Background. Expansion of maternal immunization programs is a key priority of the World Health Organization (WHO). Systematic surveillance for adverse events following immunization (AEFI) in pregnancy is needed to capture rare serious adverse events, particularly given the paucity of safety data in this population. A systematic review identified only 16 reports of AEFI surveillance programs for pregnant women and their offspring. The study objective was to identify existing but unpublished active and passive AEFI surveillance systems for pregnant women and their offspring in WHO member countries.

Methods. Immunization program managers, national regulators and vaccine safety experts in 148 countries were invited to complete a 14-item online questionnaire in English, French or Spanish. The survey captured maternal immunization policies, and active and passive AEFI surveillance systems for pregnant women and infants. Analysis was descriptive. Stratified analysis was conducted by country income level (using World Bank definitions) and WHO region. Population coverage of AEFI surveillance systems was estimated.

Results. There were 51 respondents from 47/148 (32%) countries. Responses were received from all WHO regions. Response rates were 40% among high-income countries (HIC), 30% among middle-income countries (MIC) and 21% among low-income countries (LIC) (p = 0.3). Thirty countries (64%) had a national maternal immunization policy. Active AEFI surveillance systems to detect outcomes in women and/or infants were reported in 5/19 (26%) HIC, 4/23 (17%) MIC and 2/5 (40%) LIC. Passive surveillance systems were in place in 16 (84%) HIC, 19 (83%) MIC and 4 (80%) LIC. At least 8% of the worldwide birth cohort (131,000,000 births/year) is covered by active surveillance for AEFI in mothers and/or infants, and at least 56% is covered by passive AEFI surveillance. Data from 1 active and 3 passive systems have been published.

Conclusion. This study identified 50 active and passive AEFI surveillance systems that capture outcomes in pregnant women and/or infants, but few have published findings. AEFI surveillance appears to be feasible in low and high resource settings. The findings will be used to develop recommendations for improving AEFI surveillance and for sharing of information on vaccine safety in pregnancy.

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