Observatory
25/5/2016
Observatory of recent safe medication practice research, reports, and publications

Presented by Tiffany Barrett
Senior MI Pharmacist, South West Medicines Information and Training
tiffany.barrett@uhbristol.nhs.uk
NICE Medicines Evidence Commentary: Adverse effects associated with off-label medicine use in adults

A large Canadian observational study in people prescribed new medicines found that using medicines for an off-label indication is associated with an increased risk of treatment discontinuation due to adverse drug events, particularly when strong scientific evidence is lacking. This study reinforces the importance of continuing to follow the GMC prescribing guidance and MHRA advice on unlicensed or off-label medicines, and the NICE medicines optimisation guidance which recommends shared decision making in relation to medicines.

NICE News and Features

Renewed call to tackle antimicrobial resistance comes as NICE quality standard [QS121] “Antimicrobial Stewardship” is published. Despite the warnings about antimicrobial resistance, recent figures show that use of antibiotics in the UK is increasing. Between 2010 and 2014 prescriptions rose in both primary and secondary care, the sharpest rise of which was in hospitals. Consumption in general practice increased by 6.2% and prescribing in hospital inpatients climbed by 11.7%. 

"UKMi"
Recent regulator and statutory body activity

**Drug Safety Update – May 2016**

BCR-ABL tyrosine kinase inhibitors: risk of hepatitis B reactivation

Pomalidomide (Imnovid▼): risk of hepatitis B reactivation

Idelalisib (Zydelig▼): interim measures following signal of serious infection and deaths related to infection found in clinical trials

Letters sent to healthcare professionals in April 2016
Drug Alerts

Crestor 5mg Tablets Parallel Imported by BR Lewis Pharmaceuticals Ltd (Originator name Provisacor) – rogue blister and carton

Aventis Pharma Limited trading as Sanofi Rifadin 600mg Infusion

Medical Device Alert

Accu-Chek® Insight insulin pump system, manufactured by Roche Diabetes Care – risk of inappropriate treatment
Pharmacovigilance Risk Assessment Committee (PRAC)

Nothing new from PRAC in May 2016

European Medicines Agency

Accessing key EMA information on human medicines

- A guide, released today by the European Medicines Agency (EMA), describes information the Agency publishes on centrally and non-centrally authorised medicines for human use.
- Providing an overview of the range of documents produced by EMA during the life span of a medicine, the guide covers early development, through initial evaluation, adoption of positive or negative opinions, post-authorisation changes and safety reviews.
- Details of types of EMA documents, their publication times and where to find them on the EMA’s website are listed in an easy-reference annex.
- Stakeholders will also find best-practice advice enabling coordinated, consistent and timely communication activities to ensure that information on medicines is accurate and reaches interested parties in the EU (European Union) on time.
Recent regulator and statutory body activity

**FDA Drug Safety and availability:**
FDA advises health care professionals that counterfeit BiCNU has been discovered in some foreign countries

**FDA Drug Safety Communications:**
FDA warns about new impulse-control problems associated with mental health drug aripiprazole (Abilify, Abilify Maintena, Aristada)

FDA warns about rare but serious skin reactions with mental health drug olanzapine (Zyprexa, Zyprexa Zydis, Zyprexa Relprevv, and Symbyax)

FDA advises restricting fluoroquinolone antibiotic use for certain uncomplicated infections; warns about disabling side effects that can occur together

Interim clinical trial results find increased risk of leg and foot amputations, mostly affecting the toes, with the diabetes medicine canagliflozin (Invokana, Invokamet); FDA to investigate

FDA warns that prescribing of ketoconazole oral tablets for unapproved uses including skin and nail infections continues; linked to patient death
Recent regulator and statutory body activity

Patient safety alert

- **Failure to recognise acute coronary syndromes in Kawasaki disease patients**
- Published on: 11 May 2016
- A stage one warning has been issued around the risk of death and serious harm from failure to recognise acute coronary syndromes in Kawasaki disease patients.
Product Safety reviews

Continue to use the UKMI website

Product Safety Assessments –
This month’s papers - overview

*Bundle interventions used to reduce prescribing and administration errors in hospitalized children: a systematic review
Bannan DF, Tully MP
Journal of Clinical Pharmacy and Therapeutics Jun 2016;41(3):246-255

