MedDRA Literature Commentary

Subject of commentary:

Alecu, I, Bousquet, C, Degoulet, P, and Jaulent, M-C. PharmARTS: Terminology Web Services for Drug Safety Coding and Retrieval. MEDINFO 2007, 699 – 704.

Commentary:

This article describes a software tool that the authors claim enhances data retrieval of adverse event cases to overcome what they consider to be deficiencies in WHO-ART and MedDRA. This group of authors has published several articles on similar technological topics in the past several years.[1,2,3,4,5]

The authors state that there is "some debate about the relevance of the structure" of MedDRA in data mining; however, the sole article they reference concerning the "debate" is one they had published in 2005.[2] The types of shortcomings that they identify in MedDRA are similar to what they have described in the past and are nothing more than the particular design features of MedDRA (e.g., primary SOC rules, etc.). According to the authors, both MedDRA and WHO-ART lack the ability to group relevant terms for safety queries. However, Standardised MedDRA Queries (SMQs) – which do group together terms relevant to a particular condition of interest – are not mentioned by the authors.

The authors cite as another shortcoming the lack of links in MedDRA between laboratory findings and disorders; as most MedDRA users know, this has been the way MedDRA has been designed since its inception. There are several reasons why this is the case in MedDRA. For example:

1. Laboratory abnormalities do not always reflect the presence of a disorder;
2. Because the laboratory result finding terms in MedDRA are qualitative (e.g., increased, decreased, etc.), they are meant to reflect a direction of a result or a value outside of a normal range;
3. In November 2006, a Blue Ribbon Panel of MedDRA experts, when asked if laboratory terms in MedDRA should be linked to disorder terms, recommended that no formal links be made within MedDRA. Instead, they suggested a pilot study of "concept attributes", that is, links made between certain laboratory result terms and disorder terms in files external to the terminology itself. As of the posting date of this commentary, the feasibility of implementing concept attributes in MedDRA is being researched at the MSSO.

Of note, the tool that the authors describe has SNOMED-CT as its basis – it assumes that linkages made between laboratory findings and disorders in

SNOMED-CT are accurate and relevant for pharmacovigilance purposes. It would be helpful if this were somehow validated.

Additionally, the software tool described in the article does not address linkages of laboratory/investigation terms to disorders in MedDRA nor does it provide ways to optimize the hierarchical structure of MedDRA.

The MSSO has a great deal of experience in maintaining a large terminology with many linkages between concepts. Regarding the software tool described in this article, the authors note that “development features of updating and quality checking must also be considered”. They further state regarding their tool: ".. the ontological resource must be completed. At the moment, only 86% of WHO-ART terms are completely linked to contexts (formal definitions according to SNOMED axes). MedDRA terms have been added for transcoding purposes but are not linked to SNOMED-CT contexts. We have carried out feasibility studies for adding SNOMED-CT context to MedDRA using OWL, but the main difficulty was related to the number of terms."

The three terminologies they mention have different levels of granularity, hence transferring contexts from one to another terminology should be done with care and be medically validated. Maintenance of these context links (given that all three terminologies change with time) is likely to be a major challenge.

We believe that the effort involved in such maintenance ought not to be underestimated, and we recommend to the authors that they address this in any future publications.

We agree with the authors that effective review of drug safety reports requires accurate coding of cases, that is, solid coding practices. Recently, the Uppsala Monitoring Centre has begun to incorporate MedDRA into its safety report database (Vigibase) to avoid loss of information through data conversion with WHO-ART. Given this, having the software tool capable of handling only WHO-ART terms does not seem useful.

Summary: This article describes a software tool developed by the authors that intends to enhance data retrieval of adverse event cases and to overcome perceived deficiencies in WHO-ART and MedDRA. One MedDRA deficiency – as identified by the authors – is the lack of links between MedDRA investigation terms and disorder terms. However, the article does not describe how their software tool addresses these issues in MedDRA. We would encourage the authors to also study SMQs as a tool to enhance data retrieval of MedDRA-coded data. Additionally, speaking from the point of view of a terminology maintenance organization, we feel that the maintenance of the linkages described in their tool is a substantial task that has not been fully described in the article.

We invite the authors to work with MSSO as we work to further enhance MedDRA's capabilities for all users.

References:

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