

MedDRA Coding and Medication Error Topics

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Topics for Presentation

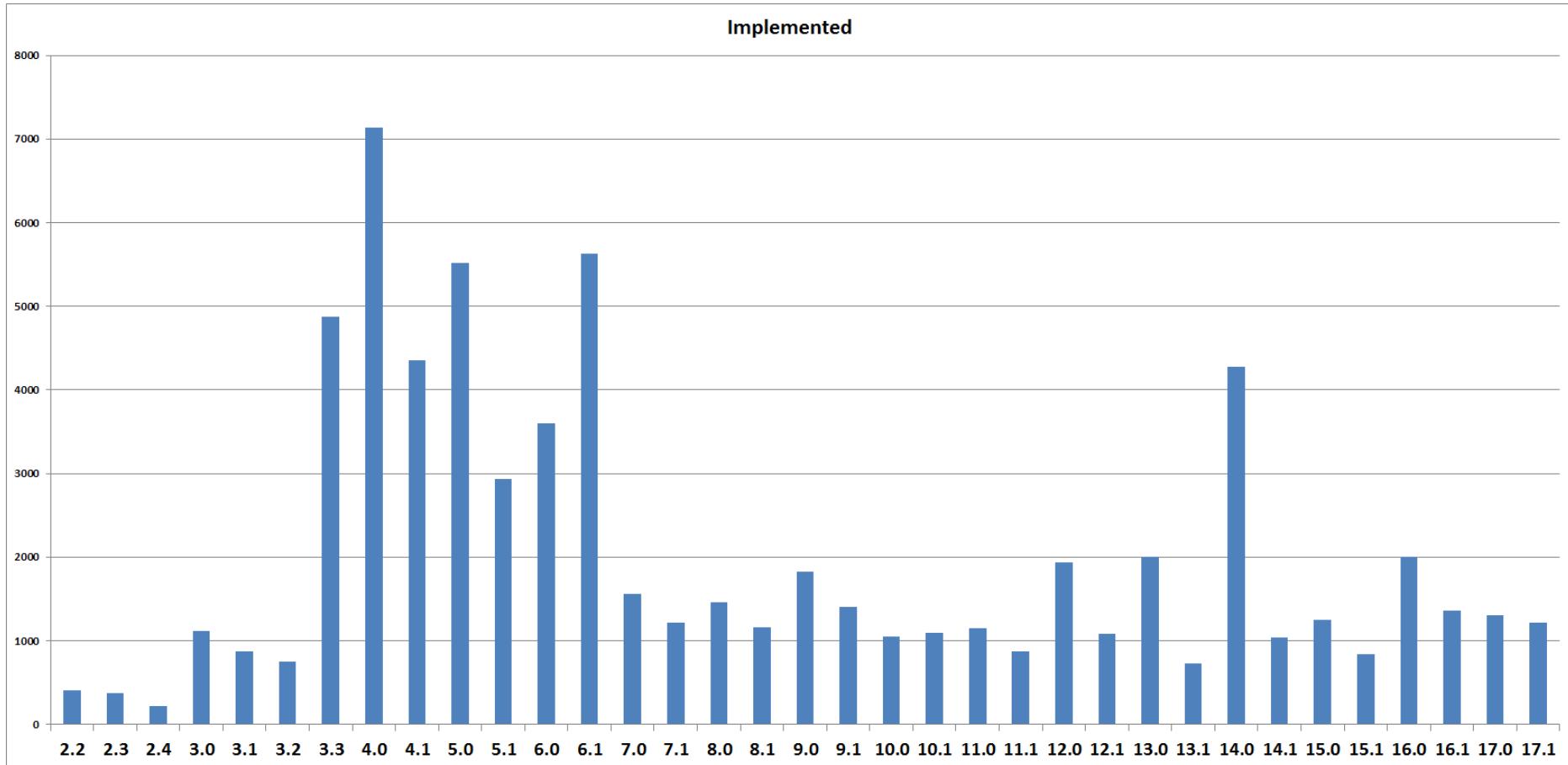
- MSSO's MedDRA maintenance role
- MedDRA's history with medication errors
- Developmental efforts
- FAERS and ICSRs
- MedDRA LLT level for coding
- Examples of coding issues

