EUROPEAN MEDICINES AGENCY
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Real-time global media monitoring and 'derived questions' for enhancing communication by regulatory bodies - the case of HPV vaccines

Symposium:
Building Trust, Managing Risk: Vaccine Confidence and Human Papillomavirus Vaccination
London, 7-8 June 2017

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Declarations:

The views expressed in this presentation are the personal views of the presenter and the authors of the referenced article and may not be understood or quoted as being made on behalf of or reflecting the position of the European Medicines Agency or one of its committees or working parties.

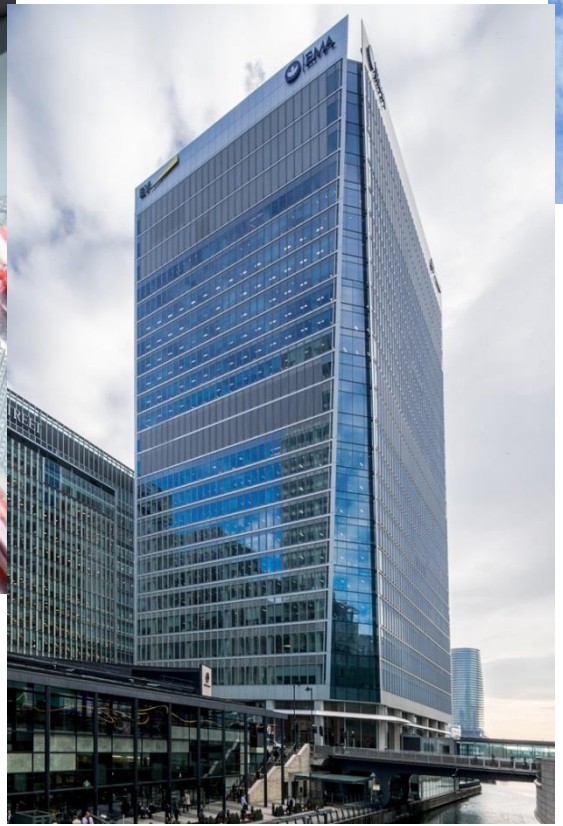
The presenter and the authors have no conflict of interests to declare.

Note: It is not the objective of this presentation or the referenced article to provide information on the safety profile of HPV vaccines or to explain the outcome of the EU referral procedure on HPV vaccines and CRPS/POTS, as these are presented elsewhere.

1 P Bahri: Media monitoring for communication at regulatory bodies – HPV vaccines

Funding

The study was conducted for the Accelerated Development of VAccine benefit-risk Collaboration in Europe (ADVANCE). The research leading to these results has received support from the Innovative Medicines Initiative (IMI) Joint Undertaking under ADVANCE Grant Agreement n° 115557, resources of which are composed of financial contribution from the European Union's Seventh Framework Programme (FP7/2007-2013) and in kind contribution of companies which are members of the European Federation of Pharmaceutical Industries and Associations (EFPIA). All authors have completed the International Committee of Medical Journal Editors (ICMJE) uniform disclosure form and declare that no support has been received from any organisation for the submitted work other than from the European Union's Seventh Framework Programme, and that there are no other financial or non-financial relationships with any organisation that could appear to have influenced the submitted work.


EMA

Usual media monitoring at a regulatory body

Daily with **reference to the organisation**:

- New medicines
- Safety concerns with medicines
- Policies and regulatory requirements
- Stakeholder interactions
- Political news relating to science, health, medicines, the organisation

Does
medicinal product-specific media monitoring
have the potential to enhance communication in
terms of proactivity and preparedness
for information provision to the public
by a regulatory body?

