

## MedDRA Literature Commentary

Subject of commentary:

Feudjo-Tepie, MA, Le Roux, G, Beach, KJ, Bennett, D., and Robinson, NJ.  
Comorbidities of idiopathic thrombocytopenic purpura: a population-based study.  
Advances in Hematology 2009, doi:10.1155/2009/963506

Commentary:

In this article, the authors describe a methodology in which they mined the UK's General Practice Research Database (GPRD) to gather information on comorbidities that accompany idiopathic thrombocytopenic purpura (ITP). Identifying these comorbidities, the authors noted, would help put potential safety signals into context and aid with clinical trial study planning and design.

The study was a case-control design where patients listed in the GPRD were identified as having ITP by their READ or Oxford Medical Information System (OXMIS) codes. However, in this study, the identified comorbid conditions were also somehow linked to MedDRA Preferred Terms (PTs). The methodology for how the case information/READ or OXMIS codes were linked to MedDRA PTs was not explained, nor was the MedDRA version mentioned. These comorbid conditions, by PT, were then further aggregated under 26 "grouped medical conditions" apparently designed by the authors.

Details of the types of comorbidities that were identified – the major thrust of the study – can be found by reviewing the article. The publication has come to the attention of the MSSO because the authors noted that using MedDRA presented some "limitations" for their research. In particular, they stated that they used their own "grouped medical conditions" rather than HLTs, HLGs or SOCs because using the MedDRA hierarchy proved challenging due to its "overlapping nature" but they did not provide additional details to describe this "overlap." (The MSSO assumes that this relates to MedDRA's multi-axiality). The authors also noted that not all medical conditions reported in the GPRD with READ or OXMIS codes have a corresponding MedDRA PT. However, the correlation between READ or OXMIS codes and the more granular MedDRA Lower Level Terms (LLTs) was not presented.

Regarding multi-axiality, the MSSO acknowledges that this can be a challenge but that multi-axiality also represents one of its main strengths, allowing safety data to be classified and viewed from more than one medical perspective. Indeed, analysis of PTs which are mainly in one SOC that is highly multi-axial (such as SOC *Vascular disorders*) can be enhanced by a secondary SOC analysis.

As for apparent “missing” medical conditions at the PT level, it is possible that had the authors made their mapping of READ or OXMIS codes at the LLT level, there may have been more granularity to accommodate their needs. (MedDRA Version 12.1 has 67,503 LLTs and 18,641 PTs). Or, submission of Change Requests for new MedDRA terms to fill in these gaps may have been a possible solution. However, as noted above, the methodology for how the READ/OXMIS codes and MedDRA PTs were linked is not specifically addressed in the article.

Finally, in reviewing this article, the MSSO had the following questions:

1. Why did the authors choose to use MedDRA for this analysis instead of the READ or OXMIS codes that were available to them directly?
2. How were the READ and OXMIS codes mapped to MedDRA PTs?
3. Was a secondary SOC analysis considered to overcome the “overlapping” limitation?
4. Was submission of Change Requests considered for bridging the gaps between GPRD RAED/OXMIS codes and MedDRA PTs?

Summary:

This is a useful and important study to extend the medical community’s understanding of comorbid conditions in ITP. The use of MedDRA in this retrospective epidemiologic study is very interesting. The limitations of MedDRA that the authors point out may be less of a concern if secondary SOC analysis had been implemented; if mapping from verbatim terms or READ/OXMIS to LLTs had been performed, rather than mapping directly to PT; and if the MedDRA Change Request procedures were pursued for requesting the addition of new MedDRA terms.