

MATERNAL IMMUNIZATION IN ARGENTINA: THE IMPORTANCE OF A SAFETY PROFILE ANALYSIS

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Background: Vaccination against flu and whooping cough (WC) is a priority within the comprehensive care strategy for pregnant women (PW) and small infants in Argentina. Flu vaccine was included in the National Immunization Schedule (NIS) in 2011. Argentina recommended a vaccination strategy for PW against WC in 2012, with the aim of reducing complications and deaths related to these diseases.

Objective: To describe the national strategy of maternal immunization, 2011-2015.

Methods: Descriptive study. National vaccination coverages (NVC) and vaccines safety profile between 2011 and 2015 were analyzed. Influenza and Tdap impact was evaluated. Adverse events following immunization (AEFI) notifications were performed passively.

Results: Since 2011 1,813,270 doses of flu vaccine were applied (NVC>95% most years). Table 1. There were no notifications of influenza related deaths in vaccinated PW during this period. Eleven AEFI were notified (rate 0.6/100,000): 4 mild reactions vaccine related and 5 program errors. A flaccid paralysis was classified as nonconclusive event due to lack of complementary studies. Table 1.

In 2012, Tdap was recommended after the 20th gestation week. Between 2012 and 2015 1,845,379 doses were applied, NVC shown in Figure 1. 27 AEFI were reported (rate 1.46/100.00), 7 vaccine related and 1 anxiety disorder. 18 events were program errors (66%). Table 1.

Comparing 2011 and 2015, the global WC fatality rate dropped 65.6% (p<0.001) while infants less than 2 months decreased 82.2 % (p < 0.001). Figure 2.

One event was notified after flu and Tdap vaccination as Guillain-Barre syndrome, without sequelae. This event was classified as related to one or both vaccines.

Table 1. Flu and Tdap. Doses applied to PW and reported AEFI, per year

| Vaccine | Flu | | | | | | Tdap | | | | |
|------------------------------|---------|---------|---------|---------|---------|-----------|---------|---------|--------|---------|-----------|
| | 2011 | 2012 | 2013 | 2014 | 2015 | Total | 2012 | 2013 | 2014 | 2015 | Total |
| Doses applied to PW | 330,701 | 367,081 | 381,658 | 353,909 | 379,921 | 1,813,270 | 372,242 | 487,781 | 522,05 | 463,306 | 1,845,379 |
| AEFI reported in PW/ rate** | 0 | 1/0.27 | 4/1.05 | 5/1.41 | 1/0.27 | 11/0.6 | 7/1.88 | 8/1.64 | 5/0.95 | 7/1.51 | 27/1.46 |
| AEFI related/ vaccine rate** | 0 | 1/0.27 | 3/0.78 | 0 | 0 | 5/0.27 | 3/0.81 | 2/0.41 | 2/0.38 | 0 | 8/0.43 |
| Program errors/rate** | 0 | 0 | 0 | 5/1.41 | 0 | 5/0.27 | 4/1.07 | 5/1.02 | 3/0.57 | 6/1.29 | 18/0.97 |

(**Rates calculated for each 100,000 doses applied)

