

4th International Conference and Exhibition on **Pharmacovigilance & Clinical Trials** August 10-12, 2015 London, UK

MedDRA SMQs: Physician ratings of important terms for diagnosis of cardiac failure and acute pancreatitis – A Delphi study

Michelle Perry

Aspen Pharmacare Trading Limited, Ireland

MedDRA (Medical Dictionary for Regulatory Activities) has improved analysis of data by using agreed terms for events, making it easier to share data for products used in many countries. Standardised MedDRA queries (SMQs), a “developed tool to assist in the retrieval of cases of interest”, can be used on clinical data that are coded with preferred terms (PTs) from a single MedDRA version. Each SMQ for a medical concept comes with medical references, inclusion and exclusion criteria and includes a list of terms from various System Organ Classes (SOCs). The use of SMQs was recommended in Guidelines Volume 9A, however the advantage of using SMQs remains unclear. Defining any medical concept is difficult; two SMQs for the medical concepts acute pancreatitis and cardiac failure were chosen for this Delphi study. The agreement between eleven health professionals when rating the importance of PTs in diagnosing these medical concepts was investigated. Attribute agreement analysis (AAA) showed the Delphi method provided slight to fair overall agreement for terms ranked as very important (Fleiss’ kappa statistic (FKS) values between 0.1-0.4) on the first review. This is unsurprising due to the large number of closely related terms they were asked to assess. There was complete agreement for these terms in the second review by four of the original reviewers (FKS 1.00, $p > 0.0001$ for cardiac failure terms, and 0.983, $p > 0.0001$ for acute pancreatitis terms). The results show the variation in rating of terms by physicians and the requirement for further investigation into the potential use of SMQs in pharmacovigilance.

Biography

Michelle Perry has completed her MPhil from the University of Portsmouth in collaboration with the Drug Safety Research Unit, Southampton. She also has a BSc (Hons) in Applied Pharmacology from Queen Margaret University, Edinburgh and is currently a Pharmacovigilance Associate at Aspen Pharmacare Trading Limited, based in Dublin, Ireland.

michelleperry@hotmail.co.uk

Notes: