accuracy, reducing therapeutic errors, and fostering the adoption of evidence-based and updated clinical protocols in patient management [10]. These results suggest that the EMA's regulatory actions, combined with hospital-level interventions such as RMPs, may have played a crucial role in influencing prescribing behaviour. The decline in fluoroquinolone use in the hospital setting is consistent with findings from other studies in Europe, where similar reductions were observed in response to regulatory measures [5]. To date, no studies or analyses have been published in the literature that report updated data from 2024. However, while the decrease in fluoroquinolones consumption is encouraging, it remains necessary due to the current antimicrobial resistance rates among key pathogens, including in WHO bacterical pathogens priority list *S. typhi* fluoroquinolones-resistant (FR), *Shigella* spp. FR, Non-typhoidal *Salmonella* spp. FR, *N. gonorrhoeae* FR and other with high level of resistance in Italy like *E. coli, K. pneumoniae* and *P. aeruginosa*, which increasingly limit the therapeutic efficacy of this antibiotic class. As a result, current clinical guidelines recommend reserving fluoroquinolones for specific, high-need cases where alternative therapies are unsuitable or ineffective (WHO, bacterical priority list 2024, AWARE book WHO). Recently AIFA has launched an information campaign for patients and healthcare professionals on the serious adverse effects of fluoroquinolones. The agency deemed it necessary to launch an information campaign on their correct use and published a guide for healthcare professionals and one for patients [11]. Further studies are needed to evaluate whether these changes have translated into improved patient outcomes and contributed to reductions in antimicrobial resistance or whether alternative antibiotics are being over-prescribed as a result.

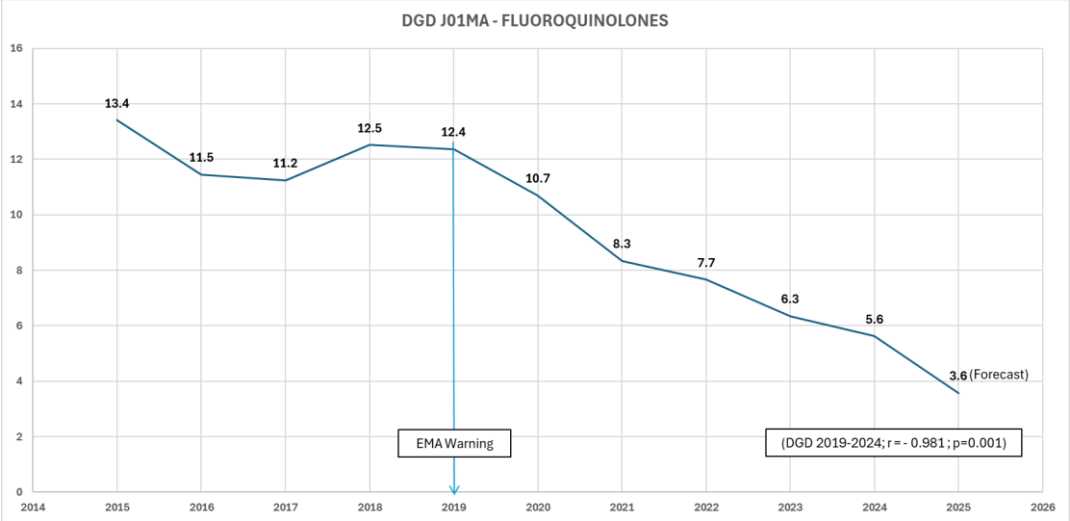

Figure 1. Fluoroquinolones consumption trend (DGDs) 2015 and 2024. Linear regression between 2019 (EMA Warning) and 2024 was significative with a forecast 2025 consumption at 3.6 DGDs.

Table 1. Floroquinolone consumption trends (DGDs) data 2015–2024.

ANTIMICROBIAL	ATC	AWARE [1]	RMP [2]	2015	2016	2017	2018	2019	2020	2021	2022	2023	2024	Δ2019–2024	r	*p* Value *
CIPROFLOXACIN	J01MA02	W	Yes	4.80	3.89	3.41	3.90	3.16	2.73	1.95	2.08	1.77	1.27	−1.89		
LEVOFLOXACIN	J01MA12	W	Yes	8.57	7.54	7.84	8.58	9.18	7.95	6.35	5.53	4.52	4.33	−4.85		
MOXIFLOXACIN	J01MA14	W	Yes	0.04	0.030	0.00	0.04	0.02	0.01	0.04	0.05	0.06	0.03	0.00		
FLUOROQUINOLONES-CLASS	J01MA	W	Yes	13.41	11.46	11.25	12.52	12.37	10.70	8.34	7.66	6.35	5.63	−6.74	−0.981	0.001

* Linear Regression on 2019–2024 DGD data; [1] WHO-AWARE Classification; [2] Personalized Physician prescription.

Author Contributions

G.B.: conceptualization, methodology, software; M.R.: data curation, writing—original draft preparation; S.V.: visualization, investigation; A.C.: supervision; M.R: software, validation; M.R., V.M., R.F.M. and S.V.: writing—reviewing and editing. All authors have read and agreed to the published version of the manuscript.

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Institutional Review Board Statement

This article does not contain any studies with animals performed by any of the author.

Informed Consent Statement

Patient consent was waived due to the retrospective design of the study, which involved the analysis of aggregated antibiotic consumption data and did not include any identifiable or individual patient information.

Data Availability Statement

We advocate for the sharing of research data by all authors contributing to publications in Scilight journals. In this section, authors may be asked to provide the raw data of their study together with the manuscript for editorial review and should be prepared to make the data publicly available if practicable. In any event, authors should ensure accessibility of such data to other competent professionals for at least 10 years after publication (preferably via an institutional or subject-based data repository or other data center), provided that the confidentiality of the participants can be protected and legal rights concerning proprietary data do not preclude their release. In instances where novel data were not generated or data remains inaccessible due to privacy or ethical considerations, a clear statement outlining these circumstances is mandatory.

Conflicts of Interest

The authors declare no conflict of interest.

Use of AI and AI-Assisted Technologies

No AI tools were utilized for this paper.

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