How could social media data be relevant to regulatory decision-making?

Social Media Workshop
PCWP and HCPWP Joint meeting
19 September, 2016
June M Raine, MHRA UK
Social media data & regulatory decision-making

Who – are patients & healthcare professionals listened to in regulatory decision-making?

Why regulatory interest in social media?

How might social media add value in pharmacovigilance?

What next for regulators to move forward from here?
Patients and HCPs expect of regulator...

**Access** to safe and beneficial medicines without unnecessary delay

Prompt identification of **signals** of harm in use and risk-proportionate action

Favourable **benefit-risk** of medicine throughout product life-cycle

**Quality** of manufacture and security of supply chain

Full, comprehensible and up to date **information** to support safe use
EU Regulatory approaches and objectives....

Monitoring benefit risk throughout product lifecycle in near real-time

Timely decision-making as evidence accrues

Using all available evidence supported by suitable methodologies

Patients & healthcare professionals’ views integrated throughout
Listening to patients’ and HCPs’ views

Public hearings

PRAC members
Receiving ADR reports from patients and HCPs

Commission Staff Working Document
Accompanying the document
Commission Report
Pharmacovigilance related activities of Member States and the European Medicines Agency concerning medicinal products for human use (2012 – 2014)

Individual Case Safety Reporting to EudraVigilance (EEA)

- Patients and HCPs
- Patients
- Healthcare professionals

Brussels, 8.8.2016
SWD(2016) 284 final
Focus on evidence in real world clinical use
Patients don’t report ADRs because they don’t know they can or should.

Physicians don’t report ADRs because reporting is time-consuming.

The information available to regulators on harms in use is incomplete.

96% adverse drug reactions are unreported.
Timeliness of sharing information

3.26pm  take-off

3.27pm  engine trouble

3.36pm  first picture on TwitPic

“There's a plane in the Hudson. I'm on the ferry going to pick up the people. Crazy.”

3.48pm: NY Times ‘breaking’
Patients may identify adverse reactions quicker

Patient reports of suspected adverse reactions associated with SSRIs preceded those of healthcare professionals

Patients may identify adverse reactions quicker

Lipoatrophy associated with certain anti HIV medicines

“Crix belly”

Information on location

Meningitis Cases Are Linked to Steroid Injections in Spine

Total of 753 cases and 64 deaths from fungal meningitis

States which received recalled steroid from New England compounding centre
During 2009 flu pandemic, mentions of symptoms on Twitter correlated closely with number of cases recorded over same time period.

Social media conversations could be used to predict the impact of outbreaks in future.
How could social media be relevant to pharmacovigilance?

Monitor risk minimisation effectiveness

Better characterised risks of medicine

Signal detection in real world use

Risk minimisation, communication, maintain favourable benefit risk

Ongoing evaluation of benefit risk
Signal detection?

@JoeC Second day off Effexor & on Viibryd here. Brain zaps are fun. And by fun, I mean horrendous & miserable.
Signal strengthening?

Social media may supplement evidence from spontaneous reports of suspected adverse drug reactions.

Differing value in detection/analysis/strengthening for different medicines or events.

A “one size fits all” approach may not be the most helpful.
### Misuse and abuse

![Map of the United States with data points showing misuse and abuse](image)

#### Latest Prices - Past 2 Weeks

<table>
<thead>
<tr>
<th>Price</th>
<th>Drug</th>
<th>Location</th>
</tr>
</thead>
<tbody>
<tr>
<td>$4</td>
<td>Ativan, 1mg pill</td>
<td>Akron, Ohio</td>
</tr>
<tr>
<td>$30</td>
<td>morphine ER pill, 60mg pill</td>
<td>Illinois</td>
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<tr>
<td>$1</td>
<td>generic Klonopin, 0.5mg pill</td>
<td>Hartford, Connecticut</td>
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<tr>
<td>$6</td>
<td>Adderall, 10mg pill</td>
<td>Eagle mountain Utah, Utah</td>
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<tr>
<td>$2.50</td>
<td>gabapentin, 600mg pill</td>
<td>Coeburn, Virginia</td>
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<tr>
<td>$0.25</td>
<td>Percocet, 5mg/325mg pill</td>
<td>Cornell, Wisconsin</td>
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<tr>
<td>$2</td>
<td>Norco, 7.5mg/325mg pill</td>
<td>Detroit mi, Michigan</td>
</tr>
<tr>
<td>$5</td>
<td>Adderall, 10mg pill</td>
<td>Cullman, Alabama</td>
</tr>
<tr>
<td>$10</td>
<td>Adderall XR, 10mg pill</td>
<td>Michigan</td>
</tr>
<tr>
<td>$5</td>
<td>methylphenidate ER tablet (generic Ritalin LA), 18mg pill</td>
<td>Rochester, New York</td>
</tr>
<tr>
<td>$2</td>
<td>Ativan, 1mg pill</td>
<td>Madison, Virginia</td>
</tr>
<tr>
<td>$28</td>
<td>Adderall, 30mg pill</td>
<td>Brooklyn, New York</td>
</tr>
</tbody>
</table>

