

Anti-Sars-CoV-2 vaccination campaign in children aged 5-11 years: the experience of a mass vaccination center in the city of Milan

Elisa Astorri¹, Francesco Mazziotta¹, Claudio Macrelli¹, Navpreet Tiwana², Matteo Letzgus², Alberto Bisesti², Dario Laquintana², Laura Chiappa², Alessandra Piatti², Marcello Sottocorno², Francesco Falbo², Matilde Rosso², Ludovica Caprini², Silvana Castaldi^{1,2}

¹Department of Biomedical Sciences for Health, University of Milan, Milan, Italy; ²IRCCS Fondazione Ca' Granda – Ospedale Maggiore Policlinico, Milan, Italy

Abstract. *Background and aim:* After the approval of the anti-Sars-CoV-2 vaccines for the pediatric population, it is necessary to encourage the immunization of children aged 5-11 years, as this can reduce intergenerational transmission. Therefore, this goal has become a priority for the COVID 19 vaccination campaign in Italy. In the city of Milan, the mass vaccination center (MVC) Fiera Milano City, previously settled for general population, became the main site to host pediatric vaccinations. The center was consequently remodeled to ensure a suitable space for children. This paper provides an overview on the organization strategy implemented by Fondazione IRCCS Ca' Granda Ospedale Maggiore Policlinico. The modular structure and the wide surface available in the center allowed the administration of hundreds of vaccines per day, especially in the first opening phase. *Methods:* All the data for the entire period of activity of Fiera MCV, from December 16th 2021 to February 20th 2022, were analyzed using descriptive statistics. *Results:* During the entire period of activity, from 16 December 2021 to 20 February 2022, 23% of the population in the province of Milan aged 5-11 years has been reached and vaccinated with at least one shot of vaccine in this center. *Conclusions:* Despite an enthusiastic response in the first weeks of the campaign, a progressive reduction in vaccination adherence was observed, maybe due to the absence of restrictive measures for unvaccinated children in Italy. (www.actabiomedica.it)

Key words: pediatric vaccination center, Sars-CoV-2 pediatric vaccines, pediatric vaccines, mass vaccination center, vaccination center organization

Introduction

The Coronavirus disease 2019 (COVID-19) outbreak, caused by Sars-CoV-2, was declared a pandemic on March 11, 2020 (1). According to the WHO reported cases from 30 December 2019 to 25 October 2021, children and younger adolescents aged 5 to 14 years account for 7% of reported global cases and 0.1% of reported global deaths (2). In Italy, since the

beginning of the epidemic, 1.403.640 cases and 27 deaths were reported in the population aged between 0 and 19 years (3). Most infected children appear to have a milder clinical course, in contrast with infected elderly population (4). However, it is possible for children to develop a severe disease requiring Intensive Care Unit (ICU) admission and prolonged ventilation (5), especially in children affected by comorbidities (6). Additionally, cases of children developing an

inflammatory multisystem syndrome (MIS-C) after Sars-CoV-2 infection have been reported world-wide (7), as well as long-COVID symptoms (8).

The BNT162b2 Comirnaty vaccine was approved for pediatric use by the EMA on 25th November 2021 (9) and by the FDA on 29th October 2021 (10). The vaccine was found to be safe, immunogenic and 90.7% effective against Covid-19 in 5-to-11-year-old children with a regimen of 2 10- μ g doses administered 21 days apart (11). Furthermore, vaccinating children can also reduce intergenerational transmission and may also help advance other highly valued societal goals. In fact, as school attendance is critical to the well-being and life prospects of children and to parental participation in the economy, vaccinating school-aged children may help minimize school disruptions because of quarantine requirements (2).

On December 1st 2021, the pediatric formulation of Comirnaty was also approved in Italy (12) and vaccinations among children aged 5-11 started in the same month. In Italy, at the time of this report, 1358360 children (37,15% of the whole 5-11 population) received at least one dose and 1153931 children (31,56% of the 5-11 population) completed the vaccination cycle (13). In Lombardy Region, children aged 5-11 years susceptible to vaccination are 637165, of which 254598 (39,96%) received the first dose; 234599 children (36,82%) received the second dose or completed their vaccination cycle with one dose (13).

