Medication errors

MedDRA User Group
Vienna, 28 March 2014

Presented by: Victoria Newbould
European Medicines Agency
HMA meeting 28 November 2013

- HMA agreed with the deliverables to be completed over the next 21 months (Jan 2014 – Sep 2015) and Member States to provide input via existing development frameworks:
  - Governance structure for the implementation of the pharmacovigilance legislation
    - Project Team 1* for good practice guide (technical) for reporting errors
    - Project Team 2# for good practice guide (scientific) for risk minimisation
  - SCOPE (EC’s Joint Action) for awareness campaign and communication toolbox
  - MedDRA Points to Consider (PTC) Expert Group on best use of terminologies

- For all deliverables, collaboration with EC’s Patient Safety & Quality of Care Working Group (PSQCWP) is foreseen

*Project Team 1: Collection of key information on medicines
#Project Team 2: Better analysis and understanding of data and information
## Development Frameworks


<table>
<thead>
<tr>
<th>Deliverable</th>
<th>Framework</th>
<th>Good Practice Guide</th>
<th>Good Practice Guide</th>
<th>Concept Paper</th>
<th>Awareness Campaign Reporting</th>
<th>Communication Toolbox</th>
</tr>
</thead>
<tbody>
<tr>
<td>SCOPE</td>
<td>SCOP (Strengthening Collaboration for Operating Pharmacovigilance in Europe)</td>
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<tr>
<td>EMA / EU-Regulatory Network</td>
<td>(PhV Legislation Implementation)</td>
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<tr>
<td>MedDRA Points to Consider</td>
<td>Working Group</td>
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<td>Patient Safety &amp; Quality of Care</td>
<td>Working Group</td>
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Legend:
- Lead Development
- Consultation/Input
Medication error term list

• EMA Internal term list utilises HLGT ‘Medication errors’ minus HLT ‘Overdose’ and excludes Counterfeit terms.

• Includes some terms from Product Quality issues.

• Further discussion needed for other product quality terms /device terms/overlap with misuse and off label.
## Cases of Medication error in EudraVigilance based on EMA internal list

<table>
<thead>
<tr>
<th>Origin</th>
<th># Cases (serious and non serious)</th>
<th>% of total cases in EV (serious and non serious)</th>
<th># Cases (serious only)</th>
<th>% of total cases in EV (serious only)</th>
</tr>
</thead>
<tbody>
<tr>
<td>EEA</td>
<td>20,257</td>
<td>1.48</td>
<td>13,690</td>
<td>1.28</td>
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<tr>
<td>Non EEA</td>
<td>68,267</td>
<td>3.06</td>
<td>41,195</td>
<td>2.17</td>
</tr>
</tbody>
</table>
EU and non EU cases (Serious and non serious)

- Inappropriate schedule of drug administration
- Medication error
- Incorrect dose administered
- Drug administration error
- Wrong technique in drug usage process
- Drug dose omission
- Incorrect route of drug administration
- Expired drug administered
- Incorrect storage of drug
- Treatment noncompliance
- Wrong drug administered
- Incorrect drug administration duration
- Drug prescribing error
- Drug dispensing error
- Drug administered at inappropriate site
- Product substitution issue
- Drug administered to patient of inappropriate age
- Circumstance or information capable of leading to medication error
- Poor quality drug administered
- Incorrect drug administration rate
- Device misuse
- Labelled drug-drug interaction medication error
- Incorrect product storage
- Incorrect drug dosage form administered
- Contraindication to vaccination
- Drug name confusion

