

The impact of COVID-19 vaccination campaign on pediatric vaccine uptake based on parents' attitudes towards mandatory and recommended vaccination in Southern Italy

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ABSTRACT

Introduction: This study investigates the association between parental attitudes towards mandatory and recommended vaccines in the National Immunization Plan (NIP) of Italy and their acceptance of the COVID-19 vaccine in children aged 5–11 years.

Methods: Using data from approximately 42,000 children in Southern Italy, parental attitudes towards previous vaccinations were examined. Mandatory and recommended vaccinations were considered for the analysis, with the first shot of each schedule being considered relevant, regardless of when it was administered or whether the recommended number of doses was administered. A multivariate logistic regression was performed to analyze associations between the covariates of age, sex, adherence to mandatory vaccinations, number of recommended vaccinations, and COVID-19 vaccination.

Results: The COVID-19 vaccine acceptance rate was 50.7% in our sample. We revealed a strong association between parental attitudes towards previous vaccinations and the acceptance of the COVID-19 vaccine. Mandatory vaccinations under the NIP showed the highest acceptance rates, and among non-mandatory vaccines, the pneumococcal conjugate vaccine had the highest acceptance rate, potentially due to its co-administration with the hexavalent vaccine. The study identified a trend of lower COVID-19 vaccine coverage in younger children. **Conclusions:** The study underscores the importance of co-administration approaches and well-planned vaccination schedules in enhancing vaccine coverage. It suggests that integrating newer vaccines, like the COVID-19 vaccine, into established vaccination schedules could potentially increase acceptance and coverage. The findings highlight the urgency of addressing vaccine hesitancy, particularly in the pediatric population, to ensure high vaccination coverage and effective disease control. Further research is needed to explore the potential strategies to increase vaccine acceptance.

1. Background & objective

The COVID-19 vaccination for the pediatric population (children 5 to 11 years old) was approved in Italy on the 1st of December 2021. The first product approved was the Corminaty-Pfizer mRNA vaccine with a reduced dose (one-third of the authorized dosage for adults and adolescents). The vaccination schedule consisted of two doses three weeks apart (21–40 days) and was the only schedule authorized for this population in Italy [1].

At the moment, the Spikevax-Moderna mRNA vaccine is also authorized for this population, but very few doses have been administered in Italy so far.

The COVID-19 immunization campaign for children (5–11) was supported by nationwide and local communication campaigns both on social media and in person, but the Italian Ministry of Health never made COVID-19 vaccination mandatory for children (unlike adults over 50 years old).

Although the clinical course of SARS-CoV-2 infection in children is

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generally mild and a minority of children with COVID-19 require hospitalization [2], severe cases have been reported [3].

One of the most severe complications is the COVID-19–Associated Pediatric Multisystem Inflammatory Syndrome with features similar to Kawasaki disease [4], a rare but potentially life-threatening condition [5].

A systematic review of clinical trials analyzed COVID-19 vaccination safety and efficacy in the pediatric population and reported mild and moderate adverse events following immunization (AEFI), with few severe reactions [6].

The common AEFI were injection-site pain, fever, headache, cough, fatigue, and muscle pain. No serious adverse events were reported in trials using mRNA vaccines. mRNA vaccines exhibited over 90 % efficacy in preventing severe disease after the second dose in clinical trials of young people aged 5–17 years, demonstrating that the policy of mass vaccination of children and adolescents is reasonable and feasible [6].

Despite the evidence on the safety and efficacy of pediatric COVID-19 vaccination, in this population vaccination coverage is still low, even in high-income countries.

For example, in the United States, only 32.9 % of individuals aged 5 to 11 have received at least one dose of COVID-19 vaccination, in contrast to the approximately 60 % coverage observed in the 12 to 17 age group [7]. Italy presents a similar situation, with a 35.37 % immunization rate among children aged 5 to 11, with remarkable differences that can be observed across Italian regions. The Italian Minister of Health's registry shows that some southern regions have higher coverage rates, yet there are significant differences even between adjacent regions. For instance, the Province of Trento reported that 33.74 % of children aged 5–11 years had received at least one dose, while the Province of Bozen reported a lower rate of 19.58 %. Moreover, a substantial disparity exists between vaccination coverage in children and adolescents in Italy, as approximately 84 % of individuals aged 12 to 19 have received at least one dose of the COVID-19 vaccine [8].