Among the sites identified to host pediatric vaccinations in the city of Milan, the massive vaccination center (MVC) Fiera Milano City managed by the IRCCS-Ca Granda Fondazione Policlinico (Fondazione) was the major one. The center is located in the city of Milan, in the commercial area of the Fiera Milano City, which covers a 1300mq surface. During the pandemic, this area had already been settled, first to an intensive care unit and then to a MVC for the general population (14). In fact, to face the first pandemic wave in Lombardy region in March 2020, the Fondazione was commissioned to set up an Intensive Care Unit, known as "Ospedale in Fiera". After the approval of the first anti Sars-Cov-2 vaccines, this area was converted to a mass vaccination center, in January 2021. Then, following the displace of most of the vaccination activity to the other MVC managed by

Fondazione, "Palazzo delle Scintille", the Fiera Milano City center was intended for pediatric vaccinations, in December 2021.

The aim of this article is to provide an overview of the organizational management of the Fiera Milano City pediatric vaccination center and its vaccination activity volumes.

Patients and methods

The data about children's vaccination are collected from the software used in the Fiera Milano City vaccination center. All the data for the entire period of activity of Fiera MCV, from December 16th 2021, to February 20th 2022, were analyzed using descriptive statistics. We used the overall vaccination activity report downloaded from the software to extract the amount of the doses administered (divided by birth cohorts, sex and received dose number), the number of daily administrations and the agenda's saturation.

General organization

In the previous organization, the vaccination process was managed in four process lines: reception, anamnestic area, administration area, vaccines supplying and stock areas, with an additional emergency department area. The modular organization on which the center was constructed allowed not only the autonomy for each process lines, but also their integration with the other lines. Modular organization means that each area in MVC interacts with other areas to reach the best optimization process and, in this way, it could be possible to guarantee a huge vaccination number per day (15).

The MVC was remodeled to meet children and caregivers' necessities. For this purpose, areas within the center were lined with posters and billboards figuring the characters of a famous amusement park, volunteer staff was recruited to entertain the children during the process and screens for cartoons was added to waiting areas and to vaccination modules. Furthermore, the presence of at least one adult each child was considered. Although the MVC is almost exclusively dedicated to children aged 5-11, vaccinations of their caregivers are still possible.

Organization-wise, the main difference between the previous and the new pediatric model is the vaccine administration: inoculation and anamnesis are no longer carried out in separated spaces and by different operators, as changing setting can be more stressful for children and less time-efficient compared to the single-step model. This increase in productivity, however, couldn't be backed up by data, since there was a decrease in the number of vaccinations, and thus a proper comparison wouldn't be possible.

The vaccination center is settled at the second floor of the Fiera Pavillion (the first floor was organized in an intensive care unit for COVID patients) and is now organized into three different areas: the reception area, the vaccination modules area and the post administration waiting area. In addition, an emergency department area is set to manage any serious reactions to the vaccine. The reception area consists in 14 reception desks and in 134 seats arranged in units of 2 or 3 chairs, to ensure the proximity of children and their caregivers. If an allergy assessment is required before carrying out the vaccination (such as in case of a past severe anaphylactic reaction to a vaccine, a contrast medium, an injective drug, or uncontrolled bronchial asthma, uncontrolled urticaria, mastocytosis, and known allergy to a specific excipient of the vaccine) an allergological evaluation can be booked at Fondazione. 7 modules with 6 medical lines each are assembled for the anamnesis and the vaccine inoculation, which occur together as a single step of the vaccination process. Beside the medical lines, a specific area is set up to store vaccines in refrigerators, so that the dilution and preparation of the syringes can be performed as needed. Television screens were also added in the modules. In the post administration area 230 seats are as well arranged in units and children can spend the waiting time watching cartoons projected on a big screen provided in the room.