A systematic review of the prevalence and incidence of prescribing errors with high-risk medicines in hospitals
Alanazi MA, Tully MP, Lewis PJ
Journal of Clinical Pharmacy and Therapeutics Jun 2016;41(3):239-245

Cognitive tests predict real-world errors: the relationship between drug name confusion rates in laboratory-based memory and perception tests and corresponding error rates in large pharmacy chains
Schroeder SR et al
BMJ Quality and Safety 2016;doi: 10.1136/bmjqs-2015-005099 (published early online 18 May 2016)
http://qualitysafety.bmj.com/content/early/2016/05/17/bmjqs-2015-005099.full.pdf+html

Incidence and treatment costs attributable to medication errors in hospitalized patients
Choi I et al

*Exploring attitudes and opinions of pharmacists toward delivering prescribing error feedback: a qualitative case study using focus group interviews
Lloyd M et al
Research in Social and Administrative Pharmacy May-Jun 2016;12(3):461-474
This month’s papers - overview

Vaccination errors in general practice: creation of a preventive checklist based on a multimodal analysis of declared errors
Charles R et al
Family Practice 2016; doi: 10.1093/fampra/cmw026 (published early online 3 May 2016)
http://fampra.oxfordjournals.org/content/early/2016/05/02/fampra.cmw026.abstract

Systematic review of errors in inhaler use: has patient technique improved over time?
Sanchis J, Gich I, Pedersen S
Chest 2016; doi: 10.1016/j.chest.2016.03.041 (published early online Apr 2016)

Workarounds to hospital electronic prescribing systems: a qualitative study in English hospitals
Cresswell KM et al
http://qualitysafety.bmj.com/content/early/2016/04/29/bmjqs-2015-005149

Digital Health and Patient Safety
Agboola SO, Bates DW, Kvedar JC
Journal of the American Medical Association 2016; 315 (16): 1697-1609

Analysis of Prescribers’ Notes in Electronic Prescriptions in Ambulatory Practice
Dhavle AA et al
JAMA Internal Medicine 2016; 176(4): 471-2

Pharmacovigilance is…. Vigilance
Edwards R and Bencheikh RS
Drug Safety 2016 29:281-285
This month’s papers - details

Bundle interventions used to reduce prescribing and administration errors in hospitalized children: a systematic review
Bannan DF, Tully MP
Journal of Clinical Pharmacy and Therapeutics Jun 2016;41(3):246-255

- The authors sought to describe and categorise the bundle interventions that are used to reduce prescribing errors and administration errors in hospitalised children and to assess the quality of the literature
- 17 studies met the inclusion criteria
- Interventions included environmental restructuring (17/17), education (16/17), persuasion (4/17), training (3/17), restriction (3/17), incentivisation (1/17), coercion (1/17), modelling (1/17) and enablement (1/17)
- This novel analysis in a systematic review showed that bundle interventions delivering 2 or more intervention functions have been investigated but that the study quality was too poor to assess impact.
Exploring attitudes and opinions of pharmacists toward delivering prescribing error feedback: a qualitative case study using focus group interviews
Lloyd M et al
Research in Social and Administrative Pharmacy May-Jun 2016;12(3):461-474

Objectives: To explore the attitudes and views of hospital pharmacists in delivering feedback on PEs to prescribers.

Methods: Twenty-four pharmacists were recruited for one of four focus groups in a large district general hospital in the Northwest of England to explore the views of pharmacists to delivering feedback on PEs. Focus groups were transcribed verbatim and analyzed using a thematic framework approach to identify current practices, beliefs and attitudes of pharmacists toward delivering PE feedback. Transcripts were independently analyzed by the research team.
Results: Pharmacists’ views on providing feedback on PEs were organized into eight major themes; Delivery of feedback, impact of feedback, prescription error, work environment, feedback facilitator, working relationships, education and training, and system improvements. Pharmacists recognized that timely feedback on PEs was essential for prescribers to learn from their mistakes and to reduce PEs. However, delivery of feedback appeared to be inconsistent, influenced by time pressures, workload, rapport and PE severity and prescriber availability. Pharmacists reported that ward-based pharmacists in particular, were suitable to facilitate PE feedback, but expressed concern that the process may adversely affect prescriber-pharmacist rapport. Pharmacists reported limited training on delivery of feedback with formalized training required for improved consistency, and quality, of constructive feedback.