The Kaiser Family Foundation (KFF), an independent organization focused on health policy research, polling, and news dissemination, monitored the COVID-19 vaccine and explored the reasons for parents not vaccinating, highlighting concerns about the newness of the vaccine and not enough testing or research, concerns over side effects, and worries over the overall safety of the vaccines [9].

A survey among Italian adolescents (aged 10–17 years) was recently conducted to explore the awareness and acceptance of COVID-19 vaccination. The survey highlighted the importance of parents' decisions and attitudes towards vaccination, showing that the most important predictor of being immunized against SARS-CoV2 was having both parents immunized [10].

Socioeconomic status is recognised as a determinant of vaccine hesitancy and may contribute to regional differences within Italy [11]. Bianchi and colleagues conducted a systematic review and meta-analysis to explore COVID-19 vaccine hesitancy among Italian parents. They reported varying levels of hesitancy, indicating that parents in Northern Italy appear slightly less hesitant at 43 % compared to 49 % among Southern Italian parents [12].

Parents' attitudes are even more important in determining younger children's (5–11 years) immunization status. It seems clear that parents' vaccine hesitancy may interfere with universal children's COVID-19 immunization [13].

Vaccine hesitancy, as defined by the European Centre for Disease Prevention and Control, refers to the delay in acceptance or refusal of vaccines despite the availability of vaccination services [14].

To address the growing vaccine hesitancy for pediatric vaccination in Italy, in 2017, the National Immunization Plan (NIP) encompassed 10 mandatory vaccinations for attending school, as defined by the National Law Decree n.119 [15].

In evaluating the possibility of making COVID-19 vaccines mandatory to attend school, the World Health Organization (WHO) suggests that policymakers have to consider two main ethical issues: whether it is

necessary and proportional to achieving an important societal or institutional objective and whether this could undermine public trust [16].

Previous studies have explored the effect of the COVID-19 pandemic in decreasing vaccine coverage of routine pediatric vaccinations, in Italy rates for mandatory vaccinations decreased in 2020 compared to 2019 with a range between –1 % to –2.7 % [17,18].

In this study, we investigate vaccine hesitancy in eligible children in Lecce (Apulia, Southern Italy). We used the COVID-19 vaccination status of children as a proxy for parents' attitudes towards vaccination and analyzed its relationship with previous attitudes towards mandatory and recommended vaccination administered to children, according to the NIP and the National Law Decree that introduced mandatory vaccinations in infants and adolescents in Italy.

Monitoring and assessing routine infant vaccination coverage is crucial for evaluating the performance of immunization services. The reasons for missed or delayed vaccination in Italy have been largely explored before the COVID-19 pandemic, especially through surveys [19,20].

The Apulia Region, with notable efforts from the Local Health Authority of Lecce, launched a campaign to promote COVID-19 vaccinations. A dedicated website was created for easy access to vaccination information and online booking, simplifying the process for families [22]. Additionally, the region utilized social media to disseminate information and organized special “open day” vaccination events specifically for 5–11-year-olds. To further increase vaccine uptake among children aged 5–11, the Local Health Authority of Lecce implemented a strategy of administering the initial dose of the COVID-19 vaccine cycle in schools. This involved dispatching public health experts and pediatricians directly to educational institutions.

These initiatives highlight Apulia's commitment to public health and could serve as a model for encouraging vaccination uptake.

Therefore we hypothesize that the large investments in sensibilization campaigns and the mediatic exposure of vaccines as a useful tool to overcome the COVID-19 pandemic may have changed parents' attitudes towards vaccination improving them, and therefore we expect to find no correlation between COVID-19 vaccine acceptance and vaccine acceptance for vaccinations included in the Italian NIP previous to the COVID-19 pandemic [23].

