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Real-world effectiveness of COVID-19 vaccination among children in Italy

Camilla Mattiuzzi 1, Giuseppe Lippi 2,*  
1Service of Clinical Governance, Provincial Agency for Social and Sanitary Services (APSS), Trento, Italy  
2Section of Clinical Biochemistry and School of Medicine, University of Verona, Italy

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In this study, we analyzed the clinical efficacy of mRNA-based COVID-19 vaccines among Italian children aged 5 to 11 years, using data published by the National Institute of Health. Vaccination status was associated with a reduced risk of COVID-19–related hospitalizations and intensive care unit (ICU) admissions, which were 41% (odds ratio, 0.59; 95% confidence interval [CI], 0.46–0.77) and 68% (odds ratio, 0.32; 95% CI, 0.04–2.63), respectively, lower in children who completed the vaccination cycle <120 days than in the unvaccinated matched population.

In a recent study, Husin and colleagues emphasized the considerable efficacy of the coronavirus disease 2019 (COVID-19) mRNA-based BNT162b2 vaccine against the risk of severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) infection in adolescents (Husin et al., 2022). Given that not only limiting the burden of SARS-CoV-2 infection but also preventing the risk of developing severe complications of COVID-19 is imperative in childhood, the real-world effectiveness of COVID-19 vaccination among Italian children was investigated in this study.

The source of our analysis was the official data of the Italian Institute of Health (Istituto Superiore di Sanità; ISS) [Istituto Superiore di Sanità, 2022]. The official bulletin of the ISS (last update, April 27, 2022) contains periodically updated nationwide data on vaccine coverage, COVID-19 related infections, hospitalizations, intensive care unit (ICU) admissions, and deaths recorded during the previous month across different ages, including the 5 to 11 years range, stratified for vaccination status. Data were analyzed with MedCalc Version 20.015 (MedCalc Software Ltd., Ostend, Belgium).

The study was conducted in accordance with the Declaration of Helsinki, under the terms of relevant local legislation. This research was based on publicly available data; thus, Ethical Committee approval was unnecessary.

The results of our analysis of COVID-19 vaccine efficacy in Italian children are shown in Table 1. Overall, at the time of our analysis, the total number of children aged 5 to 11 years who were still unvaccinated was 229,1598, and the number who received one of the two mRNA-based vaccines (either BNT162b2 or mRNA-1273, the relative proportions are not specified) was 1,204,468. We found that vaccination status was associated with a reduced risk of COVID-19–related hospitalizations and ICU admissions, which were found to be 41% and 68%, respectively, lower in children who completed the vaccination cycle within 120 days than in the unvaccinated matched population.

In conclusion, the results of our analysis complement those that emerged from the study of Husin and colleagues (Husin et al., 2022). The data of the ongoing nationwide Italian COVID-19 vaccination campaign reveals that mRNA-based COVID-19 vaccines are effective in significantly reducing the risk of COVID-19–related hospitalization among children, also displaying a notable trend toward lowering the likelihood of developing severe or critical disease that ultimately necessitates ICU admission.

Abbreviations: COVID-19, Coronavirus Disease 2019; ICU, Intensive Care Unit; 95%CI, 95% Confidence Interval; SARS-CoV-2, Severe Acute Respiratory Syndrome Coronavirus 2; ISS, Istituto Superiore di Sanità.

* Corresponding author: Prof. Giuseppe Lippi. Section of Clinical Biochemistry, Department of Neurosciences, Biomedicine and Movement Sciences, P.le LA Scuro, 10, 37134 Verona, Italy. Phone: ++39 045 8124512; Fax ++39 0458124514.  
E-mail address: giuseppe.lippi@univr.it (G. Lippi).
Table 1
mRNA-based COVID-19 vaccine efficacy in children aged 5 to 11 years in Italy.

| Endpoint                      | Unvaccinated | Primary vaccination <120 days | OR (95% CI) of vaccination |
|-------------------------------|--------------|-------------------------------|---------------------------|
| Total population              | 229,1598     | 120,4468                      | -                         |
| COVID-19 hospitalizations     | 240          | 75                            | 0.59 (0.46-0.77; p<0.001)  |
| COVID-19 ICU admission        | 6            | 1                             | 0.32 (0.04-2.63; p=0.288)  |

OR, odds ratio; 95% CI, 95% confidence interval; ICU, intensive care unit

Declaration of Competing Interest

The authors have no competing interests to declare.

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Ethical approval

Ethical approval was unnecessary (usage of freely available information).

Author contribution

GL and CM designed the study, collected the data, analyzed the data, and wrote the manuscript.

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