UKMi Observatory
27/05/2020
Observatory of recent safe medication practice research, reports, and publications

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The Medicines and Healthcare products Regulatory Agency (MHRA) has launched a dedicated Yellow Card reporting site for healthcare products that are used in Coronavirus (COVID-19) treatment to be easily reported: coronavirus-yellowcard.mhra.gov.uk

Coronavirus (COVID-19): latest guidance for medicines safety

Valproate Pregnancy Prevention Programme: temporary advice for management during coronavirus (COVID-19)

Temporary modifications to the Pregnancy Prevention Programmes for thalidomide (Thalidomide Celgene), lenalidomide (Revlimid▼) and pomalidomide (Imnovid▼)
MHWRA

Alerts and Recalls

- **ReQuip (ropinorole hydrochloride) tablets**: important changes to the colour of carton and blister packs

- **Cyproterone acetate**: restrictions in use of due to risk of meningioma
Alerts and Recalls

Class 2 Medicines Recall: Emerade 500 micrograms solution for injection in pre-filled syringe, PL 33616/0015 (EL(20)A/23 (follows previous recalls for the 150mcg and 300mcg strengths) [Bausch & Lomb UK Ltd] is recalling all unexpired batches of Emerade 500microgram autoinjectors (also referred to as pens) from patients due to an error in one component of the auto-injector believed to cause some pens to fail to activate and deliver adrenaline.

Field Safety Notice

Roche Diagnostics GmbH: Accu-Chek® Aviva test strips
Supply Disruption Alert: Update - Neuromuscular blocking agents: atracurium, cisatracurium and rocuronium. The supply position on rocuronium has now substantially improved. Therefore, Trusts can now use rocuronium as a first-choice neuromuscular blocking agent (NMBA) in all scenarios as they choose, unless there is a contraindication.

Phosphate Polyfusors – out of stock until at least October 2020

Salazopyrin (sulfasalazine) 500mg suppositories - Supply Disruption
Diprivan emulsion (Aspen propofol): Interim supply to Mitigate Supply Disruption of 10mg/ml (1%) Panamanian Stock; 20mg/ml (2%) Brazilian stock; 10mg/ml (1%) stock with Chinese tray label

Propofol 10mg/ml (1%) Emulsion for Injection/Infusion Interim Supply of Sweden Stock to Mitigate Supply Disruption

Noradrenaline supply problem – Unclear labelling of unlicensed product (4mL ampoule) manufactured by Hospira and imported for use in the UK.
Recent regulator and statutory body activity

- **Suxamethonium**: temporary foreign label product - Label and patient information leaflet (PIL) is in Portuguese
- **Midazolam 1mg/ml Solution for Injection or Infusion (Midazolam)**: supply disruption – French product supplied
- **Esmeron (rocuronium bromide) 10mg/ml solution for injection**: supply of some packs originally for Australia
- **Ioversol (Optiray) 300 mg Iodine/ml**: 100ml syringe and bottle shortage - Alternative European sources of the 100 ml bottle are available in non-UK packaging to cover the shortfall between now and May 2020
- **Polivy ▼ (polatuzumab vedotin)**: 140mg powder for concentrate for solution for injection: temporary plastic vial flip-off cap colour
- **Adoport (tacrolimus)**: limited number of packs with Italian foil - for 0.75mg and 5mg capsules and for 1 mg capsules
• Ativan 4mg/ml Solution for Injection (Lorazepam): Temporary supply of a different presentation and changes to the instructions - US product
• Calrecia, 100mmol/l, solution for infusion (calcium chloride): Interim Supply of stock from the below countries to Mitigate Supply Disruption
• Sirturo ▼ 100 mg (bedaquiline): Interim Supply of Irish Stock to Mitigate Supply Disruption
• Pancuronium bromide 2mg/ml: Temporary supply of alternative US product 10mg/10ml (1mg/ml) multiple-dose fliptop glass vials
• Chiesi release batch specific variation for Clenil 100 microgram inhaler owing to temporary increased demand
SPS – raising awareness of unfamiliar packaging

Drug packaging and labelling during COVID-19: posters and screensavers for teams

THE COVID DRUG CHECK

You may be using medicines with unfamiliar packaging and labelling. Perform the COVID drug check.

