Update on Fluoroquinolone (FQ) Warnings

The Medicines and Healthcare Regulatory Agency (MHRA) has recently reissued advice on restriction of systemic and inhaled fluoroquinolones reminding prescribers of the risk of disabling and potentially long-lasting (up to months or years) or irreversible side effects. Despite new restrictions and precautions introduced in 2019 by MHRA a new study has shown no evidence of a change in FQ prescribing patterns in the UK, and the MHRA has continued to receive Yellow Card reports of these side effects. The FQs available in the UK are levofloxacin, ciprofloxacin, ofloxacin and moxifloxacin and in NHS Tayside all are RESTRICTED to use in certain specific infections. Prescribers should refer to recent warnings (below), the BNF and/or manufacturer’s information when prescribing FQs and take account of all cautions, contraindications and interactions as well as the patient’s medical history and reports of previous adverse drug reactions.

Patients should be given advice about potential serious adverse drug reactions and to stop treatment and seek advice at the first sign of any side effects involving muscles, joints, nerves or mental health. The MHRA states a PATIENT INFORMATION LEAFLET should be given to patients.

Musculoskeletal System
- Tendon damage (including rupture) has been reported rarely which may occur within 48 hours or the effects can be delayed for several months and become apparent after stopping FQ treatment
  - Risk is increased in people older than 60 years and those with renal impairment or solid-organ transplants
  - Avoid use of a corticosteroid with a FQ since coadministration could exacerbate FQ-induced tendinitis and tendon rupture
  - Use in patients with previous tendon disorders related to FQ use is contra-indicated
- Other adverse effects include muscle pain or weakness and joint pain or swelling

Aortic Aneurysm and Dissection and Heart Valve Regurgitation
- December 2020 MHRA alert states that quinolones have been associated with small increased risk of heart valve regurgitation and a 2018 MHRA alert states that patients, particularly older patients, taking FQs are at a small increased risk of aortic aneurysm and dissection. Please refer to alerts for full list of risk factors/predisposing conditions.
- Patients should be advised about the risk and told to seek immediate medical attention in the case of rapid onset of breathlessness or heart palpitations or sudden severe and constant pain in the abdomen, chest or back.

Nervous System
- FQs can induce convulsions (with or without a history of convulsions) and risk is increased when co-prescribed with NSAIDs
- The updated MHRA alert also reminds prescribers regarding the risk and potential irreversible adverse effects of neuropathies associated with parasthesia, anxiety, fatigue, memory impairment, sleep disorders, and changes in vision, taste, smell or hearing.
- A further MHRA alert in September 2023 was issued to further remind prescribers to be alert to the risk of psychiatric reactions, including depression and psychotic reactions, which may potentially lead to thoughts of suicide or suicide attempts and are reminded to advise patients to these risks.

Other Adverse Effects (for complete information refer to the BNF and/or manufacturer’s information)
- All FQs can prolong QT interval
  - In 2018, the FDA issued an additional warning that FQs can affect blood sugars

Recommendations:
- Follow NHS Tayside Antibiotic Guidance and limit prescribing of FQs to approved indications
- For all FQ prescribing consider recent warnings and all cautions, contraindications and interactions to determine whether risks outweigh benefits and advise patients re risks
- Report any side effects via Yellow Card Scheme

For further information or advice contact the Antimicrobial Management Team (AMT) on tay.antibioticpharm@nhs.scot

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