

MedDRA® Literature Commentary

Subject of commentary:

Fescharek R, Kübler J, Elsasser U, Frank M, Gütthlein P. Medical Dictionary for Regulatory Activities (MedDRA) Data Retrieval and Presentation. *Int J Pharm Med* 2004; 18 (5): 259-269.

Commentary:

This review article considers the key features of MedDRA, including its structure, specificity and conventions, and how they impact retrieval strategies, analysis and presentation of coded data.

The first section of the article describes the structure and hierarchy of MedDRA and the concept of multiaxiality. SSCs and SMQs are mentioned briefly as search tools for clinical conditions and syndromes that may be represented by terms in more than one SOC.

In the next section, the authors present two practical examples of data presentation of MedDRA-encoded data. The first example compares the adverse drug reaction (ADR) profile of the same set of clinical study data coded using WHO-ART and then re-coded from verbatims using MedDRA. The example demonstrates how, due to MedDRA's granularity, re-coding results in 1.5 times more coded terms in MedDRA compared to WHO-ART. The groupings of terms are also quite different in the two terminologies. The second example shows different ways of presenting ADR profiles based on spontaneously reported safety data for an antibacterial. The display by primary SOC allocation is noted to underestimate the real frequency of some concepts because the relevant PTs are not all grouped in the same SOC or HLT or HLTG. The authors then showed a more meaningful way to present the data which involved moving HLTs or HLTGs from the SOC Investigations or SOC Infections and Infestations to the medically appropriate SOC based on site of manifestation.

Based on these examples and their experience with working with MedDRA version 6.0, the authors identify some limitations of MedDRA for data analysis. These include the granularity of the PT level, the heterogenous content and ambiguous nature of group terms, and MedDRA's multiaxiality. The authors also discuss the limitations of SSCs but are unable to comment on the utility of SMQs because, at the time of writing, only two had been released for review and testing. (The MSSO notes that, as of June 2005, six SMQs are in full production release and nine are undergoing testing by MedDRA subscribers).

The authors note that, in the absence of guidance from regulatory authorities, there is a risk of diminishing the benefits of MedDRA as users develop their own specific and non-standardized data analysis and presentation strategies. However, the MSSO notes, that since this article was published, an ICH-endorsed guide for MedDRA users entitled "MedDRA Data Retrieval and Presentation: Points to Consider" has been issued as a draft document.

In summarizing, the authors recommend a re-design particularly of the group terms (HLT and HLG) to become a robust, consistent and non-ambiguous level for data analysis and aggregation. They suggest that this should be done in an interdisciplinary effort coordinated by the MSSO.

The MSSO is grateful to Dr. Fescharek and his colleagues for suggesting a re-design of the grouping terms. The MSSO has recently undertaken a feasibility study to explore potential modifications to the structure hierarchy of MedDRA to improve the utility of the grouping terms in data analysis and presentation. Among the areas being considered for review are:

- Review “NEC” HLTs (including “NEC” HLGs)
- Group congenital PTs and their acquired counterparts under the same HLT where applicable
- Multi-axiality of SOC *Investigations*
- Multi-axiality of SOC *Social circumstances*
- Multi-axial HLTs in Cumulative Data Output
- Primary SOC for Post Procedural Terms
- Consider whether hyper- and hypo- metabolic disorders should be under the same HLT in SOC *Metabolism and nutrition disorders*

The proposals are posted at the MSSO website (http://www.meddrassso.com/NewWeb2003/mssosubs/subscriber_announce.htm) and the MSSO welcomes subscriber feedback.

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