# Original investigations/commentaries

# Covid-19 Massive Vaccination Center Layouts. A modular and Scalable Model for Lombardy Region, Italy

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Abstract. Background and aim of the work: The rapid evolution of Covid-19 and the availability of numerous vaccines led countries to set up Massive Vaccination campaign in a very short time. Since December 2020, due to the lack of specific guidelines, multidisciplinary groups started to investigate the minimum requirements for Massive Vaccination Centers (MVC). The aim of the paper is to shed light on the process of development of a scalable model for MVC layout design and implementation. Methods: The methodology included two phases and six steps: 1) Study of MVC with i) acquisition of process data from experimental study on an early set up vaccination hub; ii) review of scientific literature on MVC; iii) review of existing available guidelines and international examples; 2) Design proposal with iv) functional and space requirements collection; v) standard MVC layout design and vi) scalable model definition. Results: The resulting layout is compact, has a good wayfinding and address safety reducing cross-contamination risks. Different vaccine lines have been designed with a central dilution area for process efficiency. Healthcare staff wellbeing is guaranteed by the provision of resting spaces, short distances, and the correct sizing of space for the different activities. To ensure optimal vaccination capacity at the peak of vaccination, a modular and scalable model of different sizes has been designed ranging from 400 to 12000 m<sup>2</sup>. Conclusions: The modular layout has been used as basic model in the regional legislation, disclosed with the Deliberation n° XI / 4353 of 24/02/2021. Further research is encouraged to compare different national and international layouts. (www.actabiomedica.it)

**Key words:** Covid-19, Massive Vaccination Center, layout, vaccination campaign, healthcare design; healthcare facilities; case studies; safety; staff wellbeing; process efficiency

#### Introduction

# The needs of Massive Vaccination Centers (MVC) in response to Covid-19 pandemic

The pandemic of SARS-COV-2 has exploded as quickly as unprecedented in the last 100 years (the last big one was Spanish flu, from 1918 to 1920), which is why equally fast actions are needed to counteract the spread of the disease. Italy was the most affected country by the first European wave of Covid-19 and it has the highest mortality (1, 98 deaths from Covid-19 per 1000 infected) (1). Lombardy, with a total of 858.504 cases to 11/8/2021 (2), was the worst-hit region both in Italy and Europe at the beginning of 2020 with an estimated infection rate of 29% in Lombardy, and 72% in Bergamo (the hardest-hit province) (3). For this reason, the vaccination campaign becomes a real priority to force the spreading of the pandemic (4), minimizing the impacts for people and the economy (5).

Unexpectedly, due to the unprecedented situation that forced Covid-19 vaccines development

as a global priority, before the end of the year 2020 dedicated vaccines (i.e. m-RNA, viral vector, viruslike particles, cell-based, inactivated virus, subunits and/or protein-based) started to become available. The complex situation and the high demand along with complex logistics, causes delay in deployment of several and foreseeable doses worldwide. December 27, 2020, the so-called "Vaccine day"(6), is the date that marked the official start of the vaccination campaign against Covid-19 throughout Europe while in Italy, the actual distribution of the vaccine began on December 31st starting from healthcare staff, special categories and gradually expanding to the overall population according to defined priorities. This initial phase exploited the already existing vaccination hubs and the conventional hospital facilities already equipped. Nevertheless, as reported by Goralnick and colleagues, the use of conventional health care sites was soon not sufficient for several reasons among which the unprecedented volume of patient enrollment and scheduling, the varying volume and typology of vaccines supply, the need (for some types) of a subsequent second dose, the requirement of observation time after vaccination, the cold storage requirements (7).

Therefore, it has become necessary to develop a massive vaccination campaign that included reasonings on possible alternative sites in order to pursue the most promising and challenging objective of world base population vaccination. In practical terms, a hybrid model was addressed where large venue sites such as stadiums, arenas, convention centers have been temporarily transformed into healthcare space for vaccines inoculation. Such new spatial typology, called Mass Vaccination Centers (MVC) or Mass Vaccination Hubs, have been recently defined as "a location, normally used for nonhealthcare activities, set up for high-volume and high-speed vaccinations during infectious disease emergencies"(8). The lack of previous experiences, combined with the fact that, prior to the pandemic, vaccinations were performed on an outpatient basis and dedicated mostly to certain categories of people (e.g., children, elderly, workers), led to the creation of an innovative model that would allow it to be quickly replicable and adaptable to different built environments. Even if there are a few cases of MVC used for communicable disease control

programs (like for influenza in 1970s and 2008) there are no specific guidelines to create this type of structure, especially during similar emergencies like Covid-19 pandemic. In fact, when designing health care facilities of any kind, it is essential to assess the suitability of the location for hosting activities with close cooperation between experts in design, layout, hygiene and Public Health (9,10) which becomes even more evident during the Covid-19 pandemic to guarantee safety, security and resilience of healthcare settings (11).

