Data retrieval using the new SMQ Medication Errors

Christina Winter
Medical Director
Safety Evaluation and Risk Management, GSK

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Outline

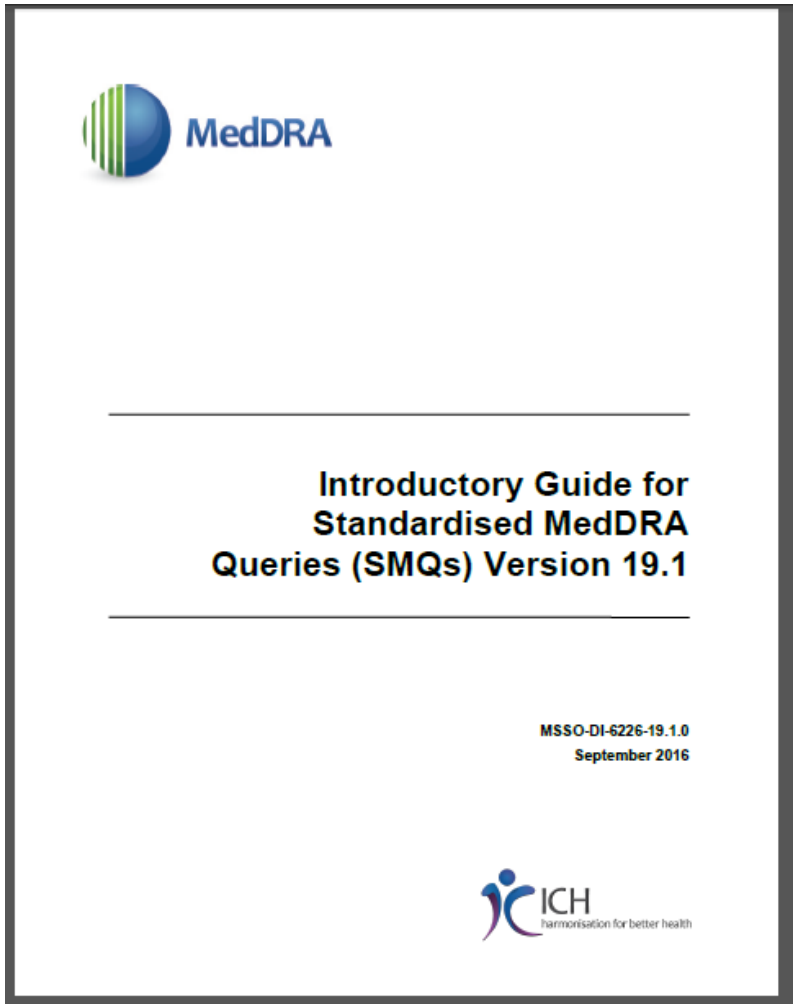
- Background of SMQs
- What is the *Medication Errors* SMQ (SMQ ME)?
  - Definition / Inclusion / Exclusion criteria
  - Advantages/ Limitations of SMQ ME
- How to use SMQ ME
- Possible applications
  - Data query (in post marketing database)
  - Signal detection
  - Risk management: frequency monitoring
  - Automated alerts
  - Periodic safety reporting (e.g. PBRERs, RMPs)

Background: Standardised MedDRA Queries (SMQs)

- Created to standardise identification and retrieval of safety data.
- Joint effort of Council for International Organizations of Medical Sciences (CIOMS) and ICH (including MSSO and JMO)
  - Representing industry and regulatory authorities.
- SMQ is a grouping of terms from one or more SOCs related to condition of interest
  - signs, symptoms, diagnoses, syndromes, physical findings, laboratory and other physiologic test data associated with the condition of interest.

What is the *Medication errors* SMQ?

