Observatory
27/4/2016
Observatory of recent safe medication practice research, reports, and publications

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NICE guidelines
Controlled Drugs: safe use and management. NICE guidelines [NG46]
Publication date: April 2016
https://www.nice.org.uk/guidance/NG46

NICE Eyes on the Evidence – Expert commentary on important new evidence.
Prescribing safety in UK general practice
An expert commentary is provided of an observational, cross-sectional study of patients from 526 UK general practices which found high variation between practices in the prevalence of potentially high-risk prescribing and in the provision of monitoring tests.
MHRA  Recent regulator and statutory body activity

Drug Safety Update – April 2016

SGLT2 inhibitors: updated advice on the risk of diabetic ketoacidosis

Natalizumab (Tysabri▼): progressive multifocal leukoencephalopathy—updated advice to support early detection

Dimethyl fumarate (Tecfidera): updated advice on risk of progressive multifocal leukoencephalopathy

Fingolimod (Gilenya▼): risks of progressive multifocal leukoencephalopathy, basal-cell carcinoma, and opportunistic infections
Apomorphine with domperidone: minimising risk of cardiac side effects

Afiblercept (Zaltrap▼): minimising the risk of osteonecrosis of the jaw

Live attenuated vaccines: avoid use in those who are clinically immunosuppressed

Paraffin-based skin emollients on dressings or clothing: fire risk
Drug Alert – Company led
Taxotere (Docetaxel) Concentrate for Solution for Infusion, 80mg per 4ml
EU/1/95/002/004 (CLDA (16)A/02)
Sanofi are recalling the listed batches of Taxotere (Docetaxel) Concentrate due
to a production fault potentially leading to an increase in the concentration of
Docetaxel in the solution.
https://www.gov.uk/drug-device-alerts/taxotere-docetaxel-concentrate-for-solution-for-infusion-80mg-per-4ml-eu-1-95-002-004-clda-16-a-02

Medical Device Alert
Manufactured by Siemens Healthcare Diagnostics Inc. / Siemens Healthcare
Diagnostics Ltd and Roche Diagnostics GmbH- assay interference from the drug
fulvestrant (Faslodex®) may cause falsely elevated estradiol results. Both
Siemens and Roche have issued field safety notices (FSNs) highlighting this
issue. Estradiol assays from other manufacturers may also be affected by
fulvestrant (Faslodex®) interference and this is currently under investigation
(MDA/2016/004).
Pharmacovigilance Risk Assessment Committee (PRAC)

EMA’s PRAC initiates review of diabetes medicine canagliflozin.

The European Medicines Agency (EMA) has started a review of the diabetes medicine canagliflozin after an increase in amputations, mostly affecting toes, was observed in an ongoing clinical trial called CANVAS.


EMA reviews direct-acting antivirals for hepatitis C

On 17 March 2016, the European Medicines Agency (EMA) started a review of medicines known as direct-acting antivirals used for treating chronic (long-term) hepatitis C (an infectious disease that affects the liver, caused by the hepatitis C virus).


The CMDh has endorsed by consensus the revocation of marketing authorisations for fusafungine sprays in the EU. This follows a review by EMA’s Pharmacovigilance Risk Assessment Committee (PRAC) which concluded that the benefits of fusafungine do not outweigh its risks, particularly the risk of serious allergic reactions.

Recent regulator and statutory body activity

FDA Drug Safety Communication:
FDA revises warnings regarding use of the diabetes medicine metformin in certain patients with reduced kidney function

http://www.fda.gov/Drugs/DrugSafety/ucm493244.htm

FDA Drug Safety Communication:
FDA adds warnings about heart failure risk to labels of type 2 diabetes medicines containing saxagliptin and alogliptin

http://www.fda.gov/Drugs/DrugSafety/ucm486096.htm
QuarterWatch Latest Edition (April 7, 2016)

- Reports of cancer associated with products used to treat psoriasis, particularly potent immunosuppressants
- New evidence that drugs for erectile dysfunction and pulmonary hypertension can cause sudden hearing loss
Product Safety reviews

Watch this space!!

