

Use of a naloxone trigger tool and multidisciplinary causality assessment to identify and confirm opioid related adverse drug events

Gillian Cavell¹, Anish Gupta², Deepal Mandaliya¹, Clare Patten³, Lena Uddin⁴

¹Medication Safety Pharmacists, ²Consultant Anaesthetist, ³Lead Nurse-Pain Relief Unit, ⁴Pharmacy Student
King's College Hospital NHS Foundation Trust and Kings College, London

Introduction

- An adverse drug event (ADE) is a potentially harmful and unintended outcome of medicines use
- Naloxone is used to reverse opioid toxicity so is a useful indicator of potential opioid related ADEs
- In the UK, ADE trigger tools have been advocated for detecting ADEs associated with high risk drugs including opioids
- We aimed to measure the sensitivity of naloxone as a 'trigger' to detect opioid related ADEs in adult inpatients in a large acute teaching hospital by applying a causality assessment tool to multidisciplinary retrospective case note review.

Objectives

- To confirm opioid related ADEs identified from the administration of naloxone and calculate the positive predictive value (PPV) of the naloxone trigger
- To identify common drug/dose regimens associated with opioid related ADEs

Method

- Medication Safety pharmacists at King's College Hospital are sent a daily 'trigger report' listing adult inpatients who have been prescribed and administered trigger drugs on our electronic prescribing and medicines administration system (EPMA)
- Case note review forms are completed for each adult patient administered naloxone as listed on the 'trigger reports'
- Case note review forms completed between October 2014-September 2015 were included in the study. Naloxone doses administered in Accident & Emergency, paediatrics and critical care units were excluded
- Each form was reviewed by a multidisciplinary panel who applied the World Health Organisation Uppsala Monitoring Centre Causality Assessment System (WHO-UMC CAS)¹ to confirm opioid ADEs
- Confirmed ADEs were then assigned a severity of harm rating according to the National Coordinating Council for Medication Error Reporting and Prevention (NCC MERP) Index²
- Positive predictive value for naloxone as a trigger event for opioid ADEs was calculated
- Ethics approval was not required for the study

Results 1

Table 1. Results of multidisciplinary case note review

Number of naloxone trigger events				142
Number of events excluded				17
Number of events categorised using the WHO-UMC scale				125
Number of unconfirmed ADEs				34
	Unlikely	Conditional	Unassessable	
	8	1	25	
Number of confirmed ADEs				91
	Certain	Probable	Possible	
	54	13	24	
NCCMERP Index harm rating				91
	Category E		Category F	
	90		1	

Results 2

- The Positive Predictive Value (PPV) for naloxone was calculated to be 72.8%
- $PPV\% = \frac{\text{Number of true ADRs detected by naloxone}}{\text{number of true ADRs} + \text{number of false positive ADEs}}$

Results 3

- Morphine sulphate accounted for 55/91 (60.4%) of confirmed ADEs
- Commonly associated regimens included IV morphine infusions in cardiac recovery (n=9) and post-operative patient-controlled analgesia following hepatic and orthopaedic surgery (n=25)

Discussion and conclusion

- We effectively used the WHO-UMC CAS tool and a multidisciplinary team approach to reduce subjectivity and guide discussions in confirming ADE causality
- Using the criteria listed within the tool ensured a more robust and consistent approach to confirming ADEs and determining the PPV compared to single reviewer assessment
- 90 out of 91 confirmed ADE cases (98.9%) were categorised as category E, and 1 as Category F. Category E ADEs are defined as ADEs that 'may have contributed to or resulted in temporary harm to the patient and required intervention'²
- Incomplete documentation in the clinical notes was a limitation
- Although time-consuming our methodology is generalizable and could be utilised in other organisations as a gold standard for confirming opioid ADEs

References

1. The Uppsala Monitoring Centre. The use of the WHO-UMC system for standardized case causality assessment. 2012. Available at <http://www.who-umc.org/Graphics/26649.pdf> Accessed 15th July 2016.
2. National Coordinating Council for medication Error reporting and Prevention. NCC MERP Index for categorising medication errors. 2001. Available at <http://www.nccmerp.org/sites/default/files/indexColor2001-06-12.pdf> Accessed 28th November 2016

Conflicts of Interest

None to declare

Abstract DI-024
ATC code N02 -
Analgesics