


How MedDRA Could Support Data Analytics in the Context of the IMI WEB-RADR Project

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Overview

- ▲ MedDRA's current role
- ▲ Collecting more data
- ▲ MedDRA prerequisites creating a hurdle?
- ▲ Social media sources vs. traditional sources
- ▲ Potential next steps?

3

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MedDRA's Current Role

- ▲ MedDRA
 - Standard for internationally accepted medical terminology for biopharmaceutical regulatory purposes
 - Incorporated in electronic submissions standards
 - In use by over 90 countries and over 5,400 organizations worldwide
- ▲ Tools and processes in place
 - Granularity
 - PtC documents for common use
 - Hierarchy and SMQs for analysis
 - Commercial software tools have embraced MedDRA

4

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MedDRA's Current Role (cont)

- ▲ With the success of MedDRA there is interest to extend the utility of MedDRA
 - Existing medication error and product quality terms
 - Manufacturing product quality terms
 - Additional device-related terms
 - Drug utilization terms
 - Labeling qualifiers
 - Discussed at the MedDRA Blue Ribbon Panel with recommendations approved by the MedDRA Management Board
- ▲ Most of this growth is organic and within the current scope of MedDRA

5



Collecting More Data

- ▲ Publications describe high levels of under reported adverse events
 - 95% of all AEs and 80% of serious AEs are under reported¹
 - Hospital staff did not report 86% of events to incident reporting systems²
- ▲ This leaves a large percentage of data to be considered

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

6



Collecting More Data (cont)

- ▲ In response to the known under-reporting of AEs, regulators and industry are under pressure to be more proactive to find alternative sources
 - Mining EHR data for AEs
 - Mining claims data
 - Social media sources
 - Direct patient reporting (e.g. Yellow Card Scheme)

7

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The Yellow Card Scheme

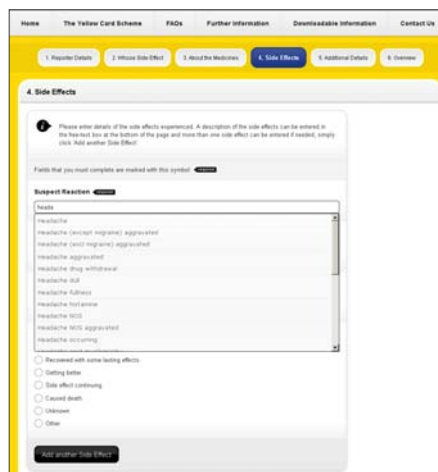
- Over 600,000 confidential reports have been received in UK
- Voluntary reports from doctors, dentists, pharmacists, coroners, nurses, midwives, health visitors
- Non-medical prescribers
- Patients since Feb 2008
- MHRA can detect duplicate reports



8

Identification of Suspect Reaction

- ▲ Start typing in suspect reaction field
 - After 3 characters MedDRA terms (LLTs) appear as potential choices
 - User can ignore the MedDRA term suggestions and enter their own text



MedDRA Prerequisites Creating a Hurdle?

- ▲ The reports collected from patients are valuable but the data must be accurately codified
- ▲ MedDRA can present challenges to patients
 - MedDRA includes over 250 rash terms
 - Accurate coding requires a knowledge of medicine, MedDRA, and the product
 - MedDRA's granularity may overwhelm some users

- ☐ Rash
 - ☐ Dry rash face
 - ☐ Dry rash neck
 - ☐ Efflorescence
 - ☐ Eruption
 - ☐ Eruption facial
 - ☐ Eruption of limbs
 - ☐ Exanthem
 - ☐ Exanthema
 - ☐ Exanthema facial
 - ☐ Extensive rash of forearm
 - ☐ Extensive rash of legs
 - ☐ Facial rash
 - ☐ Hand rash
 - ☐ Localised rash
 - ☐ Localized rash
 - ☐ Neck rash
 - ☐ Painful rash
 - ☐ Palmoplantar rash
 - ☐ Patchy rash
 - ☐ Periocular rash
 - ☐ Raised rash
 - ☐ Rash
 - ☐ Rash (nonspecific)
 - ☐ Rash aggravated
 - ☐ Rash both legs
 - ☐ Rash face
 - ☐ Rash in the outer ear
 - ☐ Rash NOS
 - ☐ Rash on face
 - ☐ Rash on legs & arms
 - ☐ Rash over arms
 - ☐ Rash peripheral
 - ☐ Rash recurrent
 - ☐ Rash trunk
 - ☐ Rash trunk & limbs
 - ☐ Skin eruption
 - ☐ Skin rash

Sample Social Media Data

- ▲ Extracts of data provided by Epidemico
- ▲ Traditional autoencoding tools without extensive tuning struggle with social media data

Reported Term	Autoencoded	Interpretation
looking like ur 5 months pregnant	Pregnancy	Abdominal distension
miss feeling hunger	Hunger	Decreased appetite
throat was bone dry	Bone in throat	Dry throat
feels like lead	Lead	Sensation of heaviness

11

Sample Social Media Data (cont)

- ▲ Other terms are just difficult to interpret

Reported Term	Autoencoded	Interpretation
merrygoround in hell	Not coded	Dizziness
shutting off my third eye	Not coded	Depressed level of consciousness
subwoofer in my head	Not coded	Headache
thinking she was a pirate	Not coded	Abnormal dreams

12

What Could be Done?

- ▲ Interoperability is needed
 - Ability of different systems to communicate, exchange data, and use the information that has been exchanged
- ▲ In MedDRA's context, develop mechanisms to allow data collected in one domain and convert it for use with MedDRA
 - Typically, this involves mappings
 - Mappings have limitations
 - In the case of social media sourced data, the focus should be on overall data, not specific reports so the limitations of mappings are reduced

13



What Could be Done? (cont)

- ▲ How can this be addressed?
 - Develop a mapping to support the conversion of patient friendly terms to MedDRA
 - Focus on commonly reported patient terms
 - Multiple sources exist
 - Regulatory systems collecting patient reports today (e.g., MHRA)
 - Reports received from manufacturers (e.g., Consumer reports)
 - Request data from current efforts (e.g., Epidemico)
 - Maintained by the MSSO with each version of MedDRA
 - Users could propose additions or revise existing terms
 - Need to limit the size
 - Can't accept all organizations' synonym lists

14



What Could be Done? (cont)

- ▲ Should this concept be extended to medical synonyms that are currently not included in MedDRA?
 - Amyotrophic lateral sclerosis (ALS), often referred to as "Lou Gehrig's Disease" in the US
 - Current MedDRA rules exclude language or cultural specific terms since they are not meaningful internationally

15

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How about languages other than English?

- ▲ Should we consider patient friendly terms or synonyms in other languages?
 - Content would be different for each language
 - Linked to a single MedDRA term
 - Extends the utility of MedDRA translations
 - Requires version specific maintenance

16

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Possible Format

Term	MedDRA Term	Category
Lou Gehrig's Disease	Amyotrophic lateral sclerosis	Synonym
Passed away	Death	Patient
Can't eat	Decreased appetite	Patient
Can't concentrate	Mental concentration difficulty	Patient
Nothing has worked	Drug ineffective	Patient

- ▲ Categorize terms for end user selection
- ▲ Made available as an ancillary file on MedDRA website

17



Potential Benefits

- ▲ Easier for patients to make reports
- ▲ Potential increased reporting
- ▲ Consistent mapping from patient data (from any source) to MedDRA
- ▲ Maintained
- ▲ Extends the utility of MedDRA

18



Your Feedback?

- ▲ I'm interested to hear your thoughts so I can bring this idea to the MedDRA Management Board