July – November 2015

at EMA's Pharmacovigilance Risk Assessment Committee (PRAC)

EU review procedure for HPV vaccines and complex regional pain syndrome (CRPS) / postural orthostatic tachycardiasyndrome (POTS) reported to the authorities as suspected adverse reactions

Communication challenges

- Media debates on vaccines
- Misinformation on vaccines
- Population diversity and vaccine hesitancy
- Debate in the public domain on HPV vaccines on benefits, risks and behavioural impact since vaccine launch
- Personal stories of CRPD and POTS with ‘dread factor’ and involving young females
- Society with complex technologies, ‘risk society’ and ‘post-trust society’

Media monitoring of
global online news on HPV vaccines
prospectively in real-time every day Sep-Dec 2015
using the Vuelio® tool

4230 selected news items
personal stories, scientific
and regulatory topics

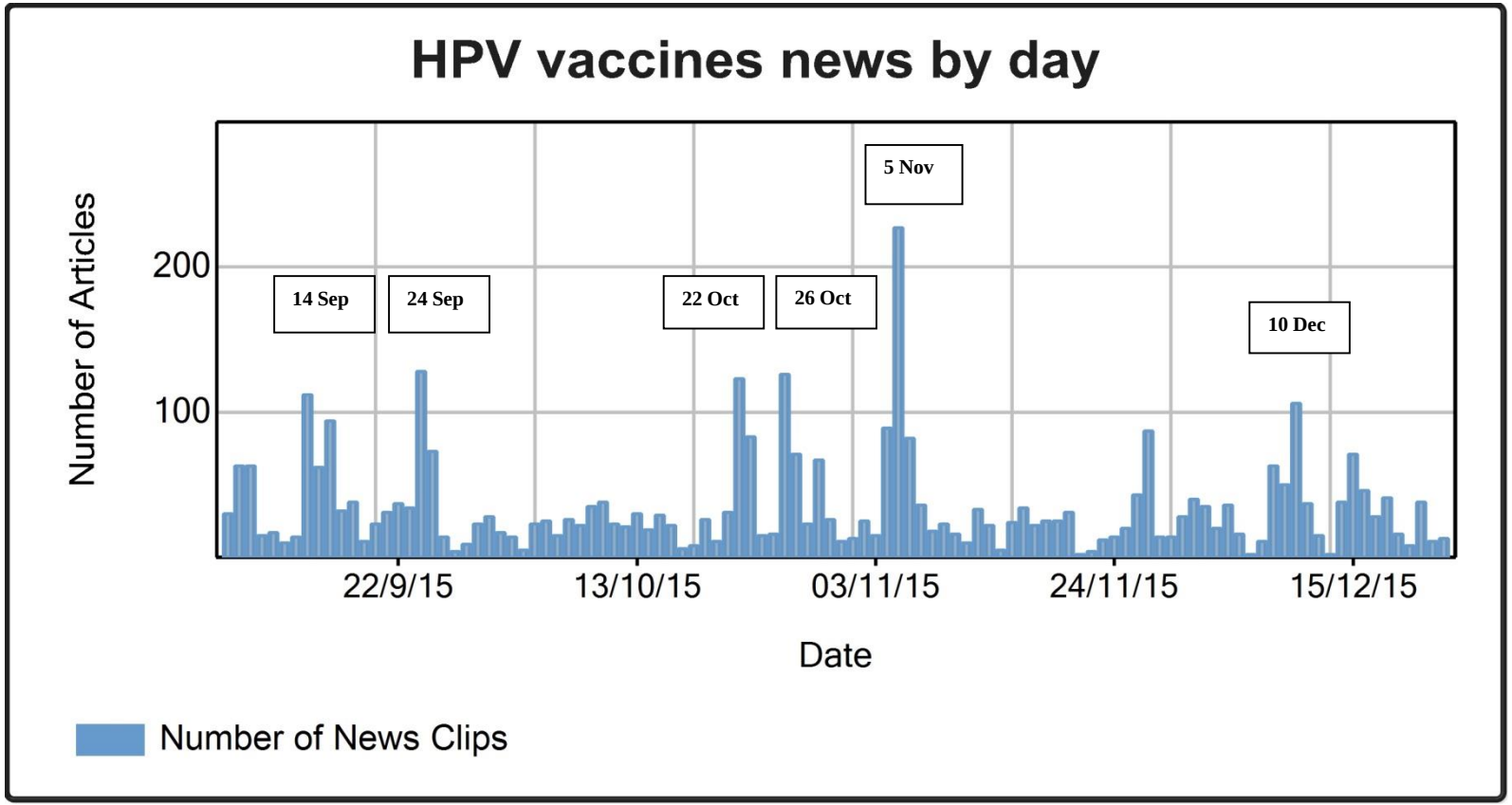


Figure 1. Time chart depicting volume of worldwide media coverage from 7 September to 23 December 2015 by day and identifying peaks (generated by the Vuelio® system)

Inductive media content analysis

- Interpreting the explicit and implicit content, connotations and underlying assumptions
- Identifying explicit and implicit questions, including those raised due to lack of specific knowledge or anticipated once more information would be provided in the public domain, information needs and expectations of the public (subpopulations)
- Formulating them as ‘derived questions’ in abstract manner and scientific-regulatory language and concepts
- Categorising 50 derived questions in 12 themes

Examples for derived questions

3.3. What is the likely magnitude of underreporting, and has a sensitivity analysis been performed for the observed/expected analysis to take underreporting into account?

8.1. What safeguards are there to ensure that marketing authorisation holders do not manipulate data they submit to the authorities?

Derived questions theme categories

1 Assessment scope

2 Case data

3 Frequency