- SMQ must match MedDRA version of dataset
- Refer to appropriate MSSO "Introductory guide to SMQs"
  - Updated for MedDRA Versions



Introductory guide to SMQs

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2.60 Medication errors (SMQ)

(Production Release March 2016)

2.60.1 Definition

- Medication errors are defined as any preventable events that may cause or lead to inappropriate medication use or patient harm while the medication is in the control of the health care professional, patient or consumer.
  - Such events may be related to professional practice, health care products, procedures and systems, including prescribing, order communication, product labeling, packaging and nomenclature, compounding, dispensing, distribution, administration, education, monitoring and use.
  - A medication error can ultimately result in an adverse drug reaction (medication error with an ADR) or may have no clinical consequences (medication error without an ADR).
  - A medication error can also be intercepted prior to the patient's exposure to the error.
  - A potential medication error is a scenario which does not involve an actual patient, and represents circumstances or information capable of leading to the occurrence of a medication error
- Medication errors cause a large number of ADRs annually:
  - create a major public-health burden representing 18.7–56% of all adverse drug events among hospital patients.
  - may cause unintended harm
  - are considered preventable.
- Medication errors result from a variety of human (e.g., healthcare professional; care giver; patient) and product-related reasons, for example:
  - miscommunication of drug orders due to poor handwriting
  - confusion between drugs with similar names
  - poor packaging design
  - confusion of dosing units
  - unclear instructions
- Medication errors can have an impact on:
  - patients
  - healthcare professionals

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Medication errors (MEs)

Definition (from SMQ Introductory guide)

- Any preventable events that may cause or lead to inappropriate medication use or patient harm
  - while the medication is in the control of the health care professional, patient or consumer.

Definition (from EMA GPG*)

- *A medication error is an unintended failure in the drug treatment process that leads to, or has the potential to lead to, harm to the patient.*

*Good practice guide on recording, coding, reporting and assessment of medication errors EMA/762563/2014

Medication errors (2)

Types of MEs* *(classification**)*

- Result in an adverse drug reaction *(Error with ADR)*
- No clinical consequences *(Error without harm)*
- Intercepted prior to patient exposure *(Intercepted error)*
- Circumstances /information that may lead to ME *(Potential error)*

*Introductory guide to SMQs

** *EMA GPG*

Inclusion criteria

- Narrow scope PTs
  - refer to a ME according to the definition

- Broad scope PTs
  - do not specifically represent a ME
  - but have significant potential to identify ME (due to frequent association with MEs)
    - E.g. product label issue terms, product exposure terms,
  - and terms referring to administration of contraindicated drugs or other unapproved uses

Exclusion criteria (1)

- Intentional/deliberate use terms: by definition these are not medication errors
- Product contamination terms
- Transmission of infectious agent terms
- Off label use terms
- Drug interaction terms
- Counterfeit product terms

Exclusion criteria (2)

- Drug incompatibility terms
- Exposure terms that do not refer to product or drug exposure such as PT *Exposure to body fluid*
- Terms for non-specific and broad concepts that might produce substantial "noise" in data retrieval, e.g., PT *Device issue, PT Product quality issue, PT Poisoning, PT Treatment noncompliance*

Advantages / Limitations of SMQ ME

- Advantages of using SMQ ME
  - Standardised – regulatory agencies and industry use common search criteria
  - Maintained by MSSO (for MedDRA versions)
- Limitations
  - Difficulties in coding (found during SMQ development) affect PT inclusion
  - SMQs evolve
    - Modifications for MedDRA versions
    - Included PTs may change as coding improves (users becoming more accustomed to and selecting more specific ME terms)

Difficulties in coding: examples (1)

- Draft SMQ tested in 4 databases (3 regulators & 1 industry)
- *Failure of child resistant mechanism for pharmaceutical product.*
  Accidental ingestion not coded. Two cases: low noise level. Narrow PT.
- *Device infusion issue, Product expiration date issue.*
  Moderate number of cases, some MEs. Broad PTs.
- *Device difficult to use.*
  >1000 cases. Mostly product complaints but may be used to code MEs. Broad PT

Difficulties in coding: examples (2)

