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Review Article

Role of MedDRA in Pharmacovigilance: Standardized Coding for Adverse Drug Reactions

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ABSTRACT

Adverse drug reactions (ADRs) are a major concern for patients, physicians and regulatory agencies worldwide. Pharmacovigilance requires a standardized approach for coding and sharing safety data for effective risk monitoring. This international standard is the Medical Dictionary for Regulatory Activities (MedDRA). This review describes the structure, regulatory mandate, signal detection capabilities, and coding challenges of MedDRA within the framework of pharmacovigilance. MedDRA is organized hierarchically in five levels from the most specific Lowest Level Terms (LLTs) to the most general System Organ Classes (SOCs). This is required by major regulators such as the European Medicines Agency (EMA) and the US Food and Drug Administration (FDA). The World Health Organization (WHO) also uses it globally to code millions of safety reports. The role of MedDRA during signal detection is important with the help of tools such as Standardized MedDRA Queries (SMQs) which facilitate rapid identification of new side effects. But the system has its own problems. Inconsistent coding, changing terminology and the need for constant training may compromise data quality. Still, MedDRA is an important basis for global safety surveillance. The future is bright for MedDRA with increased use of automation and artificial intelligence to accelerate and improve pharmacovigilance.

INTRODUCTION

Adverse drug reactions (ADRs) are of great concern to patients, doctors, and regulatory agencies. Only when ADRs are severe enough to cause significant harm or death do they trigger strict actions like mandatory Phase IV trials, black box warnings, or even removal from the market. Stakeholders are now using real-world data from routine clinical practice to make better decisions throughout the life cycle of a drug. Pharmacovigilance is the ongoing surveillance of the safety of a drug after its approval helping to monitor these risks.

This becomes really important for catching ADRs that are rare, affect only specific groups, or show up after long-term use. (1)

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The safety risks of some drugs only become apparent after approval. Thalidomide is a classic example, it was only after it reached the market that its severe teratogenic effects in pregnant women were discovered.

To overcome this challenge, standardized medical terminologies such as Medical Dictionary for Regulatory Activities (MedDRA) are used to code and classify adverse events consistently.

MedDRA is an international medical terminology developed under the auspices of International Council for Harmonisation (ICH) to facilitate the sharing of regulatory information on medical products.

It is used for registration, documentation and safety monitoring of medical products before and after a product has been authorised for use. Products covered by the scope of MedDRA include pharmaceuticals, vaccines and drug-device combination products.

However, despite its global adoption, recent studies have highlighted varying levels of coding inconsistency in MedDRA-based platforms. (2)

Therefore, this review aims to discuss the structure, regulatory mandate, signal detection role, and coding challenges of MedDRA.

MEDDRA STRUCTURE & HIERARCHY

Because the number of ADR reports kept increasing, MedDRA developed several hierarchy levels to code and report these events. (3)

There are total five levels, ranging from the broadest to most specific as follows:

1. System Organ Class (SOC) : The broadest level, which groups conditions by major body system (eg. Cardiac disorder).
2. High Level Group Term (HLGT) : Groups related high level terms.
3. High Level Term (HLT) : Groups related to preferred terms.
4. Preferred Terms (PT) : The standard levels used for data analysis and reporting.
5. Lowest Level Term (LLT) : The most specific level, which records the reporter's exact words. Each LLT maps directly to a PT.

In practice, data is entered at the LLT level but analysed at the PT level. This hierarchical grouping allows related terms to be combined, which is effective in signal detection. (4)

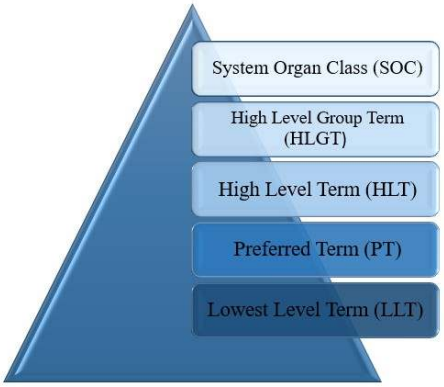


Figure 1: The Five Level Hierarchical Structure of Med'DRA. (4)

The five-level hierarchy allows data to be aggregated at different levels, from specific LLTs to broad SOCs, which is essential for signal detection. (5)

"MedDRA's hierarchical structure is not just for coding, it is also essential for advanced statistical analysis. For example, a Bayesian hierarchical model has been developed to detect MedDRA-coded adverse events in clinical trials, showing how the five-level framework supports complex data mining. (6)

REGULATORY MANDATE & GLOBAL ADOPTION

For over two decades, the adverse events have been reported to the Eudravigilance database by using MedDRA, which is mandated by the European Medicines Agency (EMA).

The Eudravigilance database contains over 9.6 million reports, making it one of the largest safety databases. Most of these reports came from outside of Europe, mainly the USA (36.9%), followed by France (10%), which shows its global reach. (7)

In the United States, the Food and Drug Administration (FDA) uses MedDRA in its Adverse Event Reporting System (FAERS). A study analyzing FAERS data from 2004 to 2020 identified 488,470 medication error reports using MedDRA's Standardized MedDRA Queries (SMQs). (8)

MedDRA is used globally by the World Health Organization (WHO) to code reports in its database. This database, which has over 40 million reports from over 160 nations as of 2024, demonstrates how MedDRA facilitates the global exchange of safety data. (9)