Specific tools, guidelines and checklists are therefore needed to address the functional and spatial requirements of this kind of strategic place in the global fight against Covid-19 (12,13).

#### Research gap and Aim of the study

Recent studies show that literature is still sparse on the topic and there is a general absence of material concerning the sites physical characteristics and layout for massive vaccination against Covid-19 (8). This lack of knowledge in the field of MVC must be filled in a scientific way, analyzing the different parts and process that are behind the vaccination systems to define a scalable and replicable model to be applied in various scenarios and built environments to create the number of centers required to complete the vaccination process of the entire eligible population.

Therefore, the aim of the study is to shed light on the process of development of a scalable model for MVC layout in Lombardy Region, Italy with specific regards to meta design indications and appropriate sizing of spaces starting from productivity data. Indeed, the research has been conducted starting from the health data studied in the first pilot center of Milan City Fair, a trade center converted into a Covid-hospital during the first wave of pandemic and then used as the first example of operating a vaccination hub outside a healthcare setting.

The objective of the work consists in creating a functional layout, scalable and declinable in different non-healthcare spaces such as gyms, fairs, auditorium, stadiums, according to an analysis of the vaccination process and the environmental units needed to establish the center.

#### Methods

#### Multidisciplinary group formation

In January 2021 a multidisciplinary working group of experts in different areas of architecture, engineering, Public Health, management, logistics, economics has been established. The group was composed of Lombardy Region's institutions and companies such as AREU (regional emergency agency), ARIA (regional operating agency), Fondazione IRCCS Ca' Granda Policlinico di Milano (hospital already in charge of the Covid hospital created in the Milano City's fair), Fondazione Fiera Milano, EY Consulting and Politecnico di Milano. The group started working on a first pilot case study of the Milano City Fair, converted into a Covid-hospital during the first wave in March 2020, and sparsely used in early 2021 due to the drop in infections ad epidemic curve made possible by the period of restrictions. This space was rapidly converted in a first MVC in order to have an operating physical and organizational setting in which measure and test optimization models to scale on the entire regional territory.

At this time the Italian Ministry of Health had not yet disclosed the vaccination plan and related strategic indications, which were released after being defined at the national level as of March 13, 2021(14), but only the document "Elements of preparation of the vaccination strategy", presented by the Minister of Health to Parliament on December 2, 2020 (15). In this document, indications are given mainly regarding operators, storage, priority categories, while it does not outline indications regarding the location and design of spaces.

Since the beginning of the project, the group focused on the MVC planning, programming and design in general - not only in relation to the one at the Fair used as the first case study - to establish a methodology that could be applied in different modalities (size and number of inoculations/day) and replicated in different contexts such as fairs, gyms, auditoriums, parking lots. The aim of the project was to plan efficient strategies to vaccinate 6.6 million people, with up to 170000 inoculations a day in about 32 weeks, considering the double and single doses vaccine types, including planning the level of coordination of the various parties involved in the process (governance).

The general objective established was to launch a model of mass vaccination suitable for the territory and the population of Lombardy but potentially applicable everywhere, with the following specific tasks: test the functionality of the model within the pavilion of the City Fair operated by hospital Policlinico di Milano and AREU (where about 2500 administrations were performed during two days of the pilot study); define a model of MVC scalable within the territory (detailing the spaces, professionals and specific requirements); simulation and dynamic sizing (mass unit of more than 4000 people / day); the evaluation of the capacity of funding and planning (target of 6.6 million vaccinated).

The study started in the first part of January 2021 and lasted only about one month, ending in the middle of February 2021.

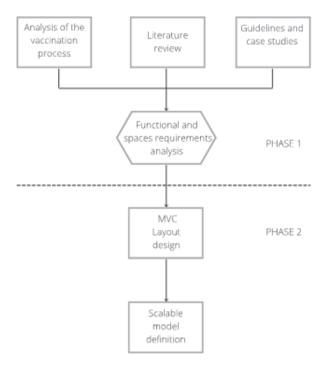
#### Study design

In terms of methodology, the multidisciplinary working group acted on two essential phases to establish a common strategy: Phase 1) *Study of MVC systems and organization* and Phase 2) *Design of functional and spatial layout and scalable model* (Figure 1). The phases developed combined testing the pilot project already implemented with the analysis of the problem, the definition of a massive vaccination model scalable in different territorial structures, the sizing of each functional area and the evaluation of performance.