The center is open from 8 a.m. to 8 p.m., 7 days a week. Two mornings a week are dedicated to the vaccination of children from the Child Neuropsychiatry Department: these emotionally fragile patients need a particular dedicated setting, to prevent interactions with other children, which may stress them out. The reservation available per day are scheduled by

Lombardy Region and transmitted to the center every week. Medical and administrative personnel for each shift are managed relying on scheduled slots. To facilitate vaccination, two open days were set up on 29 and 30 January, where the users were received without a reservation. As a catch-up strategy, in the same session as the child, caregivers can choose to have themselves vaccinated as well.

Professional figures involved

The personnel involved in the Fiera Milano city pediatric center is composed by 4 different figures: doctors, nurses, pharmacists and receptionist. The four professional figures report each to a person in charge, who can always be contacted during the vaccination activity. In the vaccination modules, doctors are responsible for anamnesis, vaccination eligibility, vaccine administration, and recommend the waiting time needed after the inoculation. The average time to carry out the vaccination is 6 minutes, and each doctor therefore concludes about 10 vaccinations per hour. Nurses attend the vaccine dilution and the syringes preparation, as well as supporting doctors during the administration, as it may be difficult in children. Pharmacists manage the vaccines displacement from the stock areas to the vaccination lines and their storage at the right temperature. In the reception desks, receptionists check the vaccination candidate's identity and their reservation. Furthermore, Civil Protection volunteers and local hospitals associations volunteers are also part of the personnel in force in the Center. The first mentioned direct the flow of people through the mandatory path between the entrance and the modules, ensuring that no crowds are formed in these areas; the others are recruited to entertain the children during their permanence in the MCV. The personnel are provided with information material, constantly updated according to the latest indications from the Minister of Health, and online courses and lessons are also guaranteed. All staff are also provided with an operational instruction, specific to the professional figure, in which national and regional guidelines on vaccination activity are summarized. Moreover, the new hires are placed alongside to expert personnel on their first shift.

Flow organization

Inside the vaccination center, users are guided to a mandatory path, in which children are always attended by an adult. After reaching the second floor of the Fiera Pavillon, temperature is measured, and a waiting number is provided by Civil Protection volunteers. Inside the center, they are seated in the waiting room before the acceptance, that takes place in the front offices. The receptionists identify the child and the parent with him and directed them to the vaccination modules. It is possible to delegate an adult other than the parent to carry the child during the vaccination process. In this case, the informed consent signed by the parent and a delegation document must be shown to receptionists and medical staff. In the modules, the anamnesis is conducted by the medical staff with caregivers and, after the informed consent is signed before the administration occurs. In this phase, screens constantly showing cartoons and volunteers dressed as clowns entertain children to make vaccination a less unpleasant moment. In addition, a “certificate for bravery” is given to the child before leaving the vaccination station. After that, the users proceed in the post-administration waiting area, where they can stay for a time ranging from 15 to 60 minutes, as defined by the doctor during the interview. To leave the center, a path parallel to that of entry is followed, without mixing flows.

Results

Vaccine administration

Since the opening of the center (16th December 2021), considering the population born from the year 2010 to 2017, up to the ending of vaccination activity in the massive pediatric center have been administered 85870 doses of vaccines (47311 (55%) first shots and 38559 (45%) second shots). In this span of time, about 23% of the population in the province of Milan aged 5–11 years has been reached and vaccinated with at least one shot of vaccine in this center. As expected, the adhesion to the vaccination campaign is higher as the age of the subjects grows up, as shown in Table 1. 2010 and 2011 cohort by themselves represent the

34% of the whole vaccinated target population (considering both first and second shots).

Analyzing the distribution of the vaccination during the week, in the first month of activity, which include Christmas festivity in Italy (the center has been closed, for this motivation, during the 25th and the 31st of December and the 1st of January), the highest flow of people has been registered during the last two days of the week, like Saturday and Sunday, as shown in Figure 1.