2. Methods

2.1. Data sources

The vaccination records of subjects eligible for pediatric COVID-19 immunization up to 15/11/2022 were anonymously extracted and analyzed from the GIAVA 6.0 platform that constitutes the Regional Vaccine Registry (AVR) of the Apulia region. GIAVA allows the registration of routine and COVID-19 vaccinations [24].

2.2. Inclusion criteria

We included in our study:

- children of age between 5 and 11 years old at the data extraction (15/11/2022), part of birth cohorts 2011–2017.
- having their residence in the province of Lecce, Apulia region, Italy.
- subjects with an Italian tax code.

2.3. Exclusion criteria

We excluded from the study:

- Subjects without an Italian tax code.
- Children of the 2017 birth cohort of age < 5 on 15/11/2022.

The vaccines included in the NIP identified in the AVR are

summarized in Table 1, it is also indicated if according to the Italian Ministry of Health are mandatory or recommended.

For the birth 2017 cohort, the vaccination with the meningococcal group C vaccine wasn't considered since for that birth cohort the conjugate vaccine ACW135Y was introduced, and data on vaccine uptake were not available.

2.4. Data analysis

Since the aim of the study is to investigate attitude towards vaccination rather than the completeness of immunization, the first shot of each schedule was considered relevant for the analysis, regardless of when it was administered or whether the recommended number of doses was administered.

Therefore, for each child, the parents' attitude towards each one of the vaccinations included in the NIP was flagged as positive (the child has received at least one shot of vaccine) or negative (the child has never received any shot of vaccine despite being eligible), according to the vaccination status of their child.

For each child, two indicators were calculated:

- adherence to mandatory vaccinations: a binary variable with two possible levels, 1 (the child had received at least 1 shot for each mandatory vaccination) and 0 (the child was administered none or only one mandatory vaccine).
- number of recommended vaccinations: a numeric variable ranging from 0 to 6–7, representing the number of recommended vaccination schedules for which the child had received at least 1 shot.

We performed a multivariable logistic regression to analyze associations between the covariates of age, sex, adherence to mandatory vaccinations (as described above), number of recommended vaccinations (as described above), and COVID-19 vaccination as an outcome.

Statistical analysis was conducted utilizing the R programming environment, setting significance (alpha) at the conventional 0.05 level. Thus, p-values under 0.05 were deemed statistically significant.

3. Results

From the 42,887 cohort of children (5–11 years) registered in the GIAVA platform as residents in Lecce, southern Italy, a total of 42,173 subjects (98.3 % of the cohort; 20,452 female and 21,727 male) were included in the study, 21,361 (50.7 %) of which received at least one dose of COVID-19 vaccine (see Fig. 1).

The number of children stratified by birth cohort that received at

Table 1

Vaccines included in the Italian National Immunization Plan that were analyzed in the study population. Mandatoriness refers to the Italian laws and Ministry of Health recommendations.

Vaccine	Abbreviation	Mandatory according to the Italian NIP
Hexavalent diphtheria, tetanus, acellular pertussis, Haemophilus influenzae type B, poliovirus and hepatitis B	DTaP-Hib-IPV-HepB	Mandatory
Measles, mumps, and rubella live attenuated vaccine	MMR	Mandatory
Varicella live attenuated vaccine	VAR	Mandatory from the 2017 birth cohort
Pneumococcal conjugate vaccine	PCV	Recommended
meningococcal group B Vaccine	Men B	Recommended
meningococcal group C vaccine	Men C	Recommended
human papillomavirus 9-valent vaccine (recombinant, adsorbed)	HPV	Recommended
Hepatitis A (inactivated) vaccine (adsorbed)	HAV	Recommended only in Apulia Region
rotavirus vaccine, live	Rota	Recommended

least one dose of each vaccine, thus representing the vaccine coverage for the first dose, is reported in Fig. 2.

The acceptance rates for the Meningococcal B and Rotavirus vaccines have been observed to be comparatively lower, with respective rates of 68 % and 34.6 %.

