Supporting Public Health Globally via the Use of Terminology Standards

Use of MedDRA in Adverse Event Reporting

ICH
harmonisation for better health

MedDRA was developed under the auspices of the International Council for Harmonisation of Technical Requirements for Registration of Pharmaceuticals for Human Use (ICH). The activities of the MedDRA Maintenance and Support Services Organization (MSSO) are overseen by an ICH MedDRA Management Board, which is composed of the six ICH parties (EU, EFPIA, MHLW, JPMA, FDA, PhRMA), the Medicines and Healthcare products Regulatory Agency (MHRA) of the UK, Health Canada, and the WHO (as Observer).

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Objectives of this Presentation

- Role of MedDRA in supporting public health:
  - What is MedDRA?
  - How MedDRA used is used?
  - Who uses it?
  - Examples of use
- Role of MedDRA in helping to improve adverse event reporting
  - Use of mobile apps to report adverse drug reactions
  - Use of social media?

Background

What is MedDRA?

Med = Medical

D = Dictionary for

R = Regulatory

A = Activities

Supports public health by facilitating safety monitoring of medical products

MedDRA Definition

MedDRA is a clinically validated international medical terminology used by regulatory authorities and the regulated biopharmaceutical industry. The terminology is used through the entire regulatory process, from pre-marketing to post-marketing, and for data entry, retrieval, evaluation, and presentation.

MedDRA Features

- 80K terms arranged hierarchically
- Classification for a wide range of clinical data
- Available in 11 languages
- Rigorously maintained
- Required component for electronic reporting

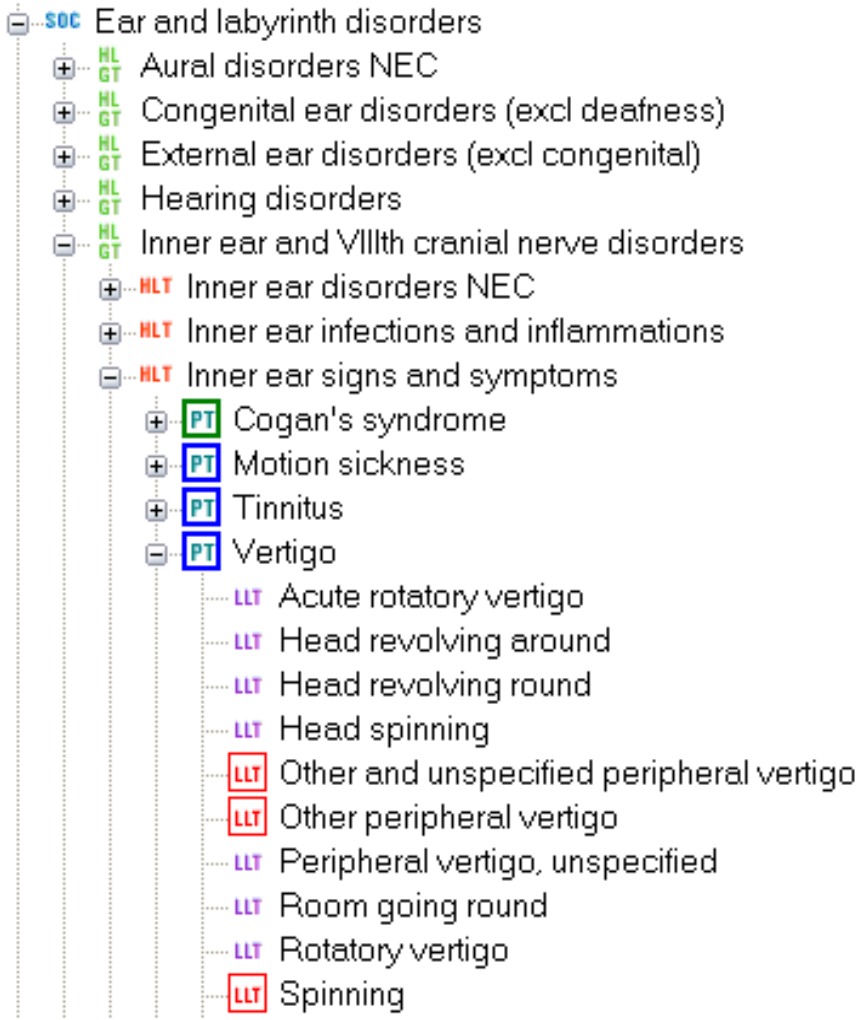
Scope of MedDRA

IN

Medical conditions
Indications
Investigations (tests, results)
Medical and surgical procedures
Medical, social, family history
Medication errors
Product quality issues
Device-related issues
Pharmacogenetic terms
Toxicologic issues
Standardized queries

MedDRA Structure

MedDRA Structure (cont)



Users

Regulatory Use

- True international standard for adverse event (AE) reporting and analysis
- US FDA
  - Not mandated but *de facto* standard in US
  - Used in several FDA databases
- Japanese Ministry of Health, Labour and Welfare
  - Mandatory use in electronic reporting
- European Union
  - Mandatory use in electronic reporting
  - EudraVigilance database
  - Good Pharmacovigilance Practices (GVP) specifically mention MedDRA
- Biopharmaceutical industry

Regulatory Use (cont)

- US FDA databases using MedDRA
  - Center for Drug Evaluation and Research (CDER)
    - FAERS (drugs and biologics)
  - Center for Biologics Evaluation and Research (CBER)
    - VAERS (vaccines)
  - Center for Food Safety and Applied Nutrition
    - CAERS (food, dietary supplements, cosmetics)

Who Else Uses MedDRA?

- Non-ICH regions
- WHO's international drug monitoring center (Uppsala Monitoring Centre)
- Academic researchers
- CDC
- Toxicologists
- Others

More than 5,000 subscribing organizations worldwide in more than 100 countries

Examples of Use

Where MedDRA is Used

Regulatory Authority and Industry Databases

Individual Case Safety Reports and Safety Summaries

Clinical Study Reports

Investigators' Brochures

Core Company Safety Information

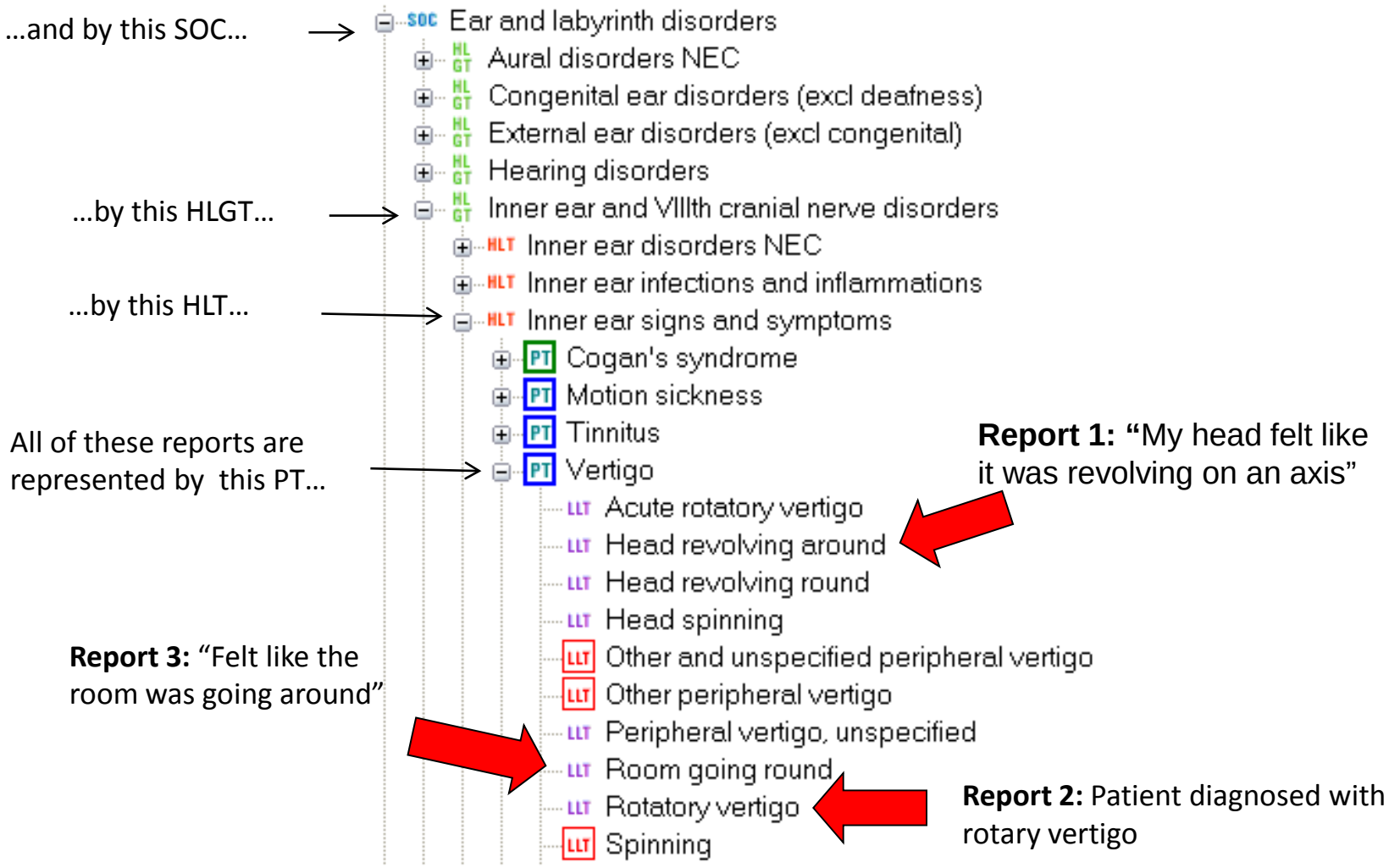
Marketing Applications

Publications

Prescribing Information

Advertising

How MedDRA is Used



Codes and Languages

Improving adverse event reporting

State of Adverse Event Reporting

- Publications describe high levels of under-reported adverse events
  - 95% of all AEs and 80% of serious AEs are under-reported[1]
  - Hospital staff did not report 86% of events to incident reporting systems[2]
- This leaves a large percentage of data to be collected

Sources: 1 – Hazell L, Shakir S. Under-Reporting of Adverse Drug Reactions - A Systematic Review. Drug Safety. 2006.
2 – Levinson D. Hospital incident reporting systems do not capture most patient harm. OEI-06-09-00091. 2012

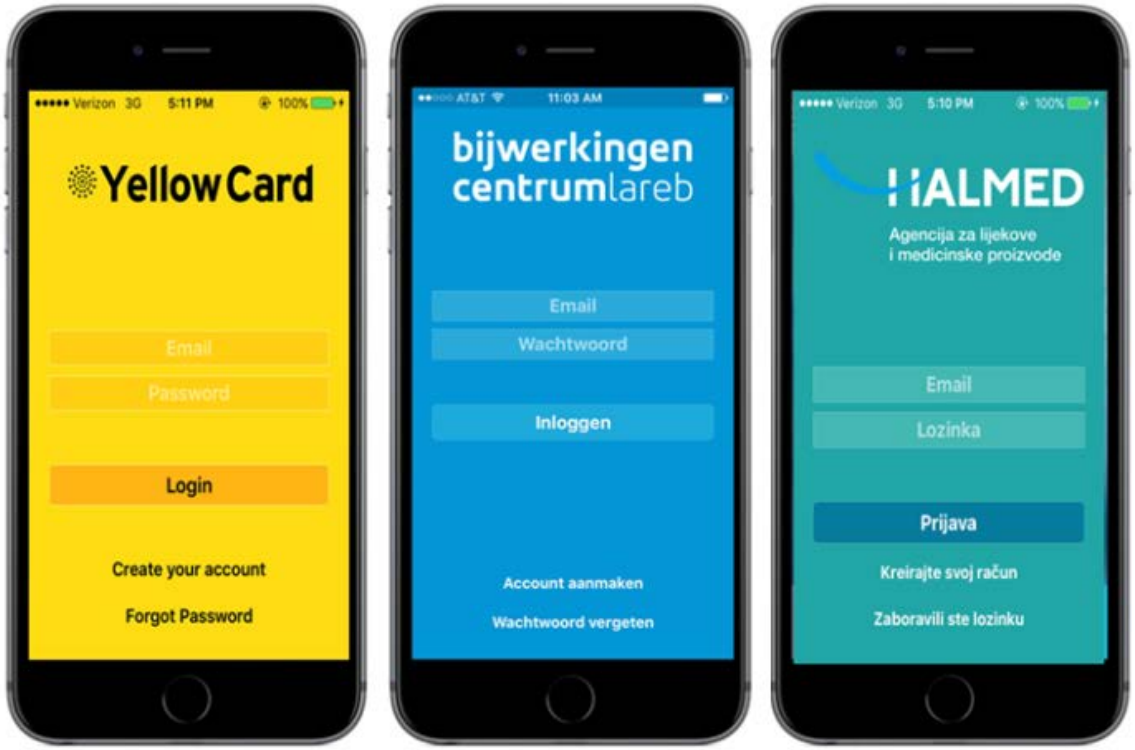
Collecting More Data

- In response to the known under-reporting of AEs, regulators and industry are under pressure to be more proactive to find alternative sources
  - Mining electronic health records
  - Mining claims data
  - Social media sources
  - Direct patient reporting via mobile apps and web portals

