National Medication Safety Network

Observatory
Bridget Rankin
UKMI
Guy’s and St Thomas’ hospitals
National Medication Safety Network
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Observatory of recent safe medication bulletins, practice research, reports, and publications

Presented by Bridget Rankin,
bridget.rankin@gstt.nhs.uk
Recent regulator and statutory body activity

NHS England

MHRA
Regulating Medicines and Medical Devices

European Medicines Agency
Science Medicines Health

FDA
U.S. Food and Drug Administration
Recent regulator and statutory body activity

Hydroxyzine (Atarax, Ucerax): risk of QT interval prolongation and Torsade de Pointes

- MHRA has reinforced previous EMA warning
- Do not prescribe hydroxyzine to people with a prolonged QT interval or who have risk factors for QT interval prolongation
- Avoid use in the elderly
- the maximum daily dose is now
  - 100 mg for adults
  - 50 mg for the elderly (if use cannot be avoided)
  - 2 mg per kg body weight for children up to 40 kg in weight
- prescribe the lowest effective dose for as short a time as possible

Recent regulator and statutory body activity

Codeine for cough and cold: restricted use in children

Guidance restricting the use of codeine for pain relief in children is already in place. Use of codeine in children under 12 is associated with a risk of respiratory side effects. The MHRA have advised that when prescribing or supplying codeine-containing medicines for cough and cold, to remember:

**Codeine is contraindicated in:**
- Children younger than 12 years old
- Patients of any age known to be CYP2D6 ultra-rapid metabolisers
- Breastfeeding mothers
- Codeine is not recommended for adolescents (12 to 18) who have problems with breathing

Several new high strength insulin products are now on the market bringing with them a risk of medication error. These have been developed for patients with large daily insulin requirements to reduce the number and volume of injections. Several are in strengths higher than the standard 100units/ml and extra care is needed with prescribing dispensing and administration to avoid a dangerous overdose or underdose .......

Recent regulator and statutory body activity

High strength, fixed combination and biosimilar insulin products: minimising the risk of medication error (continued)

• Double check that you have selected the correct product name AND the correct strength
• Consult the Summary of Product Characteristics and any educational material.
• Ensure that patients read and understand the patient leaflet and receive appropriate training on the correct use of the product
• Give patients a patient booklet and Insulin Passport (or safety card)
• Warn patients only to use insulin as they have been trained.
• Monitor glucose levels more closely after starting a new treatment.
• Details of the new insulin products and doses plus the training materials are available via the MHRA website
Enteral feeding devices and accessories, syringes, plasters, dressings and rectal straws - invalid CE markings

• (Medicina LTD) Devices are being recalled because the CE marking is invalid and there is a risk of infection from using the gastrostomy button feeding kits (MDA/2015/013).
Recent Drug Alerts

- (RelonChem Ltd/ Kent Pharmaceuticals) All unexpired batches of **50mg Tramadol** capsules recalled due to the risk of fungal contamination. (EL (15)A/04)
- **Exocin 3mg/ml eye drops** (Allergan UK Limited) Specific batch including a Danish language pack was shipped to the UK in error. Class 3 – action within 5 days. (EL (15)A/03)
Patient Safety Alert issued by NHS England to raise awareness of the introduction of new medical device connectors. The first devices to be fitted with the new ISO connectors are those used for feeding patients via a tube and they will be phased into use throughout the NHS from September 2015.

https://www.england.nhs.uk/2015/04/01/psa-isoc-connectors/

Various resources to support organisations to prepare for the change can be found at www.stayconnected.org/index.html.
Medicines optimisation: the safe and effective use of medicines to enable the best possible outcomes (NG5).

**Shared learning submission**

**Developing a multidisciplinary medicines related model of working**

**Aim** - to develop an integrated medicines optimisation pathway across Sheffield accessible to health and social care professionals and ultimately available to patients to self-refer into. Twenty GP practices and twenty community pharmacies actively participated.

**Progress** - monitored by recording all the referrals and interventions made by the assessment team during the project.

- 137 at-risk patients were referred into the scheme.
- Reduction in the use of inappropriate medication (14 medications stopped and 21 started, using the STOPP-START criteria),
- 91% success rate on goals set.
EMA and FDA

- FDA issues safety alert about SGLT2 inhibitors and potential link with ketoacidosis
- canagliflozin, dapagliflozin, and empagliflozin
- The warning is based on a search of the FDA Adverse Event Reporting System database which identified 20 cases of acidosis reported as diabetic ketoacidosis (DKA), ketoacidosis, or ketosis in patients treated with SGLT2 inhibitors from March 2013 to June 2014. All patients required emergency treatment or hospitalisations to treat the ketoacidosis.