The mandatory vaccinations have the highest acceptance rates, with 96.12 % for the hexavalent vaccination and 94.9 % for the MMR, followed by the pneumococcal vaccine (94.77 %).

As shown by our regression analysis, the number of recommended vaccinations was found to be associated with COVID-19 vaccination (OR 1.38; 95 %CI [1.35–1.41]; $p < 0.000001$). Compliance with mandatory vaccinations was a predictor for COVID-19 vaccination, as well. (OR = 2.10; 95 %CI [1.76–2.51]; $p < 0.000001$). The probability of being vaccinated against COVID-19 increased with age. (OR = 1.15; 95 %CI [1.13–1.16]; $p < 0.000001$) and no significant relationship was found between sex and COVID-19 vaccination. Overall, our regression model effectively predicts the probability of receiving the COVID-19 vaccination, as shown in Fig. 3.

4. Discussion

In our sample, the acceptance rate of COVID-19 vaccination (50.7 %) is lower than the prevalence of parental acceptance to vaccinate their children with the COVID-19 vaccine estimated by a recent systematic review (57 %) [25].

As anticipated, the vaccinations that exhibit the highest acceptance rates are those that are mandatory in the Italian NIP.

Interestingly, among the non-mandatory vaccines, anti-pneumococcal (PCV) has the highest acceptance rate. A possible explanation of this phenomenon might be that the PCV vaccine is routinely co-administered with the hexavalent vaccine (DTaP-Hib-IPV-HepB), as indicated by the Italian NIP. The superior compliance and increase in vaccination coverage that can be obtained through co-administration has well-established evidence for different types of vaccinations [2627].

Conversely, lower acceptance rates can be observed for the vaccinations that have been included more recently in the Italian vaccination calendar, for example, the rotavirus vaccine (recommended in 2017 in Italy).

It's encouraging that for the birth cohort of 2017, the first one for which the rotavirus vaccine was recommended and freely available in Italy, according to the 2017–2019 NIP, the acceptance rate rose over 70 %.

It is important to point out that in the province of Lecce, the first dose of the Rotavirus vaccine is usually co-administered during the first session together with PCV and DTaP-Hib-IPV-HepB showing the success of this strategy.

Some authors have also proposed a shorter dosing schedule of rotavirus, to allow the inclusion in the established Italian vaccination calendar easier and, ultimately, increase vaccination coverage [28].

Despite our initial hypothesis, the results show a clear association between parent's attitudes toward previous vaccinations and the one toward COVID-19, in a sample of around 42,000 infants in Southern Italy. Possibly signifying that the large investments in sensitization campaigns and the mediatic exposure of vaccines did not have the expected outcome on vaccine acceptance in our study population.

Although the recommendation for COVID-19 vaccination for children from 5 to 11 years was the same, we identified a lower vaccine coverage for younger children. This data is confirmed by other studies [29].

Our analysis shows that the COVID-19 pandemic had no positive impact on vaccine uptake, as attitudes towards previous vaccinations were confirmed for the COVID-19 vaccine. As reported by a recent study [30], vaccine safety is perceived as a concern by all parents, and this could have played an important role in COVID-19 vaccine hesitancy, as well [31].