WEB-RADR

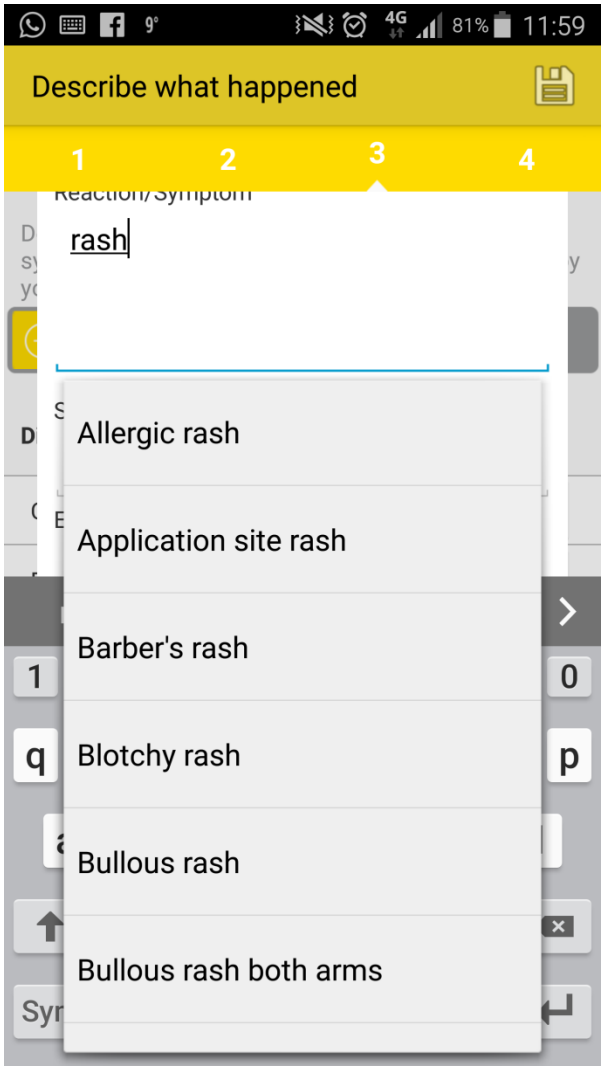
- WEB Recognising Adverse Drug Reactions
- EU consortium under Innovative Medicines Initiative
- Three year project (Sep 2014-2017)
- Developing mobile apps for ADR reporting
- Investigating use of social media to identify drug safety issues

Mobile Apps



- Report adverse drug reactions
- Receive information and news alerts
- Patients, caregivers, healthcare professionals
- Mobile apps recently launched in Burkina Faso and Zambia