COntentration
The strength may be different to the product you are used to and the decimal point may be a comma.

Volume
The volume you have to administer may be different to what you are used to.

ID
Check the approved drug name - brand names may be different.

Read the label carefully
Directions for safe administration may be different from what you are used to.

Check and Challenge
Check with colleagues (such as the pharmacy team). Local contact details: Challenge colleagues if necessary.

Conversion Table

<table>
<thead>
<tr>
<th>Percentage</th>
<th>mg/mL</th>
<th>mg/10mL</th>
<th>mg/20mL</th>
<th>mg/100mL</th>
</tr>
</thead>
<tbody>
<tr>
<td>0.1%</td>
<td>1 mg/mL</td>
<td>10 mg/10mL</td>
<td>20 mg/20mL</td>
<td>100 mg/100mL</td>
</tr>
<tr>
<td>0.5%</td>
<td>5 mg/mL</td>
<td>50 mg/10mL</td>
<td>100 mg/20mL</td>
<td>500 mg/100mL</td>
</tr>
<tr>
<td>1%</td>
<td>10 mg/mL</td>
<td>100 mg/10mL</td>
<td>200 mg/20mL</td>
<td>1 g/100mL</td>
</tr>
<tr>
<td>2%</td>
<td>20 mg/mL</td>
<td>200 mg/10mL</td>
<td>400 mg/20mL</td>
<td>2 g/100mL</td>
</tr>
<tr>
<td>2.5%</td>
<td>25 mg/mL</td>
<td>250 mg/10mL</td>
<td>500 mg/20mL</td>
<td>2.5 g/100mL</td>
</tr>
<tr>
<td>5%</td>
<td>50 mg/mL</td>
<td>500 mg/10mL</td>
<td>1 g/20mL</td>
<td>5 g/100mL</td>
</tr>
<tr>
<td>10%</td>
<td>100 mg/mL</td>
<td>1 g/10mL</td>
<td>2 g/20mL</td>
<td>10 g/100mL</td>
</tr>
<tr>
<td>12.5%</td>
<td>125 mg/mL</td>
<td>1.25 g/10mL</td>
<td>2.5 g/20mL</td>
<td>12.5 g/100mL</td>
</tr>
<tr>
<td>20%</td>
<td>200 mg/mL</td>
<td>2 g/10mL</td>
<td>4 g/20mL</td>
<td>20 g/100mL</td>
</tr>
<tr>
<td>25%</td>
<td>250 mg/mL</td>
<td>2.5 g/10mL</td>
<td>5 g/20mL</td>
<td>25 g/100mL</td>
</tr>
<tr>
<td>50%</td>
<td>500 mg/mL</td>
<td>5 g/10mL</td>
<td>10 g/20mL</td>
<td>50 g/100mL</td>
</tr>
</tbody>
</table>

*Strengths are not expressed in mmol in the above table because mmol is drug specific.

For example, 1% strength = 10 mg/mL for any drug, but the number of mmol will be different for each drug.
Leuprorelin depot medicines: PRAC recommends new measures to avoid handling errors
Only healthcare professionals familiar with the preparation steps for leuprorelin depot medicines should prepare and administer the medicines to patients. Patients should not prepare or inject these medicines themselves.

Ranitidine medicines are being suspended in the EU due to the presence of NDMA impurities
CHMP has recommended the suspension of all ranitidine medicines in the EU due to the presence of low levels of the impurity NDMA. EMA has also recommended conditions for lifting the suspension of ranitidine medicines, including requirements for companies to provide more data.

