Observatory

21st October 2015

Observatory of recent safe medication practice research, reports, and publications

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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

UKMi
UK Medicines Information
• Anoro Ellipta (umeclidinium 55mcg / vilanterol 22mcg) inhalational powders
• Incruse Ellipta (umeclidinium bromide 55mcg) inhaler
  – 6 week shelf life of inhaler once foil pack opened & desiccant removed
  – New packaging from October ‘15 to help patients use device within expiry date.
  – Careful patient counselling required.

• Toujeo (Insulin glargine 300units/ml), Sanofi-Aventis – Aug ’15
• Abasaglar (Insulin glargine 100units/ml), Eli Lilly – Sept ‘15
  – Insulin glargine biosimilars
  – Potential for confusion with Lantus – insulin glargine or Apidra (insulin glulisine)
  – Toujeo – longer acting product than Lantus
  – Insulin glargines are not interchangeable
  – Brand name prescribing

  – 6% increase in the number of incidents reported.
  – 71.2% no harm
  – 23.9% low harm
  – 4.3% moderate harm
  – <1% serious harm / death

  – Top 4 causes:
    • 19.2% patient accidents
    • 13.2% implementation of care / ongoing monitoring / review incidents
    • 10.6% treatment / procedure
    • 10.2% medication

  – Official statistics published 7/10/15 by HSCIC
  – Harm free patient figure 93.8% - 94.3%
  – New VTE: 0.4%
• CEM/CMO/2015/007 & CEM/CMO/2015/007R
• Deaths linked to the consumption of 2, 4-dinitrophenol (DNP)
• Product used by body builders or as slimming aids
• Healthcare professionals encountering individuals suspected of consuming this substance should inform them of the dangers and advise them to discontinue use immediately.
Recent regulator and statutory body activity

- New packaging of Bausch + Lomb minim single dose unit
  - Unwrapped minim no longer has code of drug printed on body of bottle
  - Evocative code now embossed on end of single dose unit
  - Difficult to read
  - **MHRA response:**

    "We have received a number of complaints about the embossed coding, therefore we have initiated discussions with the Marketing Authorisation Holder on the issue and they are looking at improving the way in which the product code is applied to individual Minims. An interim solution is being implemented, although it may take a while for any change to be seen in the market place".
Drug Shortages

• Apraclonidine 1% minims – stock due back in 5/10/15

• Haloperidol (5mg in 1ml) injection – Amdipharm Mercury Company Limited
  – Manufacturing problem – delay until mid-October expected
  – Could be unreliable supplies after this time
  – Haldol – Janssen-Cilag product discontinued
  – No other UK manufacturers
  – Foreign import of 5mg/1ml injection available – lead times may vary – not licensed in UK (but licensed product in originating country)
  – UKMi & CMU: template memo on managing the shortage to be used by NHS organisations with local amendment: http://tinyurl.com/p2wh4k5
Pharmacovigilance Risk Assessment Committee (PRAC) 
5th – 8th October 2015

• SGLT 2 inhibitors (canagliflozin, dapagliflozin and empagliflozin):
  – Used in the management of type 2 diabetes mellitus
  – Risk of diabetic ketoacidosis (DKA) to be examined
  – 101 serious cases of DKA reported worldwide – some required hospitalisation
  – In some cases caused only moderately raised BMs
  – Uncharacteristic blood glucose levels could delay diagnosis and treatment.

• HPV vaccines:
  – Clarifying safety profile
  – Looking in more detail into rarely reported complex regional pain syndrome (CRPS) and postural orthostatic tachycardia syndrome (POTS).
  – Causal link not identified between POTS, CRPS and HPV vaccine, but further review needed
  – No changes to current use of vaccine necessary.

• Tysabri (natalizumab):
  – Used for multiple sclerosis
  – Assessing whether advice given to healthcare professionals and patients on how to manage the known risk of PML with tysabri should be revised in light of new evidence.
  – Aim to identify further measures to minimise and define risk of PML
• **Anti-TNF products (etanercept & adalimumab)**
  – Largest number of injury reports received by FDA in 2014
  – Most adverse events were linked to immunosuppressant properties

• **Novel oral anticoagulant (NOAC) safety profile**
  – Long term use of NOAC (rivaroxaban, dabigatran, apixaban) is considered highest risk drug treatments in older patients
  – Injury rates 15 – 20%/year
  – Apixaban strongest safety profile
  – Dabigatran highest overall total of domestic, serious ADR reports; largest total of reported severe haemorrhages; most patient deaths

• **Tissue plasminogen activators – wrong drug errors**
  – Avoid using error-prone abbreviations: ‘TPA’ (alteplase) and ‘TNKase’ (tenecteplase)
  – Clarify indication as products licensed for different indications
  – Warning alerts on electronic prescribing to highlight error risk
This months’ papers


• **Pharmacist prescribing within a UK NHS hospital trust: Nature and extent of prescribing, And prevalence of errors.** Baqir W., Crehan O., Murray R., Campbell D., Copeland R. European Journal of Hospital Pharmacy: Science and Practice. 22 (2) (pp 79-82), 2015. Date of Publication: 2015. AN: 2015778914

