

## Background

- Vaccination during pregnancy can protect the mother and newborn from the effects of severe infection. Several immunizations are currently recommended in pregnancy, but maternal immunization programs have not been established in many countries.
- Strengthening antenatal care as a platform for maternal immunization is a priority of the World Health Organization (WHO).
- Robust systematic surveillance for adverse events following immunization (AEFI) is needed to identify vaccine safety events in pregnant women and their infants.
- We previously conducted a systematic review to identify published reports of active and passive AEFI surveillance systems for pregnant women and their offspring; only 16 articles from 6 high-income countries were identified (U.S., Australia, Belgium, France, Sweden, Taiwan).<sup>1</sup>

## Objective

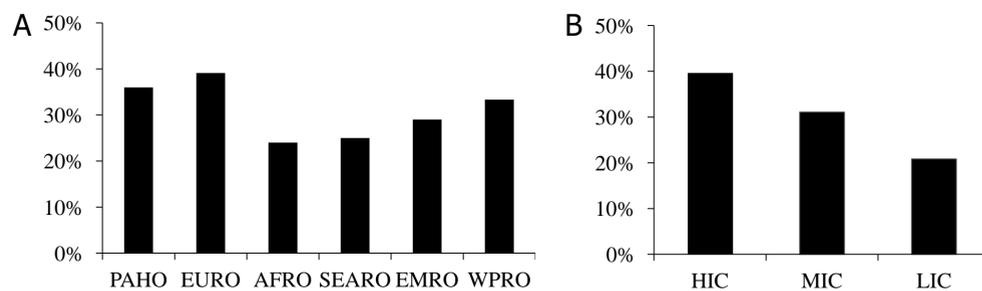
- To identify active and passive AEFI surveillance systems for pregnant women and their infants in WHO member countries.

## Methods

- A survey was conducted of all National Pharmacovigilance Centers and a convenience sample of vaccine safety experts in 148 WHO member countries from November 2014 to February 2015.
- 14-item questionnaire was distributed in English, French and Spanish using Opinio survey software.
- The survey captured information on immunization policies/programs targeting pregnant women, active surveillance programs in place or in development for mothers and/or infants, existence of passive surveillance systems and whether pregnancy status is collected.
- REB approval: Dalhousie University Research Ethics Board and WHO Ethics Review Committee
- Statistical Analysis:** Descriptive analysis was conducted stratified by presence of maternal immunization policy, WHO region, country income level. Coverage of the worldwide birth cohort by active and passive surveillance systems was estimated. SPSS version 21 (IBM, Armonk, NY) was used for the analysis.

## Results

### Response rates by WHO geographic region (A) and country income level (B)



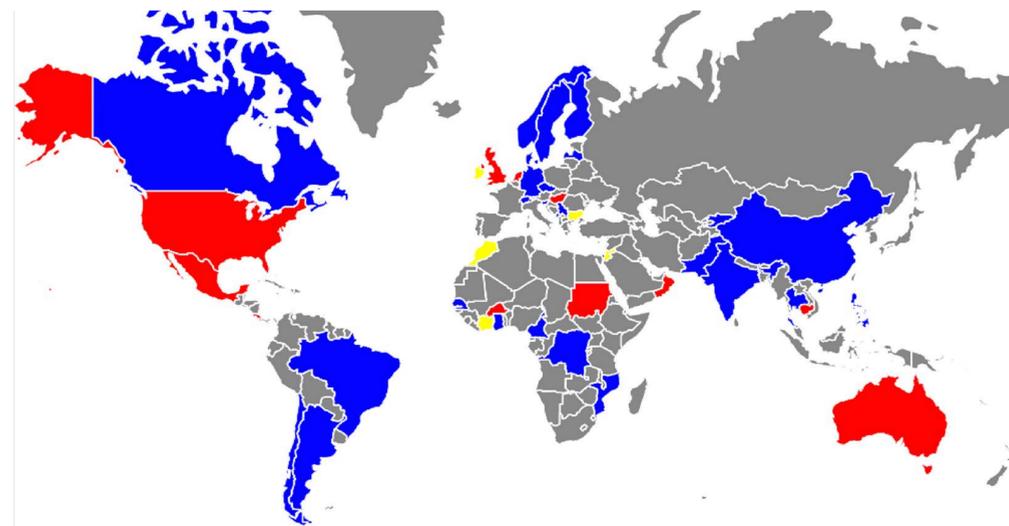
**Figure 1.** Responses were received from 51 individuals in 47 of 148 countries (32%); Respondents were 49% national regulators, 18% public health officials, 12% immunization program managers, 22% other. Response rates did not differ by WHO region ( $p=0.8$ ) or country income level ( $p=0.3$ ).

PAHO, Pan American Health Organization; EURO, European Region; AFRO, African Region; SEARO, South East Asian Region; EMRO, Eastern Mediterranean Region; WPRO, Western Pacific Region; HIC, high-income countries; MIC, middle-income countries; LIC, low-income countries.

<sup>1</sup>Cassidy C, MacDonald NE, Steenbeek A, Top KA. *Pharmacoepi Drug Saf*, 2015, 24:361.