PRAC concludes review of new information on the known risk of breast cancer with hormone replacement therapy
Updates for product information recommended based on a large study published in The Lancet in August 2019, which confirmed the known higher risk of breast cancer in women using HRT. Furthermore, the results showed that the risk may continue to be increased for ten years or more after stopping HRT, if it has been used for more than five years.
PRAC meeting recommendations for update of product information

- **Ondexxya (andexanet alfa)** – risk of erroneous assay results for levels of anti-factor Xa activity

- **Idelalisib** – risk of drug reaction with eosinophilia and systemic symptoms (DRESS) cannot be excluded

- **Insulin** – cutaneous amyloidosis at injection site may delay local insulin absorption – rotate injection site
National guidance, publications and resources

Self-Administration of Medicines – Brief Guidance and examples from practice

Minimising wastage of critical medicines during Covid-19

Coronavirus (COVID-19): reuse of medicines in a care home or hospice

Dealing with returned medicines during the COVID-19 pandemic

Refrigerated and ambient stability during COVID-19 for ITU injectable medicines

Small Batch Worksheets for ICU medicines for use in Pharmacy-led preparation in Field Hospitals or close to Clinical areas

Extended Stability of Compounded medicines for ICU’s
RPS COVID-19 Critical Care Training resource

EAHP COVID-19 Resource Centre

An update on extravasation: basic knowledge for clinical pharmacists

Update on new legislation relating to controlled drugs during the COVID-19 pandemic (The Misuse of Drugs (Coronavirus) (Amendments Relating to the Supply of Controlled Drugs During a Pandemic etc.) Regulations 2020)

Updated Medicines Q&As on SPS:

- Medicines Q&A: How should ankle oedema caused by calcium channel blockers be treated?
- What are the reported incidences of ankle oedema with different calcium channel blockers?
- Can opioids be used for pain relief during pregnancy?
- How can hot flushes in men being treated for prostate cancer be managed?
- How do you convert an oral pyridostigmine or neostigmine dose to a parenteral neostigmine dose?


**Both New and Chronic Potentially Inappropriate Medications Continued at Hospital Discharge Are Associated With Increased Risk of Adverse Events** Weir DL, Lee TC, McDonald EG, et al. [published online ahead of print, 2020 Mar 31]. *J Am Geriatr Soc.*


**Combining Social Media and FDA Adverse Event Reporting System to Detect Adverse Drug Reactions.** Li Y, Jimeno Yepes A, Xiao C. *Drug Saf.* [published online ahead of print, 2020 May 8].
Objectives: The aims of the study were to describe medication administration incidents reported in England and Wales between 2007 and 2016, to identify which factors (reporting year, type of incident, patients' age) are most strongly related to reported severity of medication administration incidents, and to assess the extent to which relevant information was underreported or indeterminate.

Methods: Medication administration incidents reported to the National Reporting & Learning System between January 1, 2007, and December 31, 2016 were obtained. Characteristics of the data were described using frequencies, and relationships between variables were explored using cross-tabulation.
Results: A total of 517,384 incident reports were analyzed. Of these, 97.1% (n = 502,379) occurred in acute/general hospitals, mostly on wards (69.1%, n = 357,463), with medicine the most common specialty area (44.5%, n = 230,205). Medication errors were most commonly omitted doses (25.8%, n = 133,397). The majority did not cause patient harm (83.5%, n = 432,097). When only incidents causing severe harm or death (n = 1,116) were analyzed, the most common type of error was omitted doses (24.1%). Most incidents causing severe harm or death occurred in patients aged 56 years or older. For the 10-year period, the percentage of incidents with "no harm" increased (74.1% in 2007 to 86.3% in 2016). For some variables, data were often missing or indeterminate, which has implications for data analysis.

Conclusions: Medication administration incidents that do not cause harm are increasingly reported, whereas incidents reported as severe harm and death have declined. Data quality needs to be improved. Underreporting and indeterminate data, inaccuracies in reporting, and coding jeopardize the overall usefulness of these data.