New website coming soon – Specialist Pharmacy Services
This month’s papers - overview

A cross-sectional observational study of high override rates of drug allergy alerts in inpatient and outpatient settings, and opportunities for improvement
Slight SP, Beeler PE, Seger DL et al
*BMJ Qual Saf* doi:10.1136/bmjqs-2015-004851
http://qualitysafety.bmj.com/content/early/2016/03/18/bmjqs-2015-004851

Impact of Stewardship Interventions on Antiretroviral Medication Errors in an Urban Medical Center: A 3-Year, Multiphase Study
Zucker J, Muttal J, Jen SP et al

Evaluation of frequency of paediatric oral liquid medication dosing errors by caregivers: amoxicillin and josamycin
Berthe-Aucejo A, Girard D, Lorrot M et al
http://adc.bmj.com/content/101/4/359.abstract

Safety risks associated with the lack of integration and interfacing of hospital health information technologies: a qualitative study of hospital electronic prescribing systems in England
Cresswell KM, Mozaffar H, Lee L et al
*BMJ Qual Saf* doi:10.1136/bmjqs-2015-004925
http://qualitysafety.bmj.com/content/early/2016/04/01/bmjqs-2015-004925
Improving feedback on junior doctors’ prescribing errors: mixed-methods evaluation of a quality improvement project

Reynolds M, Jheeta S, Benn J et al

BMJ Quality & Safety Online First, published on 4 April 2016 as 10.1136/bmjqs-2015-004717
http://qualitysafety.bmj.com/content/early/2016/04/04/bmjqs-2015-004717.full.pdf+html

Developing consensus on hospital prescribing indicators of potential harm for infants and children

A Fox, S Pontefract, D Brown, J Portlock, J Coleman

British Journal of Clinical Pharmacology 2016; doi: 10.1111/bcp.12954 (published early online 1 Apr 2016)

Reducing paediatric medication error through quality improvement networks; where evidence meets pragmatism

Cass H

Archives of Disease in Childhood May 2016; 101(5):414-416
http://adc.bmj.com/content/101/5/414.extract

'Smart' intravenous pumps: how smart are they?

Dean Franklin B

BMJ Quality and Safety 2016; doi: 10.1136/bmjqs-2016-005302 (published early online 7 Apr 2016)
http://qualitysafety.bmj.com/content/early/2016/04/07/bmjqs-2016-005302

Double checking: a second look

Hewitt T, Chreim S and Forster A

Double checking: a second look
Hewitt T, Chreim S and Forster A

Aims and objectives
• To consider how front line practitioners conceptualise double checking,
• To consider the weaknesses of double checking
• To consider what alternate views of double checking would render it a more robust process

Method
• A qualitative study based in 85 semi-structured interviews with health care practitioners in a variety of settings. (Canadian)
Results

Weaknesses in the double checking process include –

• Inconsistent conceptualisation of double checking
• Double (or more) checking as a costly and time consuming process
• Double checking accepted as a trusted and stand-alone process
• Double checking preventing reporting of near misses

Alternate views of double checking that would render it more robust

• Recognising double checking needs training and a dedicated environment
• Introducing automated double checking
• Expanding double checking beyond error checking

Conclusions

• Double checking deserves more questioning as there are limitations to the process
• Practitioners could help strengthen this rarely challenged practice by looking at it through different viewpoints
A cross-sectional observational study of high override rates of drug allergy alerts in inpatient and outpatient settings, and opportunities for improvement

Slight SP, Beeler PE, Seger DL et al

*BMJ Qual Saf* doi:10.1136/bmjqs-2015-004851

[http://qualitysafety.bmj.com/content/early/2016/03/18/bmjqs-2015-004851](http://qualitysafety.bmj.com/content/early/2016/03/18/bmjqs-2015-004851)

**Design**

A cross-sectional observational study of drug allergy alerts generated over a 3 year period

**Setting**

Undertaken in a 793-bed tertiary care teaching affiliate of Harvard Medical School and 36 primary care practices
This month’s papers - details

Results

- A total of 158,023 drug allergy alerts were displayed, 83% inpatient and 17% in the outpatient setting
- 128,157 (81%) were over-ridden – in a subset analysis these were appropriately over-ridden
- The most common over-ride reason was “patient has previously taken without allergic reaction”

Conclusions

- Patient drug allergy lists need to be regularly updated and allergies de-activated if appropriate
- Prescribers are exposed to too many computer alerts
- Side effects should not be coded as allergies
- Cross-sensitivity decision making should include clinical evidence, not relying solely on pharmacological or structural similarity