Yellow Card Scheme and MiDatabank updates

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North West Medicines Information Centre
2.3 Monitoring patients’ outcomes

Patients’ outcomes from, and experiences of, treatment with medicines are documented, monitored and reviewed.

a As part of a multidisciplinary team, pharmacy team members monitor:
   - Patients’ responses to their medicines
   - Unwanted effects of medicines.

b Appropriate action is taken where problems (potential and actual) are identified.

c The pharmacy team provides the leadership, systems support and expertise that enables healthcare professionals to:
   - Help patients to avoid adverse events resulting from their medicines
   - Document, report and manage any adverse events that do arise.

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4 Adverse events should be reported to the Medicines and Healthcare products Regulatory Agency (MHRA) via the Yellow Card Scheme.
Medicines Optimisation

Principle 3. Ensure medicines use is as safe as possible

- Safety covers all aspects of medicines usage, including unwanted effects, interactions, safe processes and systems, and effective communication between professionals.

- Outcome
  - Patients discuss potential side-effects and there is an increase in reporting to the MHRA.
CQC Outcome 9: Management of medicines

- 9B Where treatment and support involves medicines, the provider has:
  - Clear procedures followed in practice
  - Wherever they are required these procedures:
    - Include arrangements for reporting adverse events, adverse drug reactions, incidents, errors and near misses.
    - Should encourage local and, where applicable, national reporting, learning and promoting an open and fair culture of safety
Yellow Card Roadmap

A new strategy to improve patient safety

- Improving patient safety through systematic and cultural change
- Embedding Yellow Card into the healthcare system
- Making the best scientific use of Yellow Card data
- Yellow Card Scheme sustainability into the future through collaboration
Theme 1 - Improving patient safety through systematic and cultural change

- The Scheme has been extended to include all incidents that have caused harm (medicines and devices used in and outside their license).

- Using social media and other data sources to supplement Yellow Card reports to identify “signals” and increase public awareness.
WEB-RADR: Recognising ADRs
‘Working together to improve pharmacovigilance through new technology’

- A large-scale public-private partnership
- Supported by the Innovative Medicines Initiative Joint Undertaking
WEB-RADR Consortium
Yellow Card mobile app

Yellow Card

Email
Password
Login

Create your account
Forgot Password

News

Drugs and driving:
We remind you that a new law is enforced from 2 March and Wales.

Letters sent to health professionals:
Since November 2014, a warning has been issued regarding vismodegib (Erivedge) and chlorhexidine solutions.

Nitrofurantoin now available
A short course (3 to 7 days) with caution in certain patient groups eGFR of 30 to 44 ml/min.

Reissue: endobronchial tubes
Reissued – ‘Problem’ set (Teleflex Medical) Could cause coughing and hypercarbia if not in situ.

Endobronchial tubes
(Teleflex Medical) Could cause coughing and hypercarbia if not in situ.

Medicines related issues
Children exposed in utero are at a high risk of serious developmental disorders

UKMi
UK Medicines Information

Yellow Card Centre North West
80% of users look for health-related information online
- 6,000 tweets per second
- Can social media be used to identify signals of ADRs?
Theme 2 – Embedding Yellow Card into the healthcare system

- Integrating Yellow Card reporting into the NHS IT systems (e.g. MiDatabank, Cerner, SystmOne)
- Improving education for health professionals - a “Good Vigilance Practice” guide is being developed for the NHS
Theme 3 – Making the best scientific use of Yellow Card data

- Ensuring that Yellow Card data is used optimally to detect signals and provide effective feedback
- Improving Yellow Card data use by the academic community
Theme 4 – Yellow Card Scheme sustainability into the future through collaboration

- Collaborating effectively with a wide range of organisations and stakeholders e.g. professional bodies, other government agencies and NHS bodies as well as the five regional Yellow Card Centres.
MiDatabank ADR reporting
Yellow Card reporting by hospital pharmacists

Number of Yellow Cards Received

Quarter/Year

2015
- 2015 Q2
- 2015 Q1

2014
- 2014 Q4
- 2014 Q3
- 2014 Q2
- 2014 Q1

2013
- 2013 Q4
- 2013 Q3
- 2013 Q2
- 2013 Q1

2012
- 2012 Q4
- 2012 Q3
- 2012 Q2
- 2012 Q1

2011
- 2011 Q4
- 2011 Q3
- 2011 Q2
- 2011 Q1

Legend:
- EYC
- Paper
- MiDB
Reporting highlights

- 2,501 reports to August 2015
- 63% of reports are considered serious.
- Rivaroxaban is the drug with most reports
- Amoxicillin is the antibiotic with most reports
- Adalimumab is the biologic with most reports
- *Clostridium difficile* infection is the most reported reaction
Cumulative reporting via MiDatabank per million population

- Green bars: To August 2015
- Red bars: To Aug 2014
- Yellow bars: To June 2013
- Blue bars: To June 2012

Geographical regions:
- North West
- N&Y - Newcastle
- East Anglia
- Wales
- Northern Ireland
- Wessex
- West Midlands
- Scotland
- N&Y - Leeds
- South West
- London - South
- London - North
- Trent
Top 10 reporting units
August 2014 – August 2015

- University Hospital Aintree
- Royal Liverpool and Broadgreen
- Countess Of Chester Hospital
- Newcastle - R DTC
- Withybush General Hospital, Liverpool
- Mosley Hill Hospital, Liverpool
- Worcester Royal Hospital
- Edinburgh - Lothian MIC
- Central Manchester Healthcare Trust
- Victoria Hospital Blackpool
# Top 10 suspect drugs (antibiotics excluded)