Considering the week 3rd – 9th of January, during Saturday and Sunday have been administered 6771 doses of vaccine (3751 first shots and 3020 second shots), which represent the 41% of the whole administrations of that week (16482 shots). The same happened during the following week (10th – 16th of January), in which 4649 doses have been administered during Saturday and Sunday, 38% of the total of that week (12078). This trend is more evident during the week from 7th February 2022 and 13th February 2022, in which 1992 vaccinations have been administered during Saturday and Sunday, the 56% of the total of the same week (3528). During the last two days of activity of the MCV, 1346 vaccines have been administered, the 59% of the whole administrations of the same week (2271).

During the open days initiative, 4985 vaccinations have been administered, the 42% of the total of that week (11958), in trend with what happened the other weeks. Data relating to the trend of administrations during every hour of the day are not available.

Table 1. Number of doses administrated per year of birth.

Administrations per year of birth		
Year of birth	Shot n. 1	Shot n. 2
2010	8508	7119
2011	7402	6065
2012	7113	5853
2013	6690	5392
2014	6475	5256
2015	5853	4796
2016	5063	3971
2017	207	107
Total	47311	38559

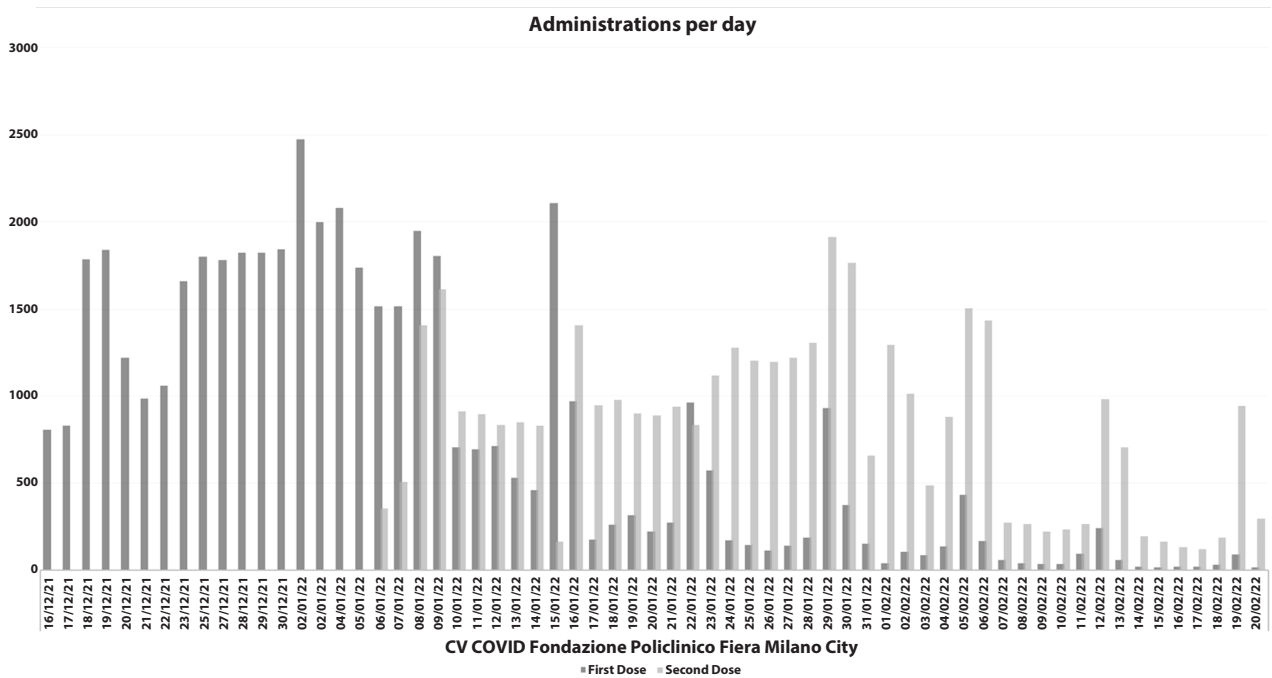


Figure 1. Administrations per day trend.

Table 2. Administrations per year of birth and sex.