## Results

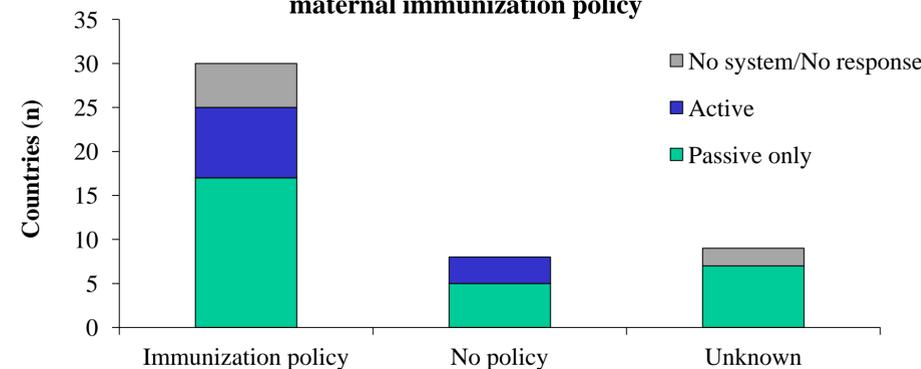
### Countries reported to have active and passive adverse event following immunization surveillance programs



**Figure 2.** In 11 countries there is an active AEFI surveillance targeting pregnant women and/or infants (red). Passive AEFI surveillance systems are in place in 39 countries (blue denotes countries with only passive systems) and respondents from 7 countries reported no AEFI surveillance systems or did not respond to that question (yellow). No data was available on the remaining countries (grey). Approximately 8% of the worldwide birth cohort (131 million) is covered by active AEFI surveillance for maternal and/or infant outcomes and at least 56% is covered by passive AEFI surveillance.

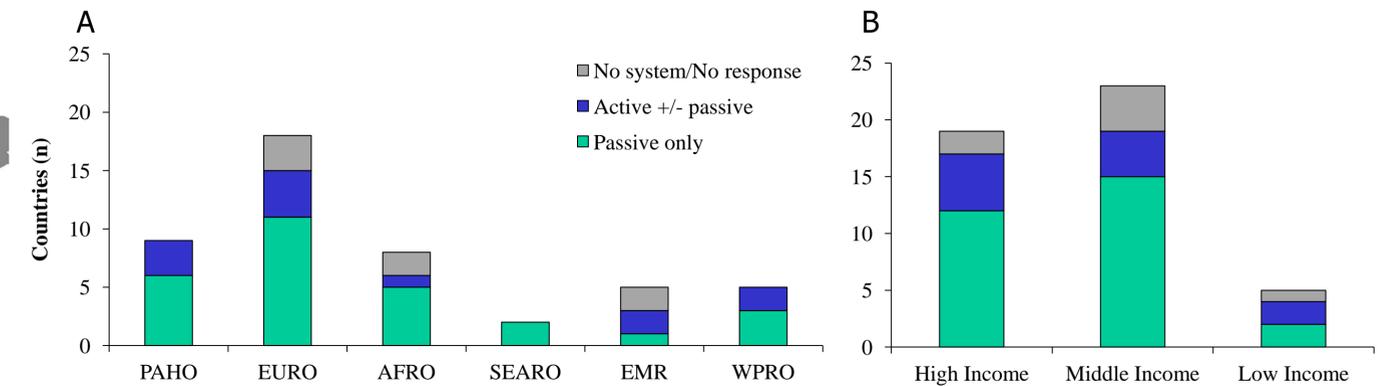
**Note:** The boundaries and names shown and the designations used on this map do not imply the expression of any opinion whatsoever on the part of the WHO concerning the legal status of any country, territory, city or area or of its authorities, or concerning the delimitation of its frontiers or boundaries.

### Active and passive AEFI surveillance programs in countries with and without a maternal immunization policy



**Figure 3.** In countries with an immunization policy targeting pregnant women, recommended immunizations included: influenza (14 countries), tetanus toxoid (14), tetanus-diphtheria-acellular pertussis (9), hepatitis B (2), meningococcal conjugate vaccine (1).

### Active and passive AEFI surveillance systems by WHO region (A) and country income level (B)



**Figure 4.** Seven countries have national active surveillance programs and in 4 countries there are active AEFI surveillance systems in one or more districts of the country. In 17/39 countries with passive systems (44%), the AEFI reporting form includes a question regarding pregnancy status. Findings from only 1 active surveillance system and 4 passive surveillance systems identified in this survey have been published in the literature. Country income level is based on the World Bank ranking.

## Discussion

### Limitations

- There may be response bias, particularly among low income countries.
- Respondents may not have complete knowledge of the surveillance activities in their country or they may not have comprehended all questions.
- Eight respondents opened the survey but did not answer any questions.

### Conclusions

- 11 active and 39 passive AEFI surveillance systems were identified that capture events in pregnant women or their infants, covering up to 8% and 56% of births worldwide, respectively.
- Few surveillance systems have published their findings.
- Active and passive systems were identified in low, middle and high income countries, suggesting that AEFI surveillance is feasible in most countries.
- Countries with existing safety data should be encouraged to publish their data.
- Including a question about pregnancy status on AEFI reporting forms can increase the value of passive surveillance. Capacity for active surveillance can be built into existing or planned electronic integrated health information systems.

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**Disclaimer:** The findings and views expressed are those of the authors alone and do not necessarily reflect those of the World Health Organization