MedDRA Maintenance

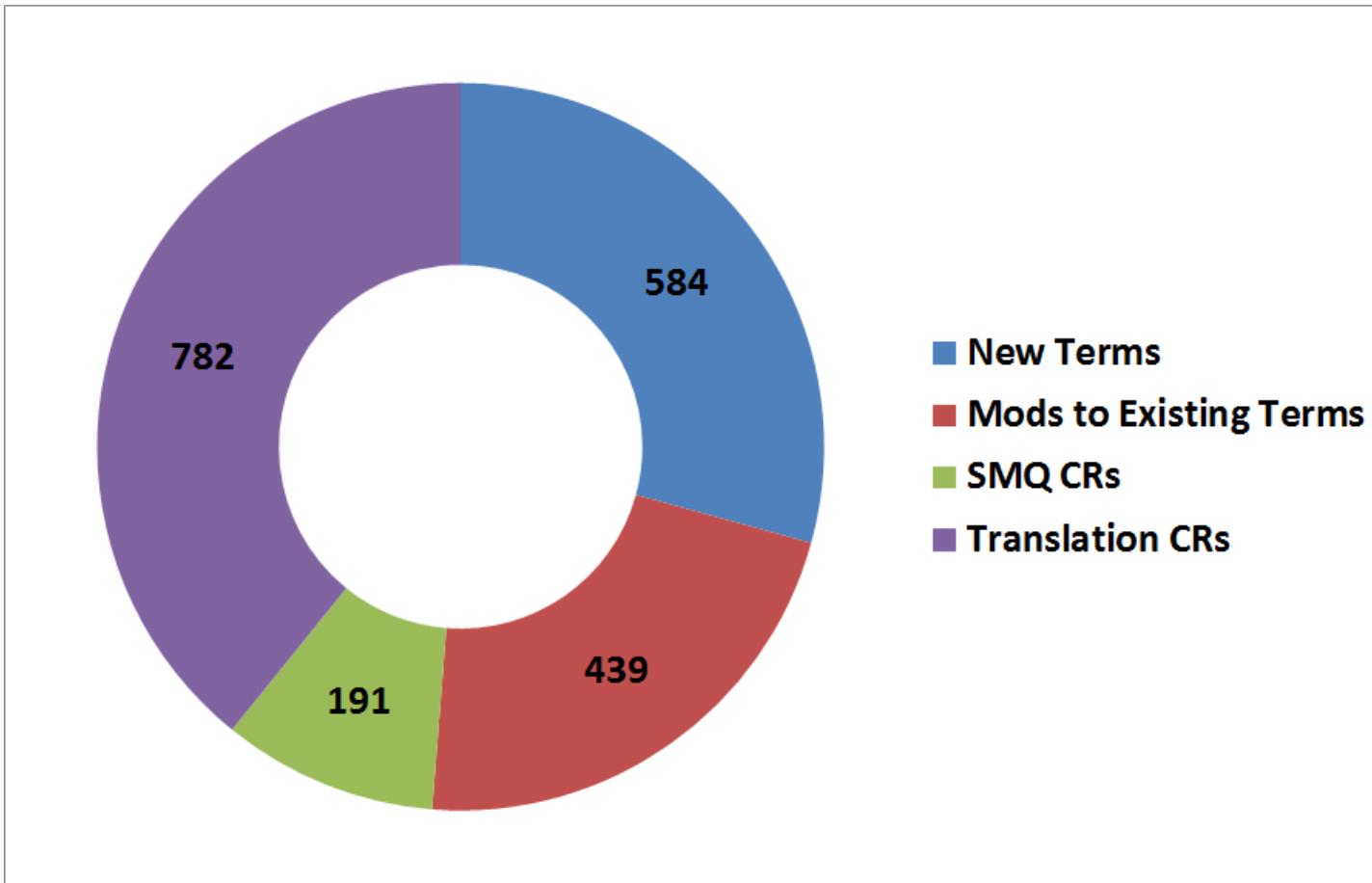


- Maintenance and Support Services Organization (MSSO)
 - Receives requests for new terms or changes to existing terms
 - Team includes 8 MDs to review and respond to requests
 - MedDRA released twice a year in 11 languages