Year of birth	Female		Male	
	Shot n. 1	Shot n. 2	Shot n. 1	Shot n. 2
2010	4111	3458	4395	3661
2011	3614	2949	3788	3115
2012	3415	2840	3697	3013
2013	3231	2582	3459	2810
2014	3155	2573	3320	2682
2015	2830	2312	3022	2484
2016	2454	1944	2609	2027
2017	86	46	121	61
Total	22896	18704	24411	19853

The highest flow was observed during the two hours after school ending or no significative difference when schools are closed, like during the weekend. This notification could be due to the fact that between 4 pm and 6 pm, both schools close and the caregivers end the work time. No associations with sex of subjects have been demonstrated by our data, so there is no difference between male and female's adhesion, as shown in Table 2.

Discussion

Critical issues

The most common and expectable issue is the resistance of children at the moment of inoculation, that leads not only to a higher vaccination time, but also more personnel needed per module.

Average vaccination time is also affected by caregivers' need of reassurances. Having some personnel with a pediatric specialization might help with these issues, since they are more used to communicate with caregivers. Vasovagal or anxiety related events represent most of the observed adverse events and none of them needed the intervention of a resuscitator. These events were managed by laying patients in dedicated stretcher in the immediate proximity of the modules. As already described, the mass vaccination center does not provide vaccinations exclusively for children, but also for their caregivers: this might cause mistakes as different vaccine types and dosages are available.

A solution adopted to minimize the risk of mistake is to directly keep the pre-filled syringes in different type of trays, easily detectable by material

(cardboard or metal) or by shape; labeling the trays is also advisable. The software also helps preventing errors thanks to an automatic block in case of mismanagement. The wrong compilation of the child's informed consent was the main bureaucratic issue encountered. The consent must always be signed by caregivers, even in case of delegation to accompany the minor to receive the vaccination. The lack of such a signature caused the inability to administer the vaccine, but data regarding this kind of event are not available as they are not collected in the database. As the mass vaccination campaign towards 5-11-aged children rolled out, Italy was struck by the fourth wave of the pandemic: unclear guidelines regarding quarantines and Covid cases in schools caused a series of issues and confusion among caregivers, who often brought children to the vaccination center, in violation of the active quarantine. The guidelines update, in fact, didn't specify what behavior had to be kept in matter of school close contacts and vaccinations.

Agenda's saturation

At least one caregiver is always with the child during the vaccination because of the informed consent procedure. In this context, could happen that the parent, or both the caregivers, ask for the vaccination for them too.

From the periodic report downloaded by the software used, it is not possible to verify the familiarity between two subjects. So, it is not possible to identify the percentage of caregivers which receive the vaccination together with their child at the moment of their vaccination, but this kind of data could be important to organize the vaccine stocking. As mentioned before, personnel for each shift are managed relying on scheduled slots, so it is important to consider agenda's saturation to avoid a human resource surplus. Up to now, the difference between the whole administrations during one day and the reservations can give an idea of the amount of people which does not register from the website or with the conventional ways of registration. Even if these numbers are rough because nominal data of the booking were not available, this trend could suggest important organizational considerations for vaccine stocking service. After the analysis of the vaccines administered and the vaccines booked, we observed that 2495 administrations have been booked more than the vaccines effectively administered: 3% of vaccinations were booked but have not been administered.

In order to evaluate another indicator about the reservations and the adhesion to the vaccinal campaign, we analyzed the saturation of the agendas for the whole period of activity.