This months’ papers

• **Use of a human factors classification framework to identify causal factors for medication and medical device-related adverse clinical incidents.** Mitchell R.J., Williamson A., Molesworth B. Safety Science. 79 (pp 163-174), 2015. Date of Publication: November 01, 2015. AN: 2015155977


This months’ papers


This months’ papers


This months’ papers

• **Errors in medicine: Causes, impact and improvement measures to improve patient safety.** <Fehler in der Medizin: Ursachen, Auswirkungen und Masnahmen zur Verbesserung der Patientensicherheit.> Waeschle R.M., Bauer M., Schmidt C.E. Anaesthesist. 64 (9) (pp 689-704), 2015. [http://www.ncbi.nlm.nih.gov/pubmed?term=Anaesthesist%5BJour%5D+AND+64%5Bvolume%5D+AND+9%5Bissue%5D+AND+689%5Bpage%5D&cmd=detailssearch](http://www.ncbi.nlm.nih.gov/pubmed?term=Anaesthesist%5BJour%5D+AND+64%5Bvolume%5D+AND+9%5Bissue%5D+AND+689%5Bpage%5D&cmd=detailssearch)

• **Reducing unacceptable missed doses: Pharmacy assistant-supported medicine administration.** Baqir W., Jones K., Horsley W., Barrett S., Fisher D., Copeland R., Campbell D., Stephenson R. International Journal of Pharmacy Practice. 23 (5) (pp 327-332), 2015. [http://www.ncbi.nlm.nih.gov/pubmed?term=International+Journal+of+Pharmacy+Practice%5BJour%5D+AND+23%5Bvolume%5D+AND+5%5Bissue%5D+AND+327%5Bpage%5D&cmd=detailssearch](http://www.ncbi.nlm.nih.gov/pubmed?term=International+Journal+of+Pharmacy+Practice%5BJour%5D+AND+23%5Bvolume%5D+AND+5%5Bissue%5D+AND+327%5Bpage%5D&cmd=detailssearch)

- **Aim**: Investigate what and how medication information is communicated during handover interactions in specialty hospital settings.

- **Design**: exploratory qualitative design and observational study.

- **Method**:
  - Nurse – incoming HCP; nurse, doctor or ambulance officer – outgoing HCP

- **Results**:
  - 130 hours of data
  - 185 (predominantly nursing) handovers observed
  - 37 nurse participants
  - Gaps in MC at handover was evident as shown by lack of communication about detailed and specific medication content.
  - Seemed to be more MC regarding IV rather than PO medication
  - Omitted information: changes to prescribed medication; whether and when medication was administered to patients; evaluation of medication effectiveness.
  - Incoming nurses rarely posed questions about medication at handover
Conclusions:
- Restricted and incomplete MC at handover.
- Often contributed to by restricted time frames
- Benefit of patient or relative involvement at handover should be considered
- Improving the transparency, completeness and accuracy of MC is vital for optimising patient safety and quality of care in speciality practice settings.
- Limitations: actual or potential medication error rate was not measured; study only conducted at one site; observation may have affected professional practice

Relevance to clinical practice:
- Breakdown in communication – contributing factor of medication incidents resulting in serious harm
- Nurses require information about all types of prescribed medication to make informed and rapid decisions regarding appropriate patient care
- Explicitly and clearly explained information required
- Jargon and assumptions should be minimised to reduce risk of misunderstandings

Focus of this article:
- Other research has not yet looked at nurse communication in these settings
- Specialty settings – numerous high risk medications routinely administered
  - E.g. Potassium, insulin, opioids, chemotherapy or anticoagulants

- Estimated that 25% of error reports involve look-alike, sound-alike drug names
- Most common cause of medication error
- Significant global concern

- Tallman lettering = capitalizing the unique portions of easily confused drug names
  - e.g. prednisoLONE vs prednisone
  - methylTESToRone vs medroxyprogesterone
  - DOXOrubicin vs daunorubicin
  - chlorproMAZINE vs chlorproPAMIDE
  - Insulin glARGine vs insulin glulisine
- Strategy for reducing medication errors, endorsed by WHO.

- **Objective**: Efficacy of Tallman lettering assessed in a visually complex environment
- **Methods**:
  - Change detection testing used for laypeople (n=40) and HCP (n = 40)
  - HCP = 16 nurses, 24 other HCP e.g. Pharmacy technicians, surgical technologists, respiratory technologists
  - Names were presented in realistic medication labels and in a complex visual environment
Results:
- When presented in Tallman lettering, confusable pairs of drug names detected by HCP and laypeople:
  - more often (p <0.0001)
  - more quickly (p <0.05)
  - benefits more pronounced for HCP (p <0.05)
- Familiarity with both drug names in a confusable pair mitigated the benefits
- Bottom-up and top-down attentional systems for processing information in context of varied healthcare environments

Discussion:
- Unique portions of a drug name in a larger font may increase visual saliency → increase bottom-up signal
- Increased benefit in nurses suggests Tallman lettering can impact via top-down attentional system also
- Top-down system requires cognitive resources – less effective in situations of high stress or anxiety → may reduce errors in non-stressful situations
- Bottom-up system is automatic – available even in stressful situations → may reduce errors in stressful situations

Conclusion:
- Lab-based testing provides evidence that Tallman lettering may be effective at reducing drug errors.
- Tallman lettering system should be adopted as a strategy to mitigate medication errors.