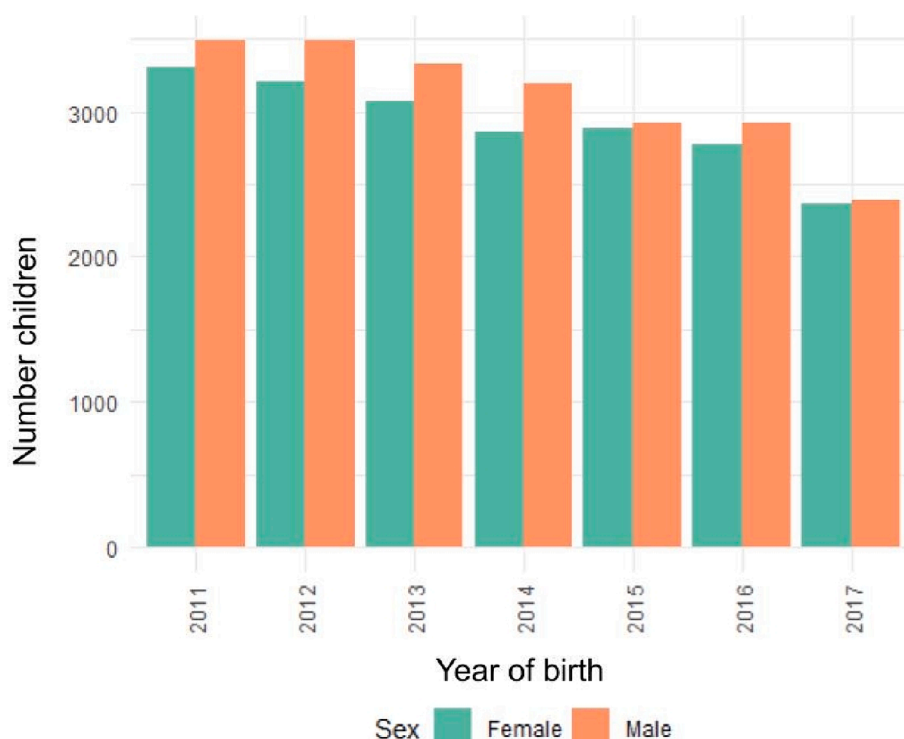


Fig. 1. Distribution of gender across birth cohorts in the province of Lecce (southern Italy). This bar chart illustrates the count of males and females within each birth cohort from 2011 to 2017. Each birth cohort is represented on the x-axis, while the y-axis shows the number of individuals. The figure provides insight into the sex distribution within each birth cohort in the studied population.

One of the limitations of our study is that the immunization status of a child is not a perfect proxy for a parent's attitude towards vaccination, as the reasons behind the choice of not vaccinating a child might lie in certain children's medical conditions or other unrelated factors [32]. The fact that parents with more than one child might have been included multiple times in our analysis could amplify the effect we measured.

Moreover, our study's methodology also necessitated the exclusion of individuals without an Italian tax code, possibly affecting undocumented migrants. This potential underrepresentation of a subset of the population with possibly distinct attitudes towards vaccination due to their unique socio-economic and legal challenges could introduce a bias towards the documented population, which may not fully represent the broader community's attitudes towards COVID-19 vaccination.

Future studies should incorporate multiple covariates encompassing children's health history, parental health literacy, risk perception, and socio-economic factors that were not evaluated in the study due to stringent privacy regulations and data availability constraints. This approach is crucial for a better understanding of vaccine hesitancy. Additionally, a targeted investigation into vaccine co-administration as a potential strategy to enhance vaccine uptake represents a promising research avenue.

5. Conclusion

Our study sheds light on the multifaceted nature of factors contributing to vaccine acceptance, underscoring the significance of co-administration approaches and well-planned vaccination schedules in bolstering vaccine coverage. We had initially postulated that the COVID-19 pandemic would potentially subdue vaccine uptake, implying a minimal association between acceptance of prior vaccinations and the COVID-19 vaccine. However, our findings revealed a strong link between the two, indicating that the pandemic did not substantially modify attitudes toward vaccinations.

Moreover, we identified a conspicuous variation in COVID-19

vaccine acceptance across different age groups, with lower rates observed in younger children. This trend persists even following the expanded recommendation for COVID-19 vaccination to include infants aged 6 months to 5 years, a directive that was not in place at the time of our data extraction.

This observation aligns with findings from other studies [29], thereby underlining a crucial area for public health intervention.

As we move towards an endemic phase of COVID-19, the pediatric population will become increasingly significant in maintaining overall immunity within the community. Therefore, vaccine hesitancy, particularly towards the COVID-19 vaccine, poses a significant public health challenge. Parental concerns regarding vaccine safety, a common factor in vaccine hesitancy, need to be addressed proactively and effectively through clear, consistent communication and evidence-based education.

Moreover, our study points to the potential value of integrating newer vaccines, such as the COVID-19 vaccine, into established vaccination schedules and co-administration strategies to potentially increase acceptance and coverage. However, additional research is needed to further investigate this potential strategy and its acceptability among parents.