We observed the following trend about the booking of the first shot: as shown in Figure 2, saturation

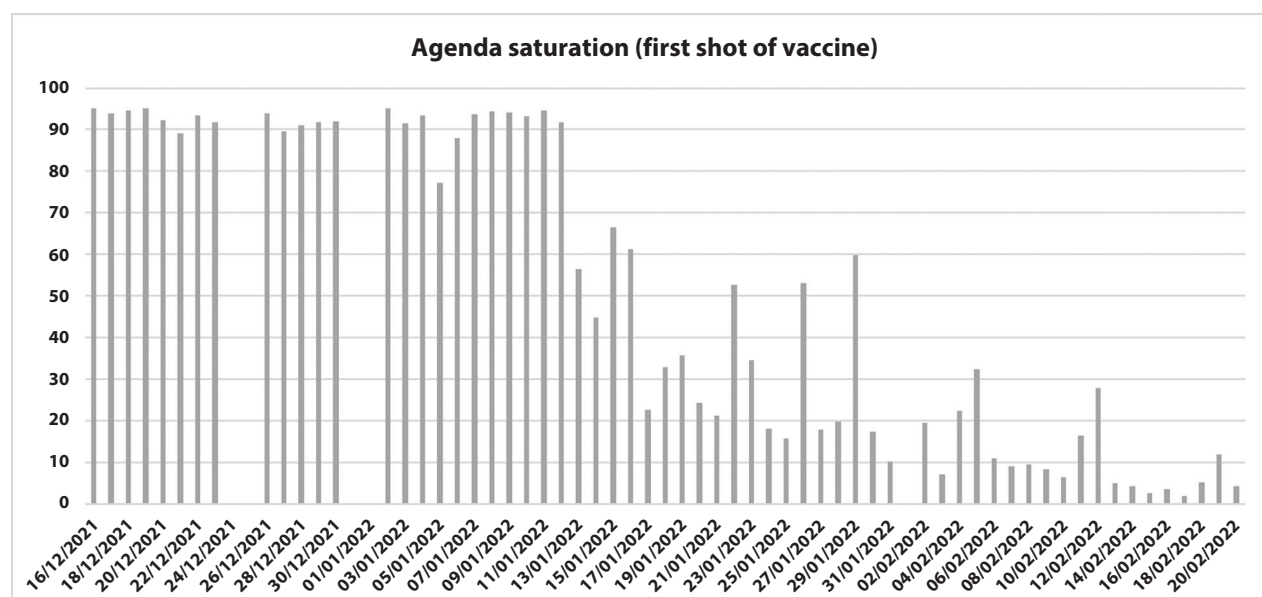


Figure 2. Agendas saturation for the first dose.

