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Expression of Concern

Title: Method and conclusion flaws using Yellow card data for adverse drug reactions

Smith AJ¹, Palmer NOA², Seaton RA³, Ternhag A⁴

- 1. Chair, Scottish Antimicrobial Prescribing Group Dental, University of Glasgow, Scotland, UK.
- 2. Clinical Adviser in Dental Education and Research Fellow, Health Education England-North West, Honorary Lecturer, University of Liverpool, England, UK
- 3. Consultant Infectious Disease Physician, Queen Elizabeth University Hospital, Glasgow, Scotland, UK and Chair of Scottish Antimicrobial Prescribing Group
- 4. Senior Consultant, Associate Professor, Department of Medicine Solna, Infectious Diseases Unit, Karolinska Institutet, Stockholm, Sweden.

Keywords

Antimicrobial resistance Antimicrobial stewardship Penicillin Amoxicillin Clindamycin Metronidazole The article (Thornhill 2019) suggest higher rates of adverse events associated with penicillin V compared to amoxicillin in dental practice. There are several methodological errors and associated misinterpretation of data derived from the National Yellow Card Drug Analysis Profile (Yellow Card MHRA 2019; Sophie Reeve, Personal Communication). To quote from MHRA;

"When using the Interactive Drug Analysis Profile, you should remember that:

- 1. The likelihood of experiencing an adverse drug reaction when taking a medicine cannot be estimated from the data in the Interactive Drug Analysis Profile....
- 2. The existence of an adverse drug reaction report in the Interactive Drug Analysis Profile does not necessarily mean that the medicine has caused the reaction.
- 3. It is not possible to compare the safety of different medicines by comparing the numbers presented in the Interactive Drug Analysis Profiles. Reporting rates can be influenced by many factors including the seriousness of the adverse drug reactions, their ease of recognition and the extent of use of a particular product. Reporting can also be stimulated by promotion and publicity about a product."

Furthermore, NHS digital data refers to NHS prescriptions in NHS practice in England only. The NHS digital prescribing data does not capture private prescriptions or from N Ireland, Wales or Scotland. The Yellowcard data is collated from all of the UK. In addition, it is inaccurate to state that private dental prescribing is insignificant. The number of patients receiving private treatment is estimated to be around 33% in the UK (Burke et al., 2015) Private provision has increased since 2015 and Denplan, a private dental insurance provider, has 6,500 dentist members covering nearly 2 million patients.

We recommend these study limitations are highlighted and that readers are made aware of the significant limitations in this manuscript.

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Author Palmer NOA: Contributed to conception, design, data acquisition and interpretation, performed all statistical analyses, and critically revised the manuscript

Author Seaton RA: Contributed to conception, design, data acquisition and interpretation, performed all statistical analyses, and critically revised the manuscript

Author Ternhag A: Contributed to conception, design, data acquisition and interpretation, performed all statistical analyses, and critically revised the manuscript

All authors gave their final approval and agree to be accountable for all aspects of the work.

Conflict of interest

There are no conflicts of interest from the authors

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