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## **DATOS Y EVIDENCIAS DEL MUNDO REAL EN LATINOAMÉRICA: ¿REALIDAD O FICCIÓN?**

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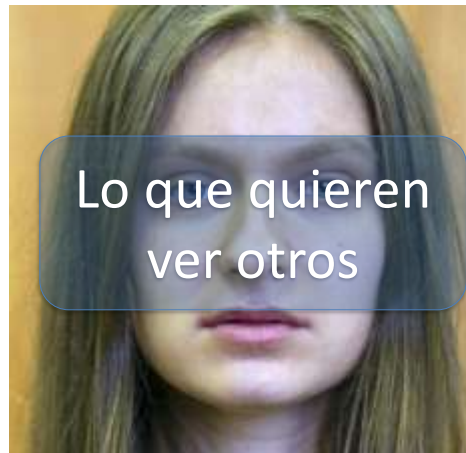
## **En esta breve presentación**

- Algo de “Real Life” o “Real World Evidence”
- Algunas experiencias
- Conclusiones



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# Dos caras de la moneda



The NEW ENGLAND JOURNAL of MEDICINE

## SOUNDING BOARD

### Real-World Evidence — What Is It and What Can It Tell Us?

cific meaning is elusive. **We believe** it refers to information on health care that is derived from multiple sources outside typical clinical research settings, including personal devices and health applications.<sup>1,2</sup> Key to (EHRs), claims and understanding the usefulness of real-world evidence registries, and evidence is an appreciation of its potential for personal devices and **complementing the knowledge** gained from tra-

The **FDA is developing guidance** on the use of “real-world evidence” — health care information from atypical sources, including electronic health records, billing databases, and product and disease registries — to assess the safety and effectiveness of drugs and devices.

# Evaluar seguridad de vacuna antigripal A/H1N1 con adyuvante MF59 en mujeres embarazadas

49 Hospitales Públicos en Argentina  
30,448 madres (7293 vacunadas)  
y 30,769 RN

Outcome 1: BPN, RNPT, Muerte Fetal o Neonatal hasta 7 días post parto

BMJ

BMJ 2013;346:f800 doi: 10.1136/bmj.f800 Published 4 February 2013 Page 1 of 12

## RESEARCH

### Influenza A/H1N1 MF59 adjuvanted vaccine in pregnant women and adverse perinatal outcomes: multicentre study

OPEN ACCESS

F Rubinstein director of epidemiology and academic affairs<sup>1,2,3</sup>, P Micone associate investigator<sup>4</sup>, A Bonetti associate investigator<sup>5</sup>, V Wiener associate investigator<sup>6</sup>, A Schwartz associate investigator<sup>7</sup>, F Augustovski director of health technology assessment and economic evaluations<sup>8,9</sup>, A Pichon Riviere executive director and director of health technology assessment and economic evaluations<sup>10</sup>, A Karolinski general coordinator and head of education and research<sup>11</sup>, on behalf of EVA Study Research Group (Estudio "Embarazo y Vacuna Antigripal")



Mujeres vacunadas menor riesgo de eventos: (7.0% (n=513) v 9.3% (n=2160))

Table 3 | Crude and adjusted main perinatal outcomes in vaccinated and non-vaccinated women

Outcome	No (%)		Odds ratio (95% CI)		Adjusted propensity score† (95% CI)
	Vaccinated H1N1 (n=7293)	Non-vaccinated H1N1 (n=23 195)	Crude	Multiple logistic regression adjusted*	
Preterm + low birth weight + perinatal mortality	513 (7.0)	2160 (9.3)			0.79 (0.71 to 0.87)
Preterm (<37 weeks)	354 (4.9)	1505 (6.5)	0.73 (0.65 to 0.83)	0.79 (0.69 to 0.90)	
Low birth weight	357 (4.9)	1605 (6.9)	0.69 (0.61 to 0.78)	0.74 (0.65 to 0.83)	
Perinatal mortality	54 (7.4)	257 (11.0)	0.63 (0.46 to 0.86)	0.68 (0.42 to 1.06)	

\*Adjusted for number of antenatal visits, level of education, maternal age, income, parity, smoking, and history of pregnancy induced hypertension.