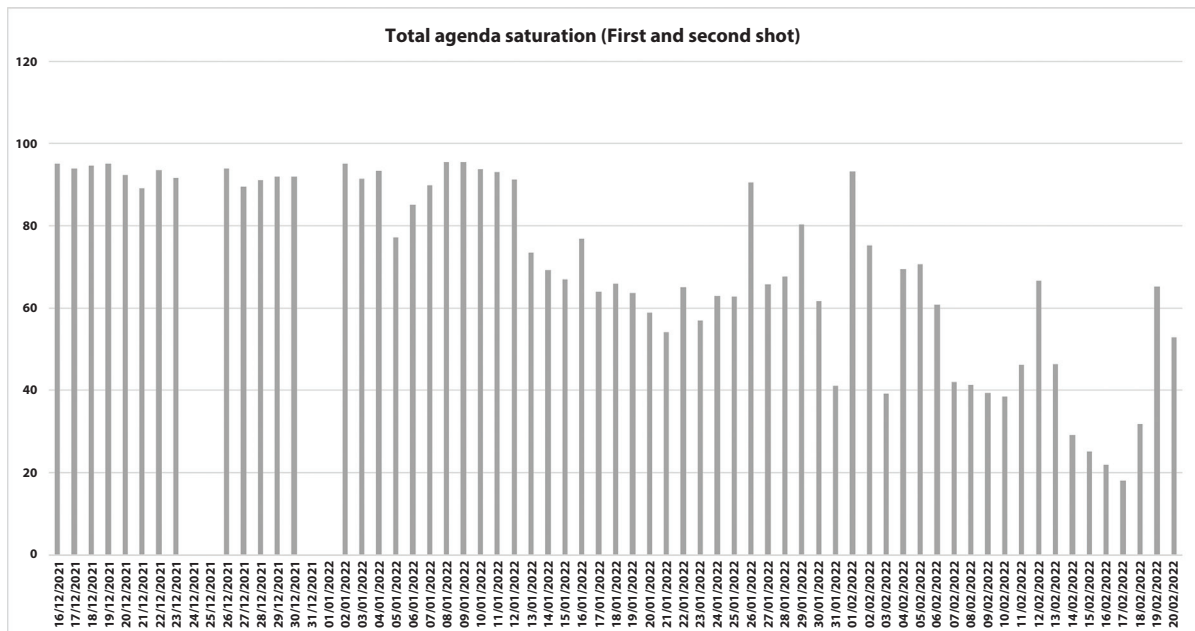


Figure 3. Total saturation of the agendas.

is very high for the first month of activity, and the net decrease of this parameter is due to beginning of the booking and administrations of the second shots of vaccine to complete the vaccination cycle.

For this reason, we analyzed the total saturation of the agendas, comprehending the first and the second shots (Figure 3).

After the same day in which we observed a decrease for the saturation of the first shots agendas, even considering the total of reservations, the same decrease is present. This decrease, considering also the second shot, is less important in the general trend.

Moreover, the data regarding 29th and 30th January (the two open days) confirm the decreasing trend of agenda saturation of the first shots: the spikes of the second shots administered match with the first doses administered three weeks before, so it is possible to assume that second shots administered during the open days were foreseen three weeks before. Furthermore, the lack of an effective communication in promoting the open days may have negatively affected the initiative adherence.

Conclusions

The modular structure of the Fiera Milano City MCV center facilitated the organization of the flows

of patients and of the management of the vaccination personnel, including nurses, doctors and volunteers. The structure can host and vaccinate a huge load of people at the same time, and this advantage has been useful during the first step of the mass pediatric vaccination campaign, in which has been observed a very enthusiastic adhesion. After the whole period of activity of the center, 7.3% of target population in Lombardy Region has been reached and vaccinated with a complete vaccination cycle, but a dramatic decrease of activity and flow of people has been observed after about 40 days of activity. This last consideration could be linked to the absence of restrictions on access to public places or social events for the unvaccinated population aged 5-11 years old and the consequence was the adhesion to the vaccination campaign of those families in which vaccine hesitancy is completely absent. According to official data updated daily, 31.56% of the whole 5-11 population has been vaccinated with at least one shot of vaccine (16). This percentage is totally not sufficient to reach the appropriate coverage in the target population. It appears to be clear that new catch-up strategies should be actuated, first studying the appropriate vaccination setting, like schools or other structures in which reaching the population is easier than what has been experienced. To corroborate this idea, it is possible to investigate data from another Italian region, like Puglia, in which the 42.34% of the 5-11 population has been

vaccinated with at least one dose (16). In this region, anti-Sars-CoV-2 vaccines are administered during the school time, in schools.

Author Contributions: Elisa Astorri, Francesco Mazziotta and Claudio Macrelli share first authorship and contributed to conceptualization, original draft preparation, writing and editing of the paper. Navpreet Tiwana and Matteo Letzgas contributed to conceptualization, data curation and original draft preparation. Alberto Bisesti, Dario Laquintana, Laura Chiappa, Alessandra Piatti, Marcello Sottocorno, Francesco Falbo, Matilde Rosso and Ludovica Caprini contributed to data curation and original draft preparation. Silvana Castaldi contributed to conceptualization, methodology, supervision and writing. All authors read and approved the final version of the manuscript.

Conflicts 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.

