

Editorial
Infectious Diseases



Surveillance Systems for Assessing Vaccine Safety: Possibilities and Limitations

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Vaccination poses a distinctive position in medicine, in that vaccines are not administered to treat those who are already ill but are primarily used to prevent future illnesses in healthy individuals. Therefore, maintaining and pursuing safety in every process of vaccination from manufacture to administration is of utmost importance. The coronavirus disease 2019 (COVID-19) pandemic has brought a lot of change in many aspects of our life, not limited to a medical concern. Perhaps, rapid development and wide implementation of vaccines against COVID-19 with tangible vaccine effectiveness in the real world is one of the most significant influences of the COVID-19 pandemic in medicine. However, the rapid development and widespread implementation of vaccines against COVID-19 provided an opportunity to address vaccine hesitancy, particularly among those who distrusted vaccinations before the pandemic.

The COVID-19 pandemic presented a significant challenge for the medical community. However, another formidable obstacle emerged: the need to combat distrust toward new platform vaccines, such as mRNA vaccines. Looking back, recalling the core attributes of vaccines, suspicion and fear which also preceded the pandemic, is understandable to some degree among individuals outside the medical industry—and perhaps even within it. Raising suspicions has been and continues to be quite easy, compared to revealing and disproving their validity.¹ Throughout the pandemic, this challenge persisted, underscoring the importance of monitoring and studying real adverse events that occur from vaccination. Only by doing so can we build trust among eligible vaccine recipients and facilitate informed decision-making about vaccination, thereby elevating their knowledge, fostering confidence in medicine, and enabling them to make better-informed decisions.²

In this issue of *Journal of Korean Medical Science*, Kim et al.³ investigate, using VigiBase, adverse events following COVID-19 vaccination in adolescents. VigiBase, the WHO's global database for reported potential side effects of medicinal products, stands as the largest of its kind globally, with over 30 million reports of suspected adverse effects submitted by WHO member countries since 1968. While clinicians involved in everyday clinical encounters may not be familiar with drug safety monitoring systems unless they actively participate in monitoring efforts, some may be willing to report adverse events to medical journals. In their study, along with the investigation on COVID-19 vaccination during pregnancy and lactation, Kim et al.³ provide readers with an opportunity to become acquainted with surveillance systems for monitoring drug safety, including but not limited to VigiBase.⁴

The findings of Kim et al.'s³ pharmacovigilance study, while valuable, echo existing knowledge regarding adverse events associated with COVID-19 vaccines, particularly the increased reporting odds for myocarditis/pericarditis and multisystem inflammatory syndrome/Kawasaki disease in adolescents, notably males. Furthermore, the study's findings regarding the absence of significant odds for anaphylaxis, Guillain-Barre Syndrome, and immune thrombocytopenia are consistent with established knowledge. Kim et al.³ employed disproportionality analysis, a method that compares adverse event rates with and without a specific drug, to conduct their study.⁵ This approach is pivotal in confirming or refuting potential associations between a drug and adverse reactions based on pharmacological hypotheses. Identifying disproportionality ratios prompts further examination of data from experimental pharmacology and randomized clinical trials.

However, it's crucial to acknowledge the study's significant limitations. Primarily, the method heavily relies on passive and self-reported data, potentially leading to disproportionate reporting in Vigibase. Moreover, the *Weber Effect*, characterized by an influx of reported adverse events for newly approved drugs, may have influenced the findings.⁶ Additionally, while Vigibase encompasses reports from over 150 countries, including South Korea via the Korea Institute of Drug Safety & Risk Management, the study's data primarily originates from Western countries. This distribution disparity could skew the findings, especially considering the varying availability and usage of newly developed vaccines across regions. Such disparities highlight the inequity in the distribution of drugs and vaccines, which can impact the quality and comprehensiveness of pharmacovigilance efforts globally.

Addressing vaccine hesitancy and countering misinformation necessitate evidence-based communication and robust monitoring systems. Actively debunking false claims and misinformation is vital in promoting vaccination as a crucial tool against infectious diseases. Despite limitations, Kim et al.'s³ study contributes valuable insights to vaccination, ultimately enhancing trust in medicine.

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