Yellow Card App

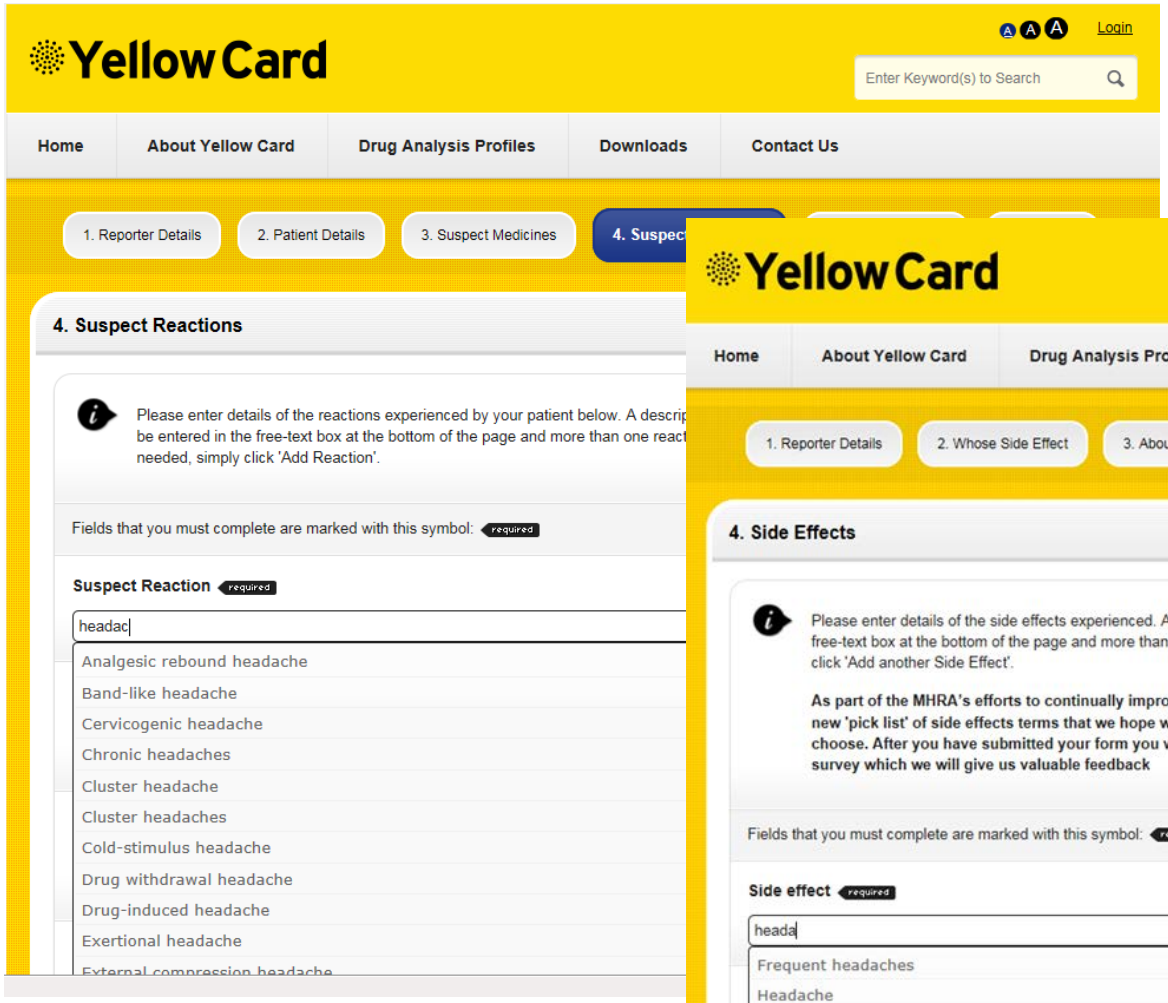


- MedDRA PTs/LLTs embedded
- Free text option
- Good specificity for analysis
- MedDRA can present challenges
  - >200 “rash” terms
  - Granularity may overwhelm users