References

- World Health Organization [Internet]. WHO Director-General's opening remarks at the media briefing on COVID-19. 11 March 2020; [cited 2022 Feb 20]. Available from: <https://www.who.int/director-general/speeches/detail/who-director-general-s-opening-remarks-at-the-media-briefing-on-covid-19---11-march-2020>
- World Health Organization [Internet]. Interim statement on COVID-19 vaccination for children and adolescents. 24 November 2021; [cited 2022 Feb 20]. Available from: <https://www.who.int/news/item/24-11-2021-interim-statement-on-covid-19-vaccination-for-children-and-adolescents>
- Istituto Superiore di Sanità [Internet]. Epidemia COVID-19. Aggiornamento nazionale 12 gennaio 2022; [cited 2022 Feb 20]. Available from: https://www.epicentro.iss.it/coronavirus/bollettino/Bollettino-sorveglianza-integrata-COVID-19_12-gennaio-2022
- Lu X, Zhang L, Du H, et al. SARS-CoV-2 Infection in Children. *N Engl J Med* 2020;382:1663–166. doi:10.1056/NEJMc2005073.
- Götzinger F, Santiago-García B, Noguera-Julián A, et al. COVID-19 in children and adolescents in Europe: a multinational, multicentre cohort study. *Lancet Child Adolesc Health* 2020;4:653–661. doi: 10.1016/S2352-4642(20)30177-2.
- Tsankov BK, Allaire JM, Irvine MA, et al. Severe COVID-19 Infection and Pediatric Comorbidities: A Systematic Review and Meta-Analysis. *Int J Infect Dis* 2021;103:246–256. doi: 10.1016/j.ijid.2020.11.163.
- Jiang L, Tang K, Levin M, et al. COVID-19 and multi-system inflammatory syndrome in children and adolescents. *Lancet Infect Dis* 2020;20:276–288. doi: 10.1016/S1473-3099(20)30651-4.
- Buonsenso D, Munblit D, De Rose C, et al. Preliminary evidence on long COVID in children. *Acta Paediatr* 2021;110:2208–2211. doi: 10.1111/apa.15870.
- European Medicines Agency [Internet]. Comirnaty COVID-19 vaccine: EMA recommends approval for children aged 5 to 11. [cited 2022 Feb 20]. Available from: <https://www.ema.europa.eu/en/news/comirnaty-covid-19-vaccine-ema-recommends-approval-children-aged-5-11>
- Food and Drugs Administration [Internet]. FDA Authorizes Pfizer-BioNTech COVID-19 Vaccine for Emergency Use in Children through 11 Years of Age. [cited 2022 Feb 20]. Available from: <https://www.fda.gov/news-events/press-announcements/fda-authorizes-pfizer-biontech-covid-19-vaccine-emergency-use-children-5-through-11-years-age>.
- Walter EB, Talaat KR, Sabharwal C, et al. Evaluation of the BNT162b2 Covid-19 Vaccine in Children 5 to 11 Years of Age. *N Engl J Med* 2021;386:35–46. doi: 10.1056/NEJMoa2116298.
- Agenzia Italiana del Farmaco [Internet]. AIFA approva il vaccino Comirnaty per la fascia di età 5-11 anni. [cited 2022 Feb 20]. Available from: https://www.aifa.gov.it/documents/20142/1289678/Comunicato_AIFA_674.
- Ministero della Salute, Presidenza del Consiglio dei Ministri, Commissario Straordinario COVID-19 [Internet]. [cited 2022 Feb 20]. Report Vaccini Anti COVID-19. Available from: <https://www.governo.it/it/cscovid19/report-vaccini/>.
- Regione Lombardia, deliberazione n° XI / 4353. Approvazione del piano regionale vaccini per la prevenzione delle infezioni da Sars-CoV-2. Seduta del 24/02/2021.
- Oliani F, Savoia A, Gallo G, et al. Italy's rollout of COVID-19 vaccinations: The crucial contribution of the first experimental mass vaccination site in Lombardy. *Vaccine* 2022;40(10):1397-1403. doi:10.1016/j.vaccine.2022.01.059.
- Istituto Superiore di Sanità [Internet]. [cited 2022 Feb 20]. Vaccini COVID-19. Available from: <https://www.iss.it/vaccini-covid-19>

Correspondence:

Received: 15 June 2022

Accepted: 27 November 2022

Elisa Astorri, MD

Department of Biomedical Sciences for Health
University of Milan

Via Pascal 36, Milan, 20133, Italy

E-mail: elisa.astorri@unimi.it