- *Overdose*

  >1000 cases. Some were accidental overdoses (miscoding). Broad PT

- *Product quality issue.*

  >2000 cases: few were ME. High noise level. PT excluded

- *Off label use*

  >7000 cases. Few co-reported terms that were MEs. Too noisy. PT excluded

- *Intentional product misuse*

  >13,000 cases. Very few ME. Too noisy. PT excluded

Coping with limitations

- Consider whether the dataset has common coding errors
  - Conduct SMQ search first?
  - Conduct supplementary search for PTs known to be common coding errors?
- SMQs change with MedDRA versions
  - Document version number so that current SMQ content can be compared against future versions of this SMQ
- Possible future revision of SMQ ME to remove “noisy” terms (currently included to retrieve inaccurately coded cases)
  - Document version number of SMQ for each search

SMQ ME v19.1 *89 Narrow & 41 Broad PTs*

Narrow	Accidental device ingestion
Narrow	Accidental device ingestion by a child
Narrow	Accidental exposure to product
Narrow	Accidental exposure to product by child
Narrow	Accidental exposure to product packaging
Narrow	Accidental exposure to product packaging by child
Narrow	Accidental overdose
Narrow	Accidental poisoning
Narrow	Accidental underdose
Narrow	Accidental use of placebo
Narrow	Booster dose missed

Broad	Complication of drug implant insertion
Broad	Contraindication to medical treatment
Broad	Contraindication to vaccination
Broad	Device adhesion issue
Broad	Device connection issue
Broad	Device difficult to use
Broad	Device infusion issue
Broad	Device use issue
Broad	Device-device incompatibility
Broad	Difficulty removing drug implant
Broad	Exposure to contaminated device

How to use SMQ ME

- Obtain “Introductory guide to SMQs” (same MedDRA version as dataset)
  - Review definition/inclusion/exclusion criteria
- Chose narrow or broad search.
  - Narrow (scope) search includes narrow PTs
  - Broad (scope) search includes narrow **and** broad PTs
- Run the appropriate search
  - If SMQ not automated in database, appropriate PTs may be copied from MedDRA browser or SMQ excel spreadsheet from MSSO
- **Manual review of the search output**

Possible applications of SMQ ME (1)

- Data query
  - In postmarketing database (as described in previous slide)
  - Clinical trials: Errors may be recorded as protocol violations instead of ME. Check protocol violations as well as use of SMQ ME.
- Signal detection
  - Signal detection often uses PTs but may apply any MedDRA hierarchical level.
  - SMQs can also be utilised in some signal detection tools.

Possible applications of SMQ ME (2)

- Risk management: frequency monitoring
  - Potentially useful tool to monitor the reporting rate of MEs
  - Standardised set of terms
  - Maintained for MedDRA versions
- Automated alerts
  - Retrieve cases coded with any of the SMQ ME PTs for medical review and follow up
- Periodic safety reporting (e.g. PBRERs, RMPs)
  - Consistent retrieval of ME cases for assessment and reporting

What SMQ ME will not do

- Data retrieved with SMQ ME requires manual review
  - Accurate coding at data entry could reduce effort required to review search output
- SMQ ME cannot fully classify retrieved cases into categories required by EU*
  - No codes for “Error with ADR” and “Error without harm”

*Good practice guide on recording, coding, reporting and assessment of medication errors EMA/762563/2014

Summary

- Check MedDRA version
- Read relevant section of “Introductory guide to SMQs”
- Determine appropriate search scope (narrow or broad)
- Consider strategy for common miscoded cases (if relevant)
- Review search output manually

References (1)

- MSSO website

http://www.meddra.org/how-to-use/support-documentation

Look for MedDRA version-specific copies of

- “Introductory guide to Standardised MedDRA Queries”
- ICH MedDRA Data Retrieval and Presentation: Points to Consider. [See section 4, Standardised MedDRA Queries]

References (2)

- Council for International Organization of Medical Sciences (CIOMS) publication

  "Development and Rational use of Standardised MedDRA Queries (SMQs): Retrieving Adverse Drug Reactions with MedDRA" 2nd Edition. 2016

- Available at

http://www.cioms.ch/index.php/publications/order-formv3

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