This months papers

- Referral letters to the emergency department: is the medication list accurate? Irish medical journal 108/2(38-40)  
  http://www.imj.ie/ViewArticleDetails.aspx?ArticleID=13491

  A wide range of patient safety conference abstracts covering all sectors  

- Use of QR and EAN-13 codes by older patients taking multiple medications for a safer use of medication. International Journal of Medical Informatics, June 2015, vol./is. 84/6(406-412)  
  http://www.ijmijournal.com/article/S1386-5056(15)00035-0/abstract

- Drug-related problems in a clinical setting: a literature review and cross-sectional study evaluating factors to identify patients at risk  
  European Journal of Hospital Pharmacy 2015;doi: 10.1136/ejhpharm-2014-000605  
  http://ejhp.bmj.com/content/early/2015/05/15/ejhpharm-2014-000605.abstract
This months papers – Error reporting and risk management

• Improving the safety of epidural steroid injections. JAMA 5 May 2015; 313(17):1713-1714

  http://www.ingentaconnect.com/content/ascp/tcp/2015/00000030/0000003/art00002

• Nursing, pharmacy, and prescriber knowledge and perceptions of high-alert medications in a large, academic medical hospital. Hospital Pharmacy, April 2015, vol./is. 50/4(287-295)

  http://www.ncbi.nlm.nih.gov/pmc/articles/PMC4412588/
This months papers - Paediatrics


Developing person-centred analysis of harm in a paediatric hospital: a quality improvement report

http://qualitysafety.bmj.com/content/early/2015/03/30/bmjqs-2014-003795.full

- Study conducted at GOSH
- Primary aim to build a user friendly system that would allow access to the patient and their family’s perception of ‘harm’
- To assess if there is a change in clinical staff’s perception of what constitutes harm
- Developed and tested a tool for patients and families to report harm
- Measured changes using ‘culture surveys’ as well as analysis of reports
Developing person-centred analysis of harm in a paediatric hospital: a quality improvement report

http://qualitysafety.bmj.com/content/early/2015/03/30/bmjqs-2014-003795.full

- 85 families participated
- Families successfully reported harm but nature differed from staff reporting
- Families reported a higher proportion of minor harm and ‘near miss’ events
- Only 3% reported by families were also reported by staff
- Datix reports increased by 67% from 1.29 to 2.05 per week (p<0.05)
Developing person-centred analysis of harm in a paediatric hospital: a quality improvement report

http://qualitysafety.bmj.com/content/early/2015/03/30/bmjqs-2014-003795.full

• The tool was easy to use but limitations included week day only engagement of families and also the study was conducted on renal unit where patients and families are often known by staff
• There was little measurable difference in staff perceptions of the ‘safety climate’ though cultural change can take longer than the 1 year period of the study
• Recommendations - Hospital units should consider ways to involve the ‘real experts’ and the tool is easy to use
• The tool needs to be tested in a wider setting to assess correlation with an improved safety culture
http://www.ncbi.nlm.nih.gov/pmc/articles/PMC4412588/

- A review of epidemiological studies quantifying ADRs in a European setting
- Literature review – Jan 2000 to Sept 2014
- Looked at inpatient and outpatient settings
- Eligible study designs were prospective or retrospective observational studies that measured the ADR occurrence rate
- Studies that executed non-random sample selection, such as those studies that only included patients who were admitted during working hours or during weekdays, were excluded. Studies that reported missing data for more than 20% of all patients admitted during the study period were also excluded
- Less rigorous selection methods were used for the inclusion of studies performed in the outpatient setting as this part of the search was more exploratory.
- 47 papers included in final review
Results

The median percentage of hospital admissions due to an ADR was 3.5 %, based on 22 studies.

Median percentage of patients who experienced an ADR during hospitalization was 10.1 %, based on 13 studies.

Only five studies were found that assessed ADRs occurring in the outpatient setting.
Estimating occurrence of ADRs in the outpatient setting is not robust. The occurrence rate reported by the 5 studies varied considerably from less than 1% to 7.8%. Variability of study methods used, and settings in which the studies were performed. The prevalence of ADRs among the general population that do not result in a hospital admission is largely unknown. Cannot exclude the possibility of having missed some publications due to the search strategy that was used. New observational studies in the outpatient setting of ADRs are needed.
Initiatives to identify and mitigate medication errors in England
(Cousins, Gerrett & Richards)
Drug Safety Apr 2015;38(4):349-357

- Describes the UK response to the EU Directive on Pharmacovigilence
- Structure and purpose of the NHSE and MHRA initiatives
- Improvements in error reporting and data quality
- An excellent review of where we are now and the direction of travel
- A must read 😊