4 Other data

5 Causal association

6 Overall safety

7 Aluminium

8 Data trustworthiness

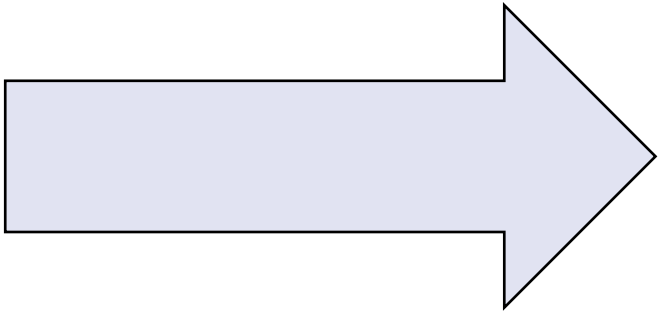
9 Standards and integrity

10 Benefit

11 Benefit-risk balance

12 Further steps and research

Media content analysis
- Weekly
- Cumulatively (derived questions)



EMA's Pharmacovigilance Risk Assessment Committee (PRAC)

EMA's Media Office

Utility of medicinal product-specific media monitoring

The evaluation demonstrated that providing the media monitoring findings to assessors and communicators resulted in:

(1) confirming that public concerns regarding CRPS and POTS would be covered by the ongoing EU review or previous assessments;

(2) meeting specific information needs proactively in the public statement on the EU review outcomes;

(3) altering the tone of the public statement with respectful acknowledgement of the health status of patients with CRSP or POTS;

(4) predicting all queries from journalists at media briefing and after.

→ Utility for regulatory bodies to support evidence-based communication proactivity and preparedness for immediate responses in talking points demonstrated

Conclusions

- Prospective real-time media monitoring could form part of regular surveillance for medicines of high public interest
- Development of efficient monitoring strategies is recommended
- Translation of media content in scientific-regulatory concepts and language with familiar **question** format and neutral framing fits regulatory thought process and focusses on fulfilling public information needs

⇨ Empowering and facilitating **dialogue**

Reference:
Bahri P, Fogd J, Morales D, Kurz X, on behalf of the ADVANCE consortium. Application of real-time global media monitoring and 'derived questions' for enhancing communication by regulatory bodies: the case of human papillomavirus vaccines. BMC Medicine. 2017; 15:91 (E-publication ahead of print 3 May 2017) [open access]

Thank you for your attention

Further information

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