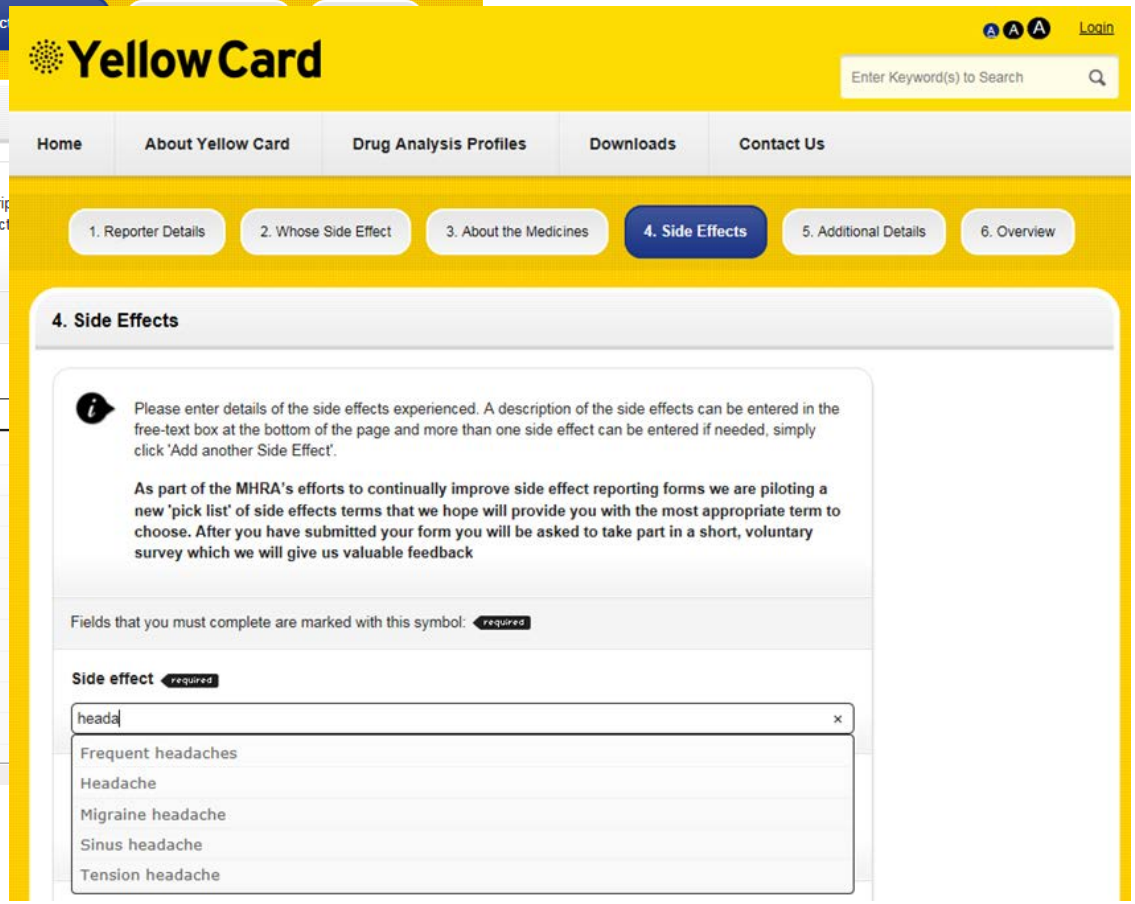
Patient Friendly Terms

- Developed a set of MedDRA terms that are “patient friendly” to support patient reporting through mobile apps and web portals
- Currently testing a set of ~1,500 terms
  - In Yellow Card app
  - Feedback from patient focus groups