0 5,000 10,000 15,000 20,000
<table>
<thead>
<tr>
<th>Prescribing</th>
<th>Dispensing</th>
<th>Preparation</th>
<th>Administration</th>
<th>Monitoring</th>
</tr>
</thead>
<tbody>
<tr>
<td>Booster dose missed</td>
<td>Booster dose missed</td>
<td>Accidental use of placebo</td>
<td>Accidental exposure to product</td>
<td>Accidental use of placebo</td>
</tr>
<tr>
<td>Circumstance or information capable of leading to medication error</td>
<td>Circumstance or information capable of leading to device use error</td>
<td>Drug administration monitoring procedure not performed</td>
<td>Circumstance or information capable of leading to device error</td>
<td>Circumstance or information capable of leading to device error</td>
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<tr>
<td>Documented hypersensitivity to administered drug</td>
<td>Drug administered to patient of inappropriate age</td>
<td>Drug administration monitoring procedure incorrectly performed</td>
<td>Drug administered in wrong device</td>
<td>Drug administration monitoring procedure incorrectly performed</td>
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<tr>
<td>Drug administered to patient of inappropriate age</td>
<td>Drug dispensing error</td>
<td>Incomplete course of vaccination</td>
<td>Drug administered at inappropriate site</td>
<td>Drug administration monitoring procedure incorrectly performed</td>
</tr>
<tr>
<td>Drug prescribing error</td>
<td>Drug label confusion</td>
<td>Interception of drug administration error</td>
<td>Incorrect drug administration</td>
<td>Drug administration monitoring procedure incorrectly performed</td>
</tr>
<tr>
<td>Incomplete course of vaccination</td>
<td>Expired device used</td>
<td>Drug administration monitoring procedure correctly performed</td>
<td>Inappropriate schedule of drug administration</td>
<td>Inappropriate schedule of drug administration</td>
</tr>
<tr>
<td>Intercepted drug prescribing error</td>
<td>Incorrect drug dosage form administered</td>
<td>Drug administration monitoring procedure correctly performed</td>
<td>Incorrect course of vaccination</td>
<td>Drug administration monitoring procedure correctly performed</td>
</tr>
<tr>
<td>Interception of medication error</td>
<td>Incorrect storage of drug</td>
<td>Drug administration monitoring procedure correctly performed</td>
<td>Incorrect dose administered</td>
<td>Drug administration monitoring procedure correctly performed</td>
</tr>
<tr>
<td>Labelled drug-disease interaction medication error</td>
<td>Incorrect drug dispensing error</td>
<td>Drug administration monitoring procedure correctly performed</td>
<td>Incorrect dose administered by device</td>
<td>Drug administration monitoring procedure correctly performed</td>
</tr>
<tr>
<td>Labelled drug-drug interaction medication error</td>
<td>Incorrectized medication error</td>
<td>Drug administration monitoring procedure correctly performed</td>
<td>Incorrect drug administration duration</td>
<td>Drug administration monitoring procedure correctly performed</td>
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<tr>
<td>Labelled drug-food interaction medication error</td>
<td>Incorrectized medication error</td>
<td>Drug administration monitoring procedure correctly performed</td>
<td>Incorrect drug administration rate</td>
<td>Drug administration monitoring procedure correctly performed</td>
</tr>
<tr>
<td>Medication error</td>
<td>Poor quality drug administered</td>
<td>Drug administration monitoring procedure correctly performed</td>
<td>Incorrect drug dosage form administered</td>
<td>Incorrect drug administration rate</td>
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<tr>
<td>Product dosage form confusion</td>
<td>Product administration monitoring procedure not performed</td>
<td>Drug administration monitoring procedure correctly performed</td>
<td>Incorrect drug administration rate</td>
<td>Incorrect drug dosage form administered</td>
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<tr>
<td>Vaccination error</td>
<td>Drug administration monitoring procedure not performed</td>
<td>Drug administration monitoring procedure correctly performed</td>
<td>Inappropriate drug administration rate</td>
<td>Incorrect drug dosage form administered</td>
</tr>
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<td>Product name confusion</td>
<td>Drug administration monitoring procedure not performed</td>
<td>Drug administration monitoring procedure correctly performed</td>
<td>Incorrect drug dosage form administered</td>
<td>Incorrect drug dosage form administered</td>
</tr>
<tr>
<td>Product substitution issue</td>
<td>Inappropriate schedule of drug administration</td>
<td>Drug administration monitoring procedure correctly performed</td>
<td>Incorrect drug dosage form administered</td>
<td>Incorrect drug dosage form administered</td>
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<tr>
<td>Drug chemical incompatibility</td>
<td>Incorrect route of drug administration</td>
<td>Drug administration monitoring procedure correctly performed</td>
<td>Incorrect route of drug administration</td>
<td>Incorrect route of drug administration</td>
</tr>
<tr>
<td>Drug physiologic incompatibility</td>
<td>Interception of drug administration error</td>
<td>Drug administration monitoring procedure correctly performed</td>
<td>Interception of drug administration error</td>
<td>Interception of drug administration error</td>
</tr>
<tr>
<td>Drug therapeutic incompatibility</td>
<td>Lack of injection site rotation</td>
<td>Drug administration monitoring procedure correctly performed</td>
<td>Lack of injection site rotation</td>
<td>Lack of injection site rotation</td>
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<tr>
<td>Contraindication to vaccine</td>
<td></td>
<td>Drug administration monitoring procedure correctly performed</td>
<td></td>
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<tr>
<td>Contraindication to medical treatment</td>
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MedDRA (16.1) HLGT Medication Errors minus HLT Overdose and exl counterfeit

MedDRA (16.1) HLGT Product Quality Issues
EU Serious only top 4 ME according to WHO classification

- Product substitution issue
- Drug prescribing error
- Drug dispensing error
- Drug administration error

- Drug therapeutic incompatibility
- Drug administered to patient of inappropriate age
- Drug therapeutic incompatibility
- Drug administered to patient of inappropriate age

- Wrong technique in drug usage process
- Expired drug administered
- Incorrect storage of drug
- Circumstance or information capable of leading...

- Incorrect dose administered
- Drug administration error
- Inappropriate schedule of drug administration
- Incorrect route of drug administration

- Treatment noncompliance
- Circumstance or information capable of leading...

