



Division of Medication Errors and Technical Support, ODS

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What is a Medication Error?

- **NCC MERP** – National Coordinating Council for Medication Error Reporting and Prevention
 - Founded in 1995; Comprised of 20+ national health care professional organizations, regulatory bodies, and industry
 - Objectives: Promote Medication Error Reporting, Medication Error Understanding, and Medication Error Prevention
 - Creation of Medication Error Taxonomy
 - www.nccmerp.org – taxonomy of medication errors available online



What is a Medication Error? (cont)

- Any PREVENTABLE event 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.

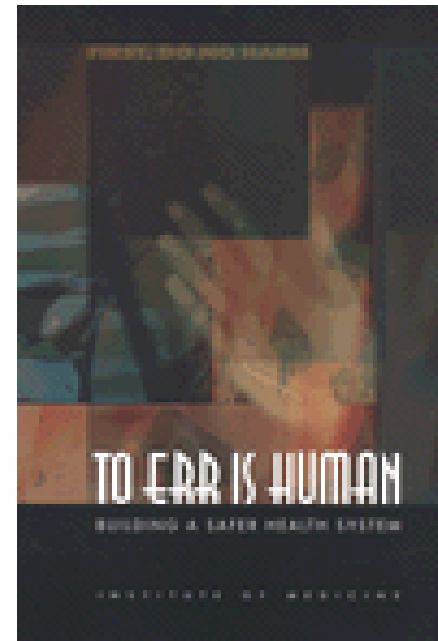


Medication Error Events

- Professional practice
- Health care products
- Procedures
- Systems
 - including prescribing; order communication; product labeling, packaging and nomenclature; compounding; dispensing; distribution; administration; education; monitoring; and use

Exposing the Problem

- The December 1999 Institute of Medicine (IOM) report, found that 48, 000 to 98, 000 people die yearly due to medical errors
- **7,000** of which are related to **Medication Errors**





DMETS' Responsibilities

Provide pre- and post-marketing assessment of medication errors resulting from nomenclature, labeling and packaging of drug products.

- **Pre-marketing**
- **Post-marketing**



Pre-marketing Assessment

- Proprietary Name Analysis (Expert Panel Review, Prescription Analysis Study, Computer Assisted Analysis)
- Labeling and Packaging Analysis
- Overall Risk Evaluation
- Written Recommendations to the Review Division



Post-marketing Surveillance

- Potential and Actual Medication Error Reports
- ~300 medication error reports per month
- Surveillance of medication errors (reports via MedWatch, USP and ISMP)
- Conduct root cause analysis
- Written recommendations to the review division (i.e., changes in the drug labels, labeling, packaging, and/or nomenclature)
- Write articles alerting and educating HCP for the purpose of error prevention
- Provides insight on how errors happen so that FDA can focus on pre-approval preventive measures

Why the expansion of medication error terms in MedDRA?

1. Limited to using only one MedDRA code in capturing, categorizing and analyzing medication error reports.
2. Difficult to retrieve under one term.
3. Inefficient use of time: Reports flagged as “medication error” were then further coded by the DMETS staff using the NCC MERP medication error taxonomy to better facilitate root cause analysis of reports.
4. IOM report and proposed SADR rule created an additional need for more medication error PTs.

Thus, the FDA proposed the expansion and inclusion of medication Error terminologies in MedDRA to help identify preventable events.

- Working in conjunction with FDA, USP, ISMP, and PhRMA, a draft of Medication Error grouping was posted on the MSSO web in August 2004 for subscriber feedback.
- A medical review team comprised of FDA, MSSO, and JMO was established to review subscriber feedback and comments.

MedDRA Version 7.1

SOC Injury, poisoning and procedural complications

- HLGT Administration site reactions
- HLGT Bone and joint injuries
- HLGT Chemical injury, overdose and poisoning
 - HLT Chemical injuries
 - HLT Injuries due too in utero exposure
 - **HLT Maladministration and accidental exposure**
 - **PTs: Medication error NEC, Accidental exposure, Underdose, Drug exposure via breast milk, Drug exposure during pregnancy, transmission of drug via semen NEC, Vaccine exposure via breast milk NEC**
 - **HLT Overdoses**
 - **PTs: Overdose, Accidental overdose, multiple drug overdose, multiple drug overdose accidental**
 - HLT Poisoning and toxicity

MedDRA version 8.0

SOC Injury, poisoning and procedural complications

- HLGT Administration site reactions
- HLGT Bone and joint injuries
- HLGT Chemical injury and poisoning
- HLGT Injuries by physical agents
- HLGT Injuries NEC
- ***HLGT Medication errors***
 - ***HLT Maladministrations***
 - ***HLT Medication errors due to accidental exposure***
 - ***HLT Medication errors NEC***
 - ***HLT Medication monitoring errors***
 - ***HLT Overdoses***

MedDRA v8.0

- Included:
 - Medication error terms and concepts related to the following medication use process: Prescribing, dispensing, administration, and monitoring
 - Only broad terms for intercepted or potential medication errors are represented at this time (e.g., PT Circumstance or information capable of leading to medication error)
- Not Included:
 - Causality medication error terms
 - Contributing factors (i.e., work environment, miscommunication, device failure etc)



Next Steps...

- FDA, NCC MERP, and MSSO working together to provide definitions of medication error concepts to facilitate consistent and accurate use of medication error terms by subscribers
- FDA will work with stakeholders to provide inclusion medication error terms in relation to causality, contributing factors, and potential medication errors