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Ethics

The study was approved (Prot.678 14-11-2023) by the Ethical Committee "Comitato Etico Locale IRCCS Istituto Oncologico Gabriella Serio" Bari, Italy D.G.R. Apulia Region n° 712 of 22-05-2023 and n°806 12-06-2023.

Declaration of AI and AI-assisted technologies in the writing process

During the preparation of this work, the authors used ChatGPT and Grammarly for English grammar checks. After using this tool/service, the authors reviewed and edited the content as needed and take full responsibility for the content of the publication.

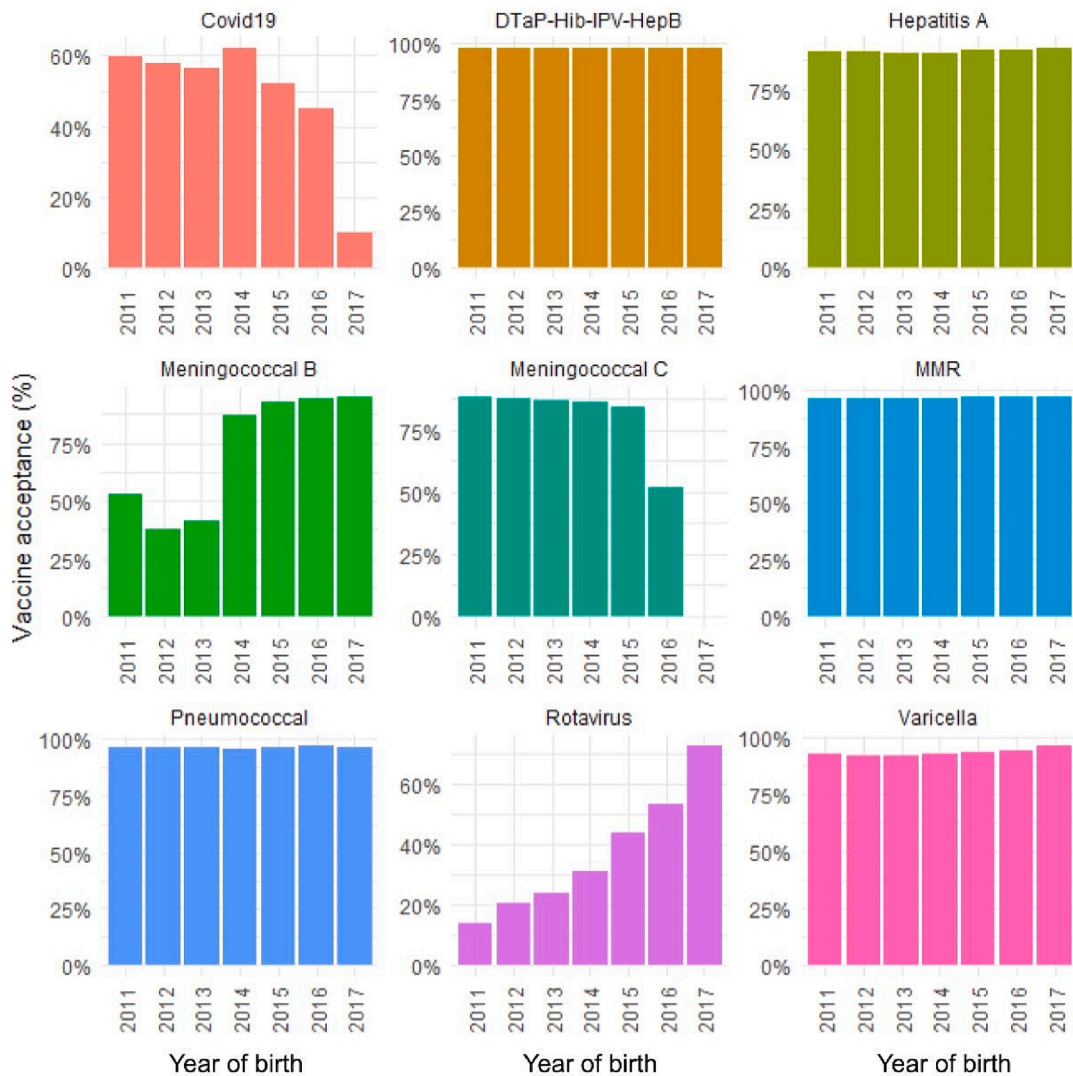


Fig. 2. Parental Vaccine Acceptance Across Birth Cohorts for Italian NIP Vaccines in Lecce, southern Italy: In each facet is displayed the vaccine acceptance rate of parents (derived from the percentage of children who received at least one shot of vaccine) divided by birth cohort for different vaccines identified in the NIP.

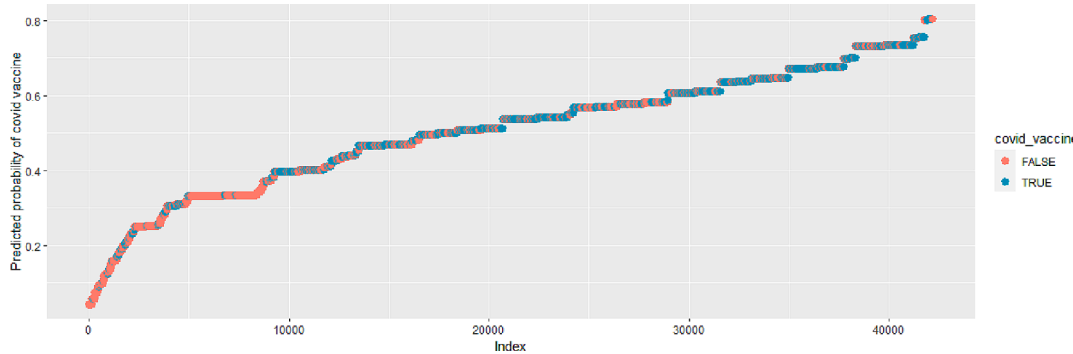


Fig. 3. Assessing COVID-19 Vaccination Prediction: A Regression Model Visualization: On the x-axis is represented each subject included in the study is ordered by his/her predicted probability of COVID-19 vaccination based on the regression model. On the y-axis is reported the predicted probability of COVID-19 vaccination. For each subject is displayed if he/she received (blue) or not (red) the vaccination. (For interpretation of the references to colour in this figure legend, the reader is referred to the web version of this article.)

CRediT authorship contribution statement

Francesco Baglivo: Conceptualization, Formal analysis, Methodology, Writing – original draft, Writing – review & editing. **Luigi De**