**streetRx**: latest street prices for prescription drugs

**Did you get a good deal?**

*Submissions are anonymous*

- Name of drug
- Formulation
- Price per unit

Continue
Methylphenidate (Ritalin)

Study of Twitter “proto-AEs” for Ritalin has over 5,000 records.

Further analysis yielded series of threads suggestive of patterns of misuse at educational institutions including colleges, universities at time of examinations.

<table>
<thead>
<tr>
<th>Verbatim text</th>
<th>Active substance(s)</th>
<th>Proto-AEs 08 Jan 15</th>
<th>Mentions Jan 15</th>
<th>% proto AEs</th>
</tr>
</thead>
<tbody>
<tr>
<td>Ritalin</td>
<td>methylphenidate</td>
<td>4912</td>
<td>117492</td>
<td>4.18%</td>
</tr>
<tr>
<td>Methylphenidate</td>
<td></td>
<td>130</td>
<td>7940</td>
<td>1.64%</td>
</tr>
</tbody>
</table>

Personal communication, D Lewis 2016
Social media conversations on Ritalin over time

October → November – academic work, cold season, contributing to increase mentions

March → April – academic work contributing to increase
HPV vaccine and link with chronic fatigue syndrome

Pre-planned epidemiology study using Clinical Practice Research Datalink confirmed no evidence of increased risk of chronic fatigue syndrome

Results: The number of spontaneous reports of chronic fatigue following Cervarix vaccination was consistent with estimated background rates even assuming low reporting. Ecological analyses suggested that there had been no change in the incidence of fatigue syndromes in girls aged 12–20 years after the introduction of the vaccination, despite high uptake (IRR: 0.94, 95% CI: 0.78–1.14). The SCCS, including 187 girls, also showed no evidence of an increased risk of fatigue syndromes in the year post first vaccination (IRR: 1.07, 95% CI: 0.57–2.00, p = 0.84).
Media Monitoring of the HPV Vaccines Debate – What the public wants to know and experts should address

Priya Bahri, Julianna Fogd, Irina Caplanusi, Andrej Segec, Xavier Kurz, European Medicines Agency (EMA), on behalf of the IMI-ADVANCE consortium. For more information email: priya.bahri@ema.europa.eu
4. Results

A total of 4230 articles ("news clips"), including 493 blog posts were collected.

MM of online news in most EU languages **60-100 items** identified daily

Analysis of topics, concerns and information gaps, translation into “**virtual questions**”

When EU review started, public debate moved from **personal** to **scientific** points

Virtual questions grouped into 12 question areas - public had **wide** information needs

MM helped **assessors & decision-makers** ensure that **public concerns** were covered by the EU assessment, & adequate **details** provided in public statements on outcome
Moving forward on the basis of evidence

Where to look?

How collect, analyse data?

Language/terminology?

Validation?

Duplicate detection?

Etc, etc

Blogs

Email alerts

Forums
Moving forward on the basis of evidence

Innovative Medicines Initiative WEB-RADR consortium

How can we make **best use** of these new technologies to enhance pharmacovigilance?

Can use of social media be harnessed to support regulatory **decision-making in PV**?

What are the **legal & ethical** implications?

What **policy & guidance** need to be in place to ensure that data are used appropriately?
How may social media contribute to regulatory decisions?

- Signals in certain therapeutic areas and types of harms (quality defects)
- Hard-to-reach areas outside “traditional” pharmacovigilance eg misuse & abuse
- Timeliness and geographical location
- Research tool that identifies ‘user needs’, feeding into content strategies

Helping regulators to fill the “knowledge gap” more comprehensively and quickly
Patients are speaking - shouldn’t we be listening?

Meet patients where they’re at

Protect their privacy

Give them easy to-use tools