Note on Delafloxacin from HSE-Antimicrobial Resistance & Infection Control (AMRIC) Team

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For: Consultant Microbiologists, Infectious Disease Physicians, Antimicrobial Pharmacists

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Recommendation

Currently HSE-AMRIC consider that circumstances in which delafloxacin is preferred to established agents in the management of acute bacterial skin and skin structure infections (ABSSSI) in patients in Ireland are very rare.

Background

Delafloxacin is a fluoroquinolone antibiotic.

Delafloxacin is licensed in Ireland and is approved for reimbursement by the HSE for the treatment of ABSSSI in adults when it is considered inappropriate to use other antibacterial agents that are commonly recommended for the initial treatment of these infections.

The principal clinical evidence to support the use of delafloxacin in ABSSSI is from two phase 3 randomised controlled trials (Pullman *et al.* 2017, O'Riordan *et al.* 2018) which compared delafloxacin monotherapy to vancomycin plus aztreonam.

The general principle of ABSSSI management is to use a narrow spectrum penicillin with activity against *Staphylococcus aureus* as well as *Streptococcus pyogenes* whenever possible and a narrow spectrum cephalosporin as an alternative in people with a history of rash (but not anaphylaxis) related to penicillins. These are generally accepted as most effective, safest and least expensive approach to treatment. There are no clinical trials for delafloxacin using this standard treatment for ABSSSI as a comparator. Vancomycin plus aztreonam is not considered first or second line standard of care for this indication in Ireland.

In general, the requirement for a new fluoroquinolone antibiotic is unclear. It is worth noting fluoroquinolones have been associated with the post-marketing emergence of adverse events, leading to license restrictions and withdrawals in some cases.

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