<table>
<thead>
<tr>
<th>Suspect drug</th>
<th>Number of reports</th>
</tr>
</thead>
<tbody>
<tr>
<td>Rivaroxaban</td>
<td>46</td>
</tr>
<tr>
<td>Citalopram</td>
<td>45</td>
</tr>
<tr>
<td>Aspirin</td>
<td>40</td>
</tr>
<tr>
<td>Sertraline</td>
<td>33</td>
</tr>
<tr>
<td>Omeprazole</td>
<td>32</td>
</tr>
<tr>
<td>Adalimumab</td>
<td>28</td>
</tr>
<tr>
<td>Furosemide</td>
<td>26</td>
</tr>
<tr>
<td>Simvastatin</td>
<td>25</td>
</tr>
<tr>
<td>Methotrexate</td>
<td>25</td>
</tr>
<tr>
<td>Gabapentin</td>
<td>25</td>
</tr>
<tr>
<td>Amiodarone</td>
<td>25</td>
</tr>
</tbody>
</table>
# Top 10 suspect antibiotics

<table>
<thead>
<tr>
<th>Suspect antibiotics</th>
<th>Number of reports</th>
</tr>
</thead>
<tbody>
<tr>
<td>Amoxicillin</td>
<td>45</td>
</tr>
<tr>
<td>Ciprofloxacin</td>
<td>37</td>
</tr>
<tr>
<td>Co-amoxiclav</td>
<td>30</td>
</tr>
<tr>
<td>Tazocin</td>
<td>24</td>
</tr>
<tr>
<td>Clarithromycin</td>
<td>23</td>
</tr>
<tr>
<td>Teicoplanin</td>
<td>18</td>
</tr>
<tr>
<td>Flucloxacillin</td>
<td>17</td>
</tr>
<tr>
<td>Doxycycline</td>
<td>14</td>
</tr>
<tr>
<td>Trimethoprim</td>
<td>12</td>
</tr>
<tr>
<td>Cefalexin</td>
<td>12</td>
</tr>
</tbody>
</table>
### Top 10 suspected reactions

<table>
<thead>
<tr>
<th>Suspected reaction</th>
<th>Number of reports</th>
</tr>
</thead>
<tbody>
<tr>
<td>*C.*difficile related</td>
<td>157</td>
</tr>
<tr>
<td>Liver related abnormalities/injury</td>
<td>91</td>
</tr>
<tr>
<td>Rash (various)</td>
<td>81</td>
</tr>
<tr>
<td>Abdominal pain/discomfort</td>
<td>81</td>
</tr>
<tr>
<td>Anaphylactic/anaphylactoid/hypersensitivity reactions</td>
<td>57</td>
</tr>
<tr>
<td>Acute kidney injury</td>
<td>53</td>
</tr>
<tr>
<td>Hyponatraemia</td>
<td>44</td>
</tr>
<tr>
<td>Dyspnoea</td>
<td>40</td>
</tr>
<tr>
<td>Diarrhoea</td>
<td>37</td>
</tr>
<tr>
<td>Alopecia</td>
<td>35</td>
</tr>
<tr>
<td>Herbals/supplements</td>
<td>Hepatic abnormalities</td>
</tr>
<tr>
<td>---------------------------------------------------------</td>
<td>-----------------------</td>
</tr>
<tr>
<td>Aftamas advanced fat burners</td>
<td>Retinervus luffae fructus</td>
</tr>
<tr>
<td>T500 Fury</td>
<td>St John’s Wort</td>
</tr>
<tr>
<td>Natrasleep</td>
<td>Cordydis Yanhusuo rhizhome</td>
</tr>
<tr>
<td>Radix Angelicae, Radix Codonopsis, Radix Scrophulariae</td>
<td>Tangkuei root</td>
</tr>
<tr>
<td>Green coffee</td>
<td>Raspberry ketone (2)</td>
</tr>
<tr>
<td>Flos Carthami</td>
<td>Ab-Fubinaca</td>
</tr>
</tbody>
</table>
Signal - Dronedarone and arthralgia
Contribution from MiD report

- Routine signal review
- MHRA experts assessed an MiD report of dronedarone induced arthralgia
- A review of all Yellow Card cases was triggered
- 5 UK spontaneous cases were identified
Signal - Dronedarone and arthralgia
Contribution from MiD report

- The EMA and the Rapporteur country for dronedarone in Europe have been notified
- The pharmaceutical company holding the licence for dronedarone has been requested to review the signal
- The signal is being kept under close review by the MHRA
MiDatabank - update from CoAcS

- **New** upgrade v3.2.1.5
  - Spell checking in MiEnquirymanager
  - Improved e-submission of ADRs to the MHRA
    - Added warning when closing an ADR report to flag when not electronically submitted to the MHRA.
  - Reporter
    - top 20 origins and keywords.
    - checkbox for ‘enquiry types’
    - ADR reports – dates submitted if received/problems
    - option to include Quarterly and Monthly period sub-reports to workload report.
MiDatabank - update from CoAcS

- **DM+D updates** – via MiDatabank website
  - Latest - 1\(^{st}\) September 2015
  - keeps your drug keywords updated
  - will soon highlight black triangle drugs

- MiDatabank **sharer** for all
  - contact CoAcS for the software download

- **Please** use the 'Request renewal' button when your licence expires (admin function)

- Have you completed the CoAcS survey monkey?