†Propensity score was entered in model as five level dummy variable, both in fifths of probability of vaccination and range of probability, from 0-10% to >40%.

Odds Ratio → 0,8

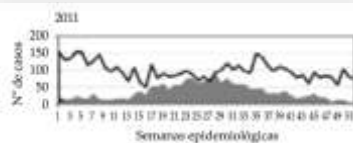
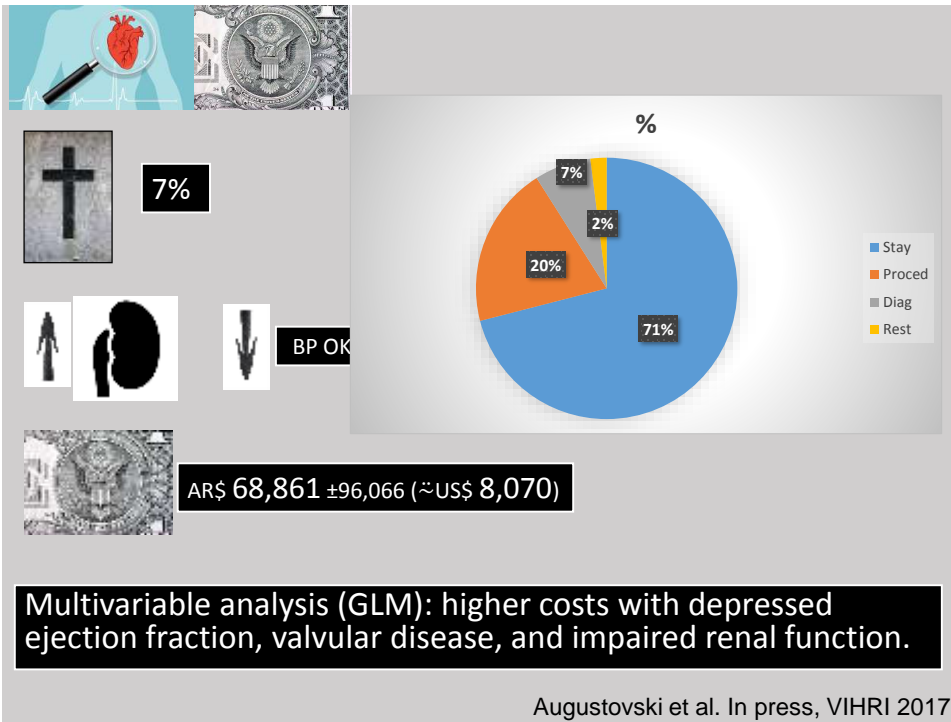


**Conclusion** This large study using primary data collection found that MF59 adjuvanted A/H1N1 influenza vaccine **did not result in an increased risk of adverse perinatal events** and suggested a lower risk among vaccinated women. These findings should **contribute to inform stakeholders and decision makers** on the prescription of vaccination against influenza A/H1N1 in pregnant women.



- Estudio multicéntrico retrospectivo, tres hospitales de Argentina del sector privado
- Basado en recolección de datos de HC (E o P)
- 301 sujetos, edad promedio 75 años, 37% mujeres

Augustovski et al. In press, VIHRI 2017



# Conclusiones

- Los estudios «real life» son muy heterogéneos y pueden tener muchos usos
- En nuestra región aún no existe mucha infraestructura para realizarlos de manera eficiente (acceso a datos de razonable calidad - big data)
- Complementan la evidencia inicial al registro
- Cada vez más requeridos por decisores (aunque reguladores....)



¡Muchas gracias!

Federico Augustovski

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