Figure 1. Maternal vaccination coverage 2011-2015

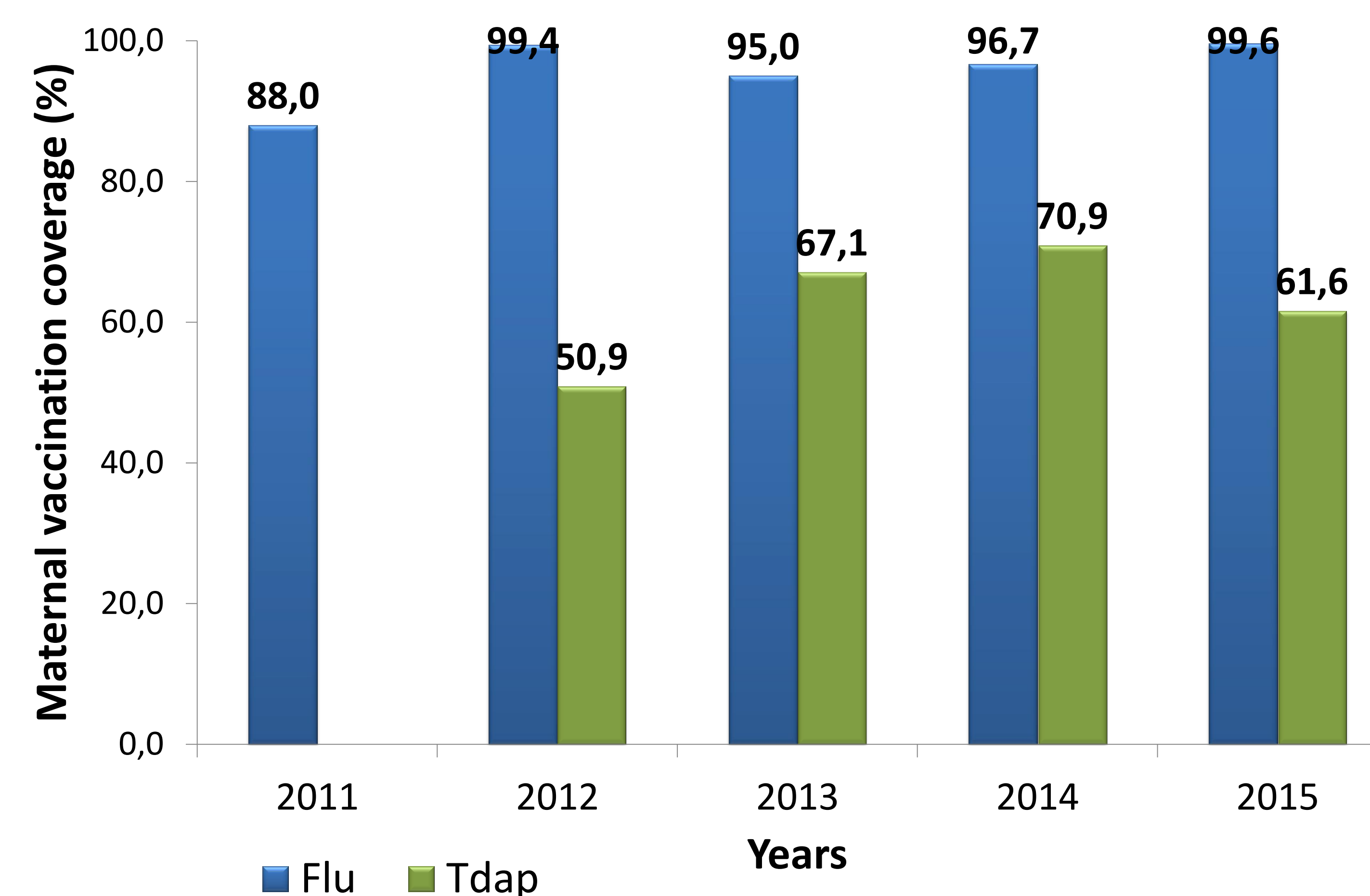
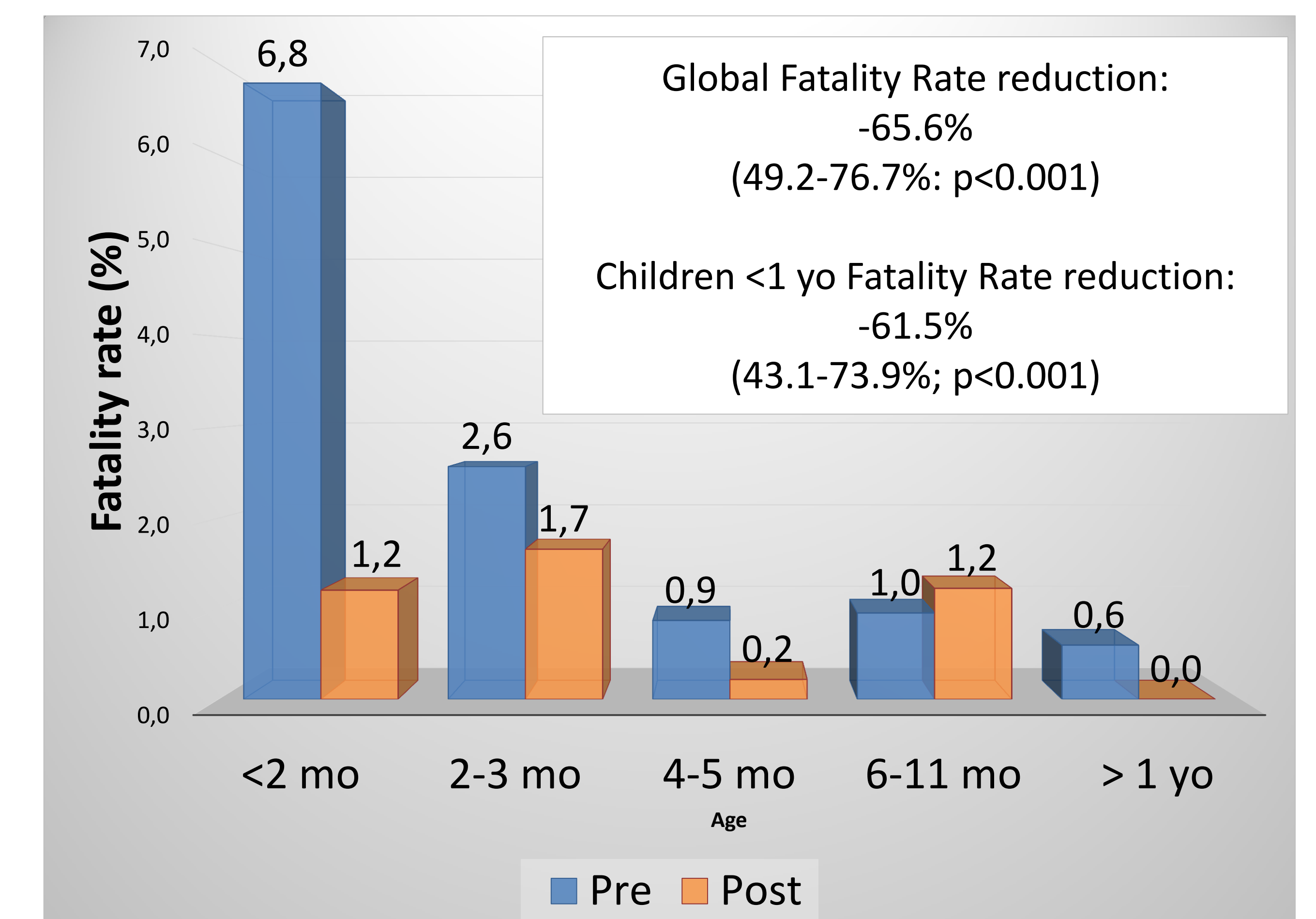


Figure 2. WC fatality rate (%) pre and post vaccination periods



Conclusion:

Both vaccines presented a suitable safety profile. Since 2012 a downward trend in pertussis mortality was evident and no deaths from influenza in vaccinated were notified in pregnant women. Our country became the first Latin-American country to have a strategy of vaccination against WC universally and consolidated as an example of influenza vaccination in the region.

