

COVID-19 vaccination surveillance: a public health commitment

*Giacomo Pietro Vigezzi*¹, *Vincenza Gianfredi*^{1,2}, *Alessandra Lume*¹, *Massimo Minerva*¹, *Paola Nizzero*³, *Anna Biancardi*³, *Anna Odone*⁴, *Carlo Signorelli*^{1,2}, *Matteo Moro*³

¹ School of Medicine, Vita-Salute San Raffaele University, Milan, Italy; ² Clinical Epidemiology Unit, IRCCS San Raffaele Hospital, Milan, Italy; ³ Infection Control Committee, IRCCS San Raffaele Hospital, Milan, Italy; ⁴ Department of Public Health, Experimental and Forensic Medicine, University of Pavia, Pavia, Italy

To the Editor,

We read with interest the letter by Joob et al. (1). We strongly believe that, due to the novelty of the mRNA vaccines, surveillance on both safety and efficacy is extremely important. Indeed, it should be highlighted that because of SARS-CoV-2 newness, the susceptibility of the whole population, as well as the severity of the disease – especially in specific population subgroups – along with the high reproduction rate of the virus, many efforts were required in order to obtain safe and effective vaccines in the shortest time (2).

This timing contraction was partially obtained by the rolling review of available clinical trial data for faster approval, while information on long-term efficacy and safety are still being gathered and monitored through national surveillance systems and field research. In fact, data on long-term efficacy and safety are still under construction. In light of this, we performed two studies. The first one was conducted among healthcare workers and assessed the prevalence and severity of medium-term adverse events following COVID-19 vaccination (both first and second dose) (3); the second one was conducted among the general population and was aimed to assess the immediate adverse events following COVID-19 vaccination (both first and second dose) (4).

We share the same concerns of Joob et al. regarding the reliability of self-reported data. Indeed, since the reliability of self-reported data might be affected by several different factors (e.g., level of knowledge,

self-perception, awareness, educational level, social desirability bias, recall bias, and many others), we used two different approaches. On the one hand, in the study among healthcare workers, we opted for self-reported data because we believed that due to this target population's high level of awareness and knowledge, reliability was not a major issue but, on the contrary, a specific strength. On the other hand, for the study we conducted among the general public, data analysed came from an electronic database filled in by physicians. Regardless of the type of data (self-reported vs registry-based), in the two studies, we employed digital tools. As a matter of fact, electronic health records are extremely useful both for administrative purposes, clinical outcomes analysis, and offer opportunities to conduct research (5-7). Nevertheless, acquisition costs, maintenance costs, and personnel training costs are only some of the aspects that, especially in low/middle-income countries, may hinder their implementation (8). However, benefits for patients, researchers, and policymakers are so relevant that scientists should support shaping public health policies and programs (9). Public health authorities should implement safety monitoring systems of vaccines and disseminate safety issues in a proactive mode (10, 11). The system should be able to make objective and clear communication regarding safety issues of vaccines (12). Staff preparedness and basic training to report adverse events and strengthen local resilience should involve stakeholders (13). Data should be reported to the public regularly to maintain confidence

in vaccination programs (14, 15). Implementing such a vaccines safety monitoring system is helpful in all countries (both high and low/middle-income countries). As reminded by WHO in the context of the COVID-19 pandemic, monitoring vaccine safety is a shared responsibility (16).

Conflict of Interest: Each author declares that he or she has no commercial associations (e.g. consultancies, stock ownership, equity interest, patent/licensing arrangement etc.) that might pose a conflict of interest in connection with the submitted article.

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Correspondence:

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Vincenza Gianfredi, MD, DrPH

School of Medicine,

Vita-Salute San Raffaele University

Via Olgettina, 58, 20132,

Milan, Italy.

Orcid.org/0000-0003-3848-981X

E-mail: gianfredi.vincenza@hsr.it