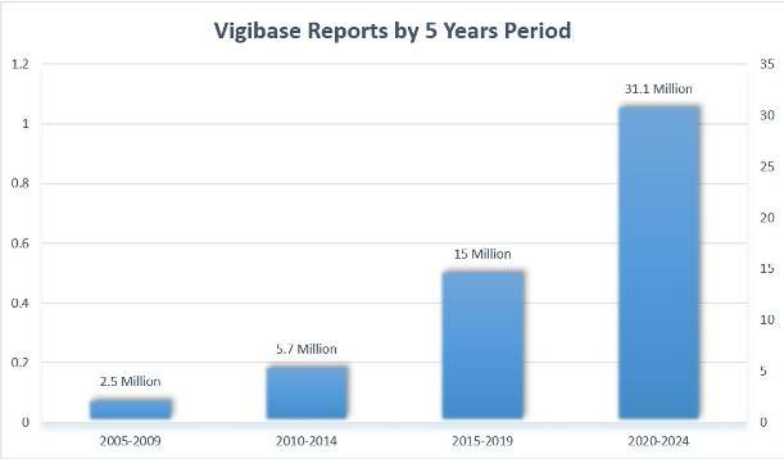


Figure 2: Growth of Vigibase Reports by 5 Years Period.(9)

Japan has also mandated electronic reporting using MedDRA since 2003, achieving near complete compliance. A recent study using the Japanese Adverse Drug Event reporting (JADER) database, which uses MedDRA coding, shows how actively this system is used in real world pharmacovigilance.(10)

International harmonisation of pharmacovigilance practices helps to ensure consistency of drug safety monitoring across countries. MedDRA is a standardised medical terminology used to code adverse drug reactions and allows analysis and comparison of safety information. Harmonised reporting and coding practices can contribute to signal detection and to the monitoring of the benefit–risk profile of medicines.(11)

ROLE IN SIGNAL DETECTION

Regulators are unable to manually review all of the millions of reports that are submitted from all over the world. Signal detection is useful in this situation. For this vast amount of data, it is the process of identifying novel or uncommon side effects. In this case, MedDRA plays a significant role by offering structured tools for the retrieval and analysis of this data.(3)

One of the main tools that MedDRA provides for this is Standardized MedDRA Queries (SMQs). These are pre-defined search filters that combine related terms together to quickly identify cases for a particular medical condition. For example, a recent study used the SMQ 'Pregnancy and neonatal topics' to identify pregnancy-related ADRs in EudraVigilance. But this query could only correctly identify 54% of cases, as it also picked up unrelated events. To make this better, researchers created a new algorithm that got 90% accuracy and retrieved over 202,000 instances.(12)

However the accuracy of these queries very much depends on the way they are designed. A recent analysis of VigiBase cases of interstitial lung disease (ILD) demonstrated that the Preferred Term 'ILD' accounted for less than 40% of all terms within the broad SMQ for ILD. This makes it possible that researchers could

miss a large number of relevant cases by searching only for one specific term. Therefore, careful design of the queries is crucial for robust signal detection.(13)

A great example of this in the real world was during the COVID-19 pandemic. With the global rollout of vaccines and treatments, safety reports started to include a huge number of new side effects. To address this, MedDRA rapidly made new terms and Standardized MedDRA Queries available outside the normal cycle of updates. The rapidity of the response meant that regulators and companies were able to view and examine safety signals as they arose, while the situation was still developing. It demonstrated how a standardized coding system can respond quickly when the world needs it most.(14)

CHALLENGES AND CODING QUALITY

MedDRA is a powerful tool but only as good as the people using it. One of the biggest issues is inconsistency in coding. Different coders looking at the same adverse event report may select different terms. A recent study found that when the information is not clear, pharmacovigilance officers tend to make mistakes such as failing to recognize a relevant term or selecting the wrong one.(2)

Another challenge is that the MedDRA terminology keeps evolving. The dictionary is updated twice a year. So, terms that existed a few years ago may be split, renamed, or replaced today. For example, a study of interstitial lung disease (ILD) found that different countries and different time periods use different Preferred Terms for the same condition. This makes it harder to do consistent searches over long periods of time.(13)

Bad code can really hurt your ability to detect signals. Badly coded reports may miss true safety signals. You saw that in the rollout of the Covid-19 vaccine. A recent study revealed that many medication error reports were either missing important information or were inconsistent. That makes it very hard for regulators to recognize patterns. This is where ongoing coder training, periodic quality audits and careful query development come into play. These steps are important for a good system to work well.(15)

FUTURE DIRECTIONS

AI is slowly changing the way MedDRA coding is done. One recent study looked at how AI can be used in clinical data management. Instead of manually reading every single report, automated systems can now suggest the correct MedDRA terms. The researchers found that using AI cuts down on the time spent on manual coding and speeds up the whole process.

Recent advancements in Large Language Models show promising results in automating the coding process with high accuracy.(16)

Another interesting direction is using social media and web content for safety monitoring. A recent study built a language model tool to scan social media posts during the COVID-19 pandemic. It pulled out possible vaccine side effects from these posts and mapped them to MedDRA terms. This approach lets regulators hear from everyday people, not just doctors, and it happens in real time.

Natural Language Processing (NLP) tools are also being developed to automatically extract adverse events from clinical narratives and map them to MedDRA terms.(17)

CONCLUSION

MedDRA is an integral part of pharmacovigilance. It provides a common language for regulators, doctors and companies to share safety data. MedDRA has a five-level structure that allows for quick detection of new side effects. However the system only works if the coding is done correctly. This is why constant training is so important for coders. With the increased use of AI and automation, MedDRA has a very bright future. It will remain a crucial tool to help guarantee the safety of medicines across the globe.

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