Number of Implemented Changes over time



MedDRA 17.1 Changes



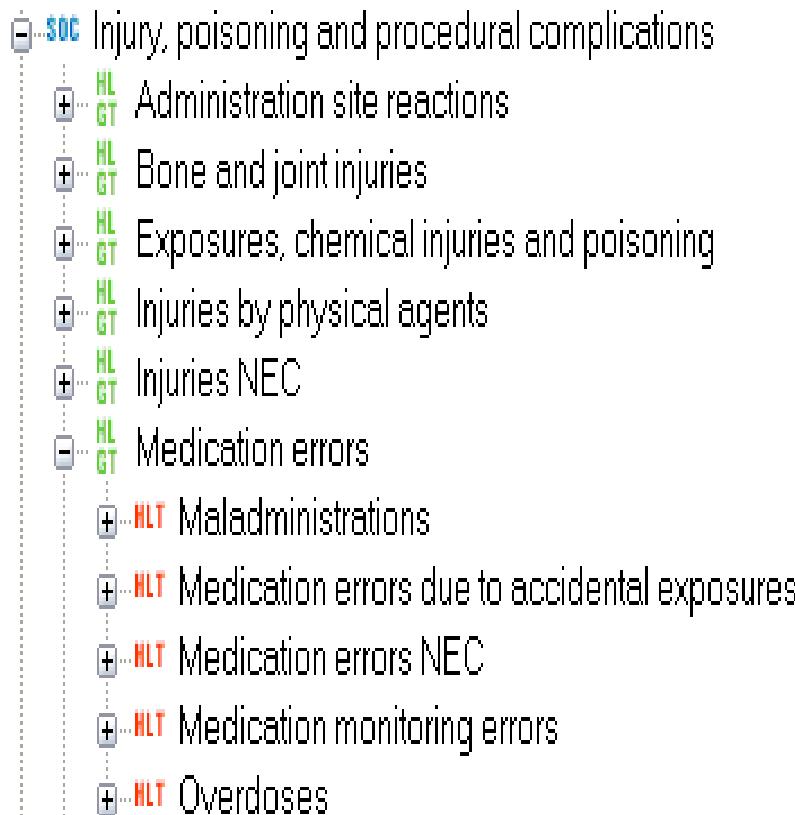
Expansion of Medication Error Terms

- Prior to MedDRA Version 8.0 (March 2005), only one term existed - PT *Medication error*
- Medication error section expanded in v8.0
 - Added HLGT *Medication errors in Injury, poisoning and procedural complications SOC*
 - HLT *Maladministrations*
 - HLT *Medication errors due to accidental exposures*
 - HLT *Medication monitoring errors*
 - HLT *Overdoses*
 - HLT *Medication errors NEC*

Expansion Of Medication Error Terms (cont)

- FDA requested the initial set of Medication Errors terms to be added to MedDRA
 - Support goal of accurately capturing various types of medication errors and ultimately preventing them
 - HLGT *Medication errors* was added in *Injury, poisoning and procedural complications SOC*
 - HLTs added to support stage at which the error occurred in the patient care system, the types of medication errors

Medication Errors – Terms in MedDRA



- Approx. 200 terms under **HLGT Medication errors**
- Examples
 - *LLT Intramuscular formulation administered by other route*
 - *LLT Wrong drug dispensed*

EU Action Plan on Medication Errors

- Since July 2012 EU pharmacovigilance legislation requires
 - Reporting of ADRs associated with medication errors
 - Involvement of patient safety organizations
 - Facilitation of direct patient reporting
- EU regulatory network agreed on several deliverables to be completed by September 2015
 - Includes “Good practice guide on coding and reporting medication errors”
- EU requested PtC WG to provide consultation on sections of good practice guide that reference PtC documents

Concept Descriptions

- Appendix B in MedDRA Introductory Guide
- To assist in understanding and appropriate use of medication error and product quality issue terms in regulatory reporting
- Medication error descriptions developed by FDA and MSSO

Medication Error Concept Description

- **Documented hypersensitivity to administered drug:** This medication error refers to the situation when a patient is administered a drug that is documented in the patient's medical file to cause a hypersensitivity reaction in the patient.
Example: Despite the fact that the patient's medical record indicated "sulfa allergy," the physician prescribed a sulfa antibiotic. Subsequently, the patient took the antibiotic and experienced hives.

MedDRA PTC Documents

MedDRA® TERM SELECTION: POINTS TO CONSIDER

ICH-Endorsed Guide for MedDRA Users

Release 4.8

Based on MedDRA Version 17.1

1 September 2014

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- Two PTC documents
 - Term Selection
 - Data Retrieval and Presentation
- Using MedDRA is a big step forward
- Using MedDRA the same way is a leap toward harmonization

PTC Extract

- 3.15.1 Medication/Administration Errors
 - 3.15.1.1 Medication errors reported with clinical consequences
 - 3.15.1.2 Medication errors and potential medication errors reported without clinical consequences
 - 3.15.1.3 Medication errors in the context of labeled interactions
 - 3.15.1.4 Do not infer a medication error

Developmental Efforts

- Medication monitoring errors – changes in v17.1
 - New medication monitoring error terms
 - Expanded section with examples in MTS:PTC
- Complex change proposals for v18.0
 - Change placement of HLT *Overdoses* and new HLT *Underdoses*
 - Rationale: intentional overdose/underdose concepts are not medication errors and are not appropriately placed under HLGT *Medication errors*
 - Add new HLT *Off label uses*
 - Rationale: Need more specificity for coding and retrieving reports of off label use; currently only one PT *Off label use*
- Changes to MedDRA and updated guidance in PtC documents will be in MedDRA Version 18.0 in March 2015

SMQ *Medication errors*

- Rationale for development
 - Not all medication error concepts are in HLGT *Medication errors*
 - Compliance terms in SOC *Social circumstances*
 - Exposure and poisoning terms (SOC *Injury, poisoning and procedural complications*)
 - Product quality terms (SOC *General disorders and administration site conditions*)
- Current status
 - Approved by ICH Advisory Panel for development
 - Term list developed by CIOMS SMQ team of regulators and industry representatives (including the MSSO)
 - CIOMS SMQ Working Group starting testing

Thank you for your
attention

Any Questions?