- Contraindication to medical treatment
- Incomplete course of vaccination

- Drug therapeutic incompatibility
- Drug prescribing error
- Drug dispensing error
- Drug administration error

- Product substitution issue
- Drug prescribing error
- Drug dispensing error
- Drug administration error
Intercepted errors

- Intercepted errors or near misses are not reportable as ICSRs but there is some misunderstanding for intercepted errors, where some coders use the intercepted term to signify that the medication error did not result in any permanent harm, or that the potential for a medication error had been noticed (but still occurred)

- Intercepted errors are those which do not reach the patient and should reflect the point of interception
Monitoring errors

- ME workshop categorisation considered monitoring errors to also be where clinical/lab data is required for use of medicine e.g. blood counts for medicines with haematological effects, pregnancy tests for teratogenic drugs

- New MedDRA terms being used correctly: V 17.0
Use of plain medication error term

- Overuse of LLT ‘Medication error’
- Underuse of more specific terms:
  - Vaccine specific term, many are actually vaccine errors
  - Many of those coded as ‘Medication error’ are errors in dosing/administration/contraindication to medical treatment or misuse
  - It is not necessary to code LLT ‘Medication error’ in addition to the more specific terms
Overdose/Underdose

• Overdose is considered to be a medication error in MedDRA hierarchy. EMA consider overdose as a separate issue and have excluded this HLT from the proposed list of medication error terms as presented at the medication error workshop. (perhaps could include PT accidental overdose?)

• ‘Prescribed overdose’ in ‘Overdose’ HLT in HLGT ‘Medication errors’:
  • Should prescribed overdose to be off label use rather than a medication error

• ‘Prescribed underdose’ which is a ‘Maladministration’ in hierarchy, should we consider prescribed underdose to be off label?
  – Both require further discussion- do the concepts need to be separated?
Dose omission vs underdose

- Example: ‘Patient taking warfarin had decreased INR because container contained 2 different medicines’.

- Coded as ‘Wrong product and correct product in same container’

- Should also be a corresponding medication error term:

- Use ‘Drug dose omission’ rather than ‘insufficient dosage’
Off label vs medication error

- Drug administered to patient of inappropriate age (medication error) vs Drug use in unapproved population (off label)

- Select LLT based on knowledge of setting of ADR (off label/medication error/misuse)

- Key message – follow up if possible when it is unclear if it is an off label use or medication error
Potential off label use

• Verbatim is potential off label

• Pharmacist noticed a case of ‘off label’ and drug was not delivered to patient- would be normal practice to follow up with prescriber

  • Error- Intercepted drug prescribing error

• Off label use is intentional- ‘Intentional use for unlabelled indication’. This implies the patient did receive the drug.

• MedDRA principles for verbatim coding vs ‘intercepted off label use’ - can not occur
Examples from NHS England

- 91 year old with stage 4 chronic kidney disease on long term aspirin 75mg od. She was then prescribed Naproxen 500mg bd without gastro protection which led to gastric erosion which perforated.

  - Code: ‘Gastric perforation’
  - The lack of gastro protection is not possible to code

- Q&A following webinar- use ‘Labelled drug-drug interaction medication error’ According to EU SmPC guideline harmful additive effects are included in interactions section
Examples from NHS England

• Patient known to have seizures well controlled on carbamazepine. Ran out of supplies and could not get a repeat prescription or emergency supply and was without medication for 3 days. Went into status and admitted to hospital

• Code: ‘Status epilepticus’
• The supply issue not possible to code
V 16.1 new terms

- Accidental use of placebo (CT only)
- Lack of injection site rotation
- Therapeutic drug monitoring analysis incorrectly performed
- Therapeutic drug monitoring analysis not performed
- Device use error
- Circumstance or information capable of leading to device use error
- Booster dose missed (v 16.0*)
- Drug administration monitoring procedure incorrectly performed/Drug administration monitoring procedure not performed
  - Electrolytes not checked after diuretic/contraception not ensured with isotretinoin/muscle activity not measured in anaesthesia

- * cases in EV
V 17.0 additional terms

• Medication errors NEC HLT
  • Drug dispensed to wrong patient
  • Intercepted wrong patient selected
  • Both imply ‘near misses’

• Maladministrations HLT
  • Wrong patient received medication
    • ICSR reporting- Which patient is subject of report?
    • How to code ADRs occurring as result of NOT receiving medication? Eg lack of Insulin
    • Which medication is suspect?
V 17.0 additional terms and other considerations

• Economic circumstances HLT- ‘Unable to afford prescription medication’

• In cases where this leads to treatment non compliance and an ADR, also code ‘Treatment noncompliance’ and associated reaction.

• Treatment noncompliance has been included in EMA internal list for medication errors, for discussion if economic factors can be considered as medication errors- out of scope?

• To consider adding additional terms for incorrect quantity (eg 28 days dispensed/prescribed instead of 7)
Concepts not within scope of MedDRA

- Medication errors due to problems with supply/ordering/delivery

- Medication errors due to errors in healthcare system for example discharge medications not explained properly
Thank you
Acknowledgements (alphabetical order)

- EMA
  - Thomas Goedecke
  - Steven Le Meur