Angelis: Conceptualization, Formal analysis, Investigation, Methodology, Writing – original draft, Writing – review & editing. **Mariano Magri:** Supervision, Validation, Writing – review & editing. **Ingrid De Nicola:** Data curation, Validation, Writing – review & editing. **Erica De**

Vita: Supervision, Writing – original draft, Writing – review & editing. **Pietro Luigi Lopalco:** Supervision, Writing – review & editing. **Caterina Rizzo:** Supervision, Writing – review & editing. **Alberto Fedele:** Project administration, Supervision, Writing – review & editing.

Declaration of competing interest

The authors declare the following financial interests/personal relationships which may be considered as potential competing interests: Luigi De Angelis reports a relationship with Moderna Inc that includes: travel reimbursement. Alberto Fedele reports a relationship with Seqirus Vaccines Ltd that includes: board membership. Francesco Baglivo reports a relationship with Moderna Inc that includes: travel reimbursement. Francesco Baglivo reports a relationship with AstraZeneca that includes: educational grant. Caterina Rizzo reports a relationship with Seqirus Vaccines Ltd that includes: board membership. Caterina Rizzo reports a relationship with MSD that includes: board membership. Caterina Rizzo reports a relationship with GlaxoSmithKline (GSK) that includes: board membership. Caterina Rizzo reports a relationship with Sanofi that includes: board membership. Caterina Rizzo reports a relationship with AstraZeneca that includes: board membership.

Data availability

The authors do not have permission to share data.

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