All Headaches vs. Patient Friendly Headaches



75 terms

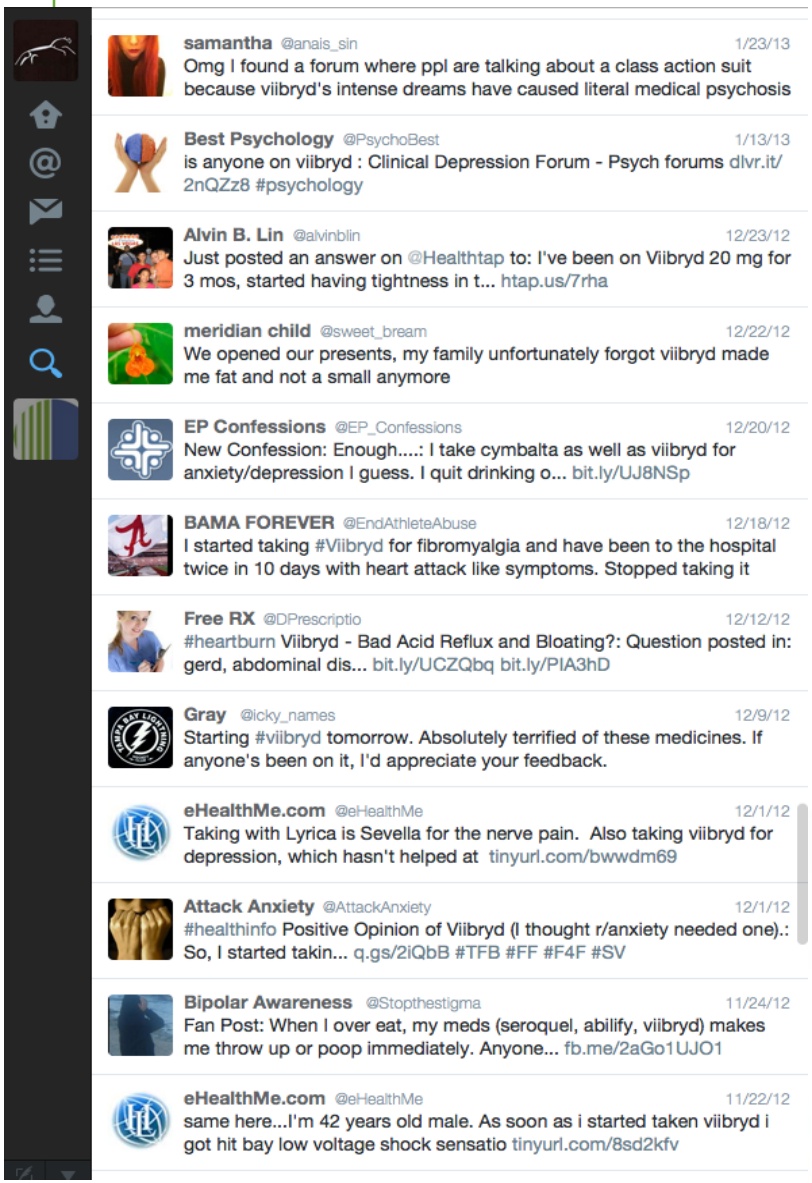


5 terms

Use of Social Media to Identify Adverse Events?

- WEB-RADR project investigated using Facebook, Twitter, internet patient forums as data sources
  - Look for mention of drug name and words that might represent an adverse event
  - Could “adverse event” words be converted into MedDRA terms for reporting?

Twitter Data



samantha @anais_sin 1/23/13
Omg I found a forum where ppl are talking about a class action suit because viibryd's intense dreams have caused literal medical psychosis

Best Psychology @PsychoBest 1/13/13
is anyone on viibryd : Clinical Depression Forum - Psych forums dlvr.it/2nQZz8 #psychology

Alvin B. Lin @alvinblin 12/23/12
Just posted an answer on @Healthtap to: I've been on Viibryd 20 mg for 3 mos, started having tightness in t... htap.us/7rha

meridian child @sweet_bream 12/22/12
We opened our presents, my family unfortunately forgot viibryd made me fat and not a small anymore

EP Confessions @EP_Confessions 12/20/12
New Confession: Enough....: I take cymbalta as well as viibryd for anxiety/depression I guess. I quit drinking o... bit.ly/UJ8NSp

BAMA FOREVER @EndAthleteAbuse 12/18/12
I started taking #Viibryd for fibromyalgia and have been to the hospital twice in 10 days with heart attack like symptoms. Stopped taking it

Free RX @DPrescriptio 12/12/12
#heartburn Viibryd - Bad Acid Reflux and Bloating?: Question posted in: gerd, abdominal dis... bit.ly/UCZQbq bit.ly/PIA3hD

Gray @icky_names 12/9/12
Starting #viibryd tomorrow. Absolutely terrified of these medicines. If anyone's been on it, I'd appreciate your feedback.

eHealthMe.com @eHealthMe 12/1/12
Taking with Lyrica is Sevella for the nerve pain. Also taking viibryd for depression, which hasn't helped at tinyurl.com/bwwdm69

Attack Anxiety @AttackAnxiety 12/1/12
#healthinfo Positive Opinion of Viibryd (I thought r/anxiety needed one).: So, I started takin... q.gs/2iQbB #TFB #FF #F4F #SV

Bipolar Awareness @Stopthestigma 11/24/12
Fan Post: When I over eat, my meds (seroquel, abilify, viibryd) makes me throw up or poop immediately. Anyone... fb.me/2aGo1UJO1

eHealthMe.com @eHealthMe 11/22/12
same here...I'm 42 years old male. As soon as i started taken viibryd i got hit bay low voltage shock sensatio tinyurl.com/8sd2kfv

Use of Social Media to Identify Adverse Events? (cont)

- Study showed limited utility of social media to detect drug safety issues
  - May be niche areas where it is more useful
    - Misuse and abuse
    - Product quality complaints
- Regulatory authorities do not recommend any changes in current adverse event reporting practices
- Use of social media data is optional

Conclusion

MedDRA supports global public health and positively impacts patient safety by providing:

- Support for safety monitoring of medical products
  - Facilitates the collection of data for analysis of potential safety signals
  - An international standard used by regulatory authorities, biopharmaceutical industry and others
  - Support for improving adverse event reporting by healthcare professionals and patients via mobile apps and web portals

Brian J. O’Hare
MedDRA Terminology Maintenance Manager

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