

# 2ND INTERNATIONAL SYMPOSIUM ON INFECTIOUS DISEASES AND VIROLOGY

November 14-15, 2025 | London, UK



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## Restructuring of the COVID-19 Vaccine Safety Committee 2020-2023 in Mexico

#### **Objective**

To describe the process of restructuring the National Expert Committee and its impact on the causality assessment of events supposedly attributable to vaccination or immunization (ESAVI) in the context of vaccine safety monitoring during the COVID-19 pandemic, 2020-2023. A report was prepared on the experience of creating and operating Mexico's National Expert Committee during the aforementioned period. During the 2020-2023 period, 1293 severe ESAVIs were reported after COVID-19 vaccination; after 98.6% (1275) of them had been assessed and classified, 10 specialized subcommittees were formed. Restructuring of the committee, assessment of adverse events with a series of prior steps, and use of the World Health Organization's causality assessment tool made it possible to generate scientific documents to validate vaccine safety and maintain trust in vaccination. The experience gained from the restructuring, operation, and evaluation, together with the WHO causality assessment tool (9), can serve as a model for other countries seeking to streamline processes and strategies for AEFI causality assessment. In addition to improving vaccine safety in the country and generating scientific evidence, there is a responsibility to share this experience and the knowledge acquired. The future challenge lies in maintaining the integration of the CNE and the participation of the different actors in the health sector. This is essential to respond to future pandemics, to address the introduction of new vaccines, and to strengthen the AEFI surveillance cycle for these vaccines as well as those included in the official immunization schedule at all levels of management—fundamental actions to sustain public confidence in vaccination.

### Keywords

Drug-related side effects and adverse reactions, COVID-19 vaccines, drug evaluation commission, professional staff committees, Mexico

#### **Biography**

Ana María Santibañez Copado holds a Master's Degree in Health Institutions Administration with honors from Universidad La Salle and a Medical Degree from UNAM. Certified in Pediatric Advanced Life Support and Neonatal Resuscitation, she also completed certificates in Basic Epidemiology and Project Management. She has authored and co-authored articles in Neurology, Immunology, Pediatrics, and on vaccine safety, including Stroke Among SARS-CoV-2 Vaccine Recipients in Mexico. Contributor to COVID-19 vaccination guidelines, she was recognized by WHO as GAPIII Auditor. She teaches at IPN, UNAM, and Epidemiology residencies, serving as Deputy Technical Secretary of the National Committee for Vaccine Safety in Mexico.