The study design included two phases and six steps: in Phase 1 the i) analysis of the vaccination of process data from an experimental study on an early set up vaccination hub; the ii) review of scientific literature on the topic; and the iii) review of existing available guidelines and international examples have been made; in Phase 2 the iv) functional and space requirements analysis and collection; the v) standard MVC layout design and the vi) scalable model has been defined (Figure 1).

#### i) Analysis of the vaccination process

Initially, the vaccination process was analyzed to underline the different phases that are required and,



**Figure 1.** Flow chart of the process followed in this study with the highlight of the two phases

using the pilot case, verify the effectiveness of the model used in the fair.

Thanks to the active participation of physicians and hospital managers, three phases were identified: a) list, schedule, and convocation, b) vaccination process, c) monitoring and research.

The experimentation was carried out on two pilot days within the vaccination center of Fiera Milano (January 16 and 17, 2021). On this occasion, the routes, total and partial timings of the process, spatial organization, the number of resources used in each process, as well as other characteristics such as the presence of signage were noted. Data have been collected and reported looking at the whole supply chain and simulations have been performed.

#### ii) Literature review

The study started with an analysis of the needs related to the inoculation of the different available SARS-CoV-2 vaccines and the environmental units needed. First, in January 2021, a literature survey was conducted to understand what studies had already been published regarding the implementation of massive vaccination centers to address the Covid-19 pandemic.

The search was conducted on databases such as Scopus, PubMed, and Web Of Science using a set of keywords combined forming different strings such as:

Vaccin\* process OR Mass vaccin\* center\* OR Vaccin\* site

AND Layout OR Space OR Design AND Covid-19 OR SARS-CoV-2 OR Coronavirus

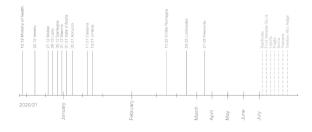
#### iii) Guidelines, regulations and case studies analysis

Further guidance documents and guidelines to the vaccination campaigns of the various Italian regions, produced as of December 2020, were analyzed, starting from the Strategic Plan for Anti-SARS-CoV-2/Covid-19 Vaccination presented by the Minister of Health to Parliament on 2<sup>nd</sup> December, 2020.

As is noticeable in Figure 2, only a few regions did guidelines for Mass Vaccination Process before February 2021 and others have not drafted it yet.

These, while not presenting a distributional hypothesis of the internal layout of the centers, indicate, consistently, the necessary steps to be followed for the vaccination process: acceptance, anamnesis, inoculation, and observation.

Then case studies were examined, using the materials made available from various states on the creation of vaccination centers, specifically the UK and Germany, because they were among the first states to



**Figure 2.** Timeline of the different Italian region's vaccination plans.

create massive vaccination centers within fairs, gyms, logistic buildings. These were consulted both on the countries institutional websites and through their media dissemination. In doing so, although it is not always possible to trace the architectural drawings, it was possible to understand and analyze the internal configuration by macro areas.

# *iv)* Functional analysis and needs of different spaces for a MVC

Finally, the various environmental units necessary for the realization of MVC have been examined at the level of size, technological equipment, and furnishings. Thus, the needs of the spaces were analyzed, starting from the *reception area*, with boxes for administrative staff, the *anamnesis*, the medical station dedicated to the doctor to identify the pathologies of the vaccine recipient and direct him to the correct vaccine, the actual *inoculation box*, with the necessary furniture and instruments, and finally the *shock room*, the room used for emergencies. For each of these, the minimum size and equipment necessary to ensure proper functioning has been defined.

## v) Layout design and vi) Scalable model definition

From the aggregation of functional units defined according to the evidence that emerged from the study, different dimensional models were then created, following various "sizes", to make them scalable in different types of buildings.

#### Results

#### Data analysis

#### Results from the Pilot Study

The pilot study conducted on the Fair underline the vaccination process that was found to be divided into:

- A. acceptance and consent (7 volunteers, 1min30s per user),
- B. anamnesis (13 physicians, 3min 30s per user),

- C. inoculation (25 nurses, 3min 30s per user),
- D. monitoring (8 nurses, 15/45 minutes based on what was established based on patient characteristics).

From the point of view of distribution, a single circuit was created, which made the distances to be covered too long and with frequent overlaps. The spatial organization proved to be inefficient because it presented a lot of unused space (e.g., areas that were used to house an ICU bed were used only with an inoculation chair) and signage was found to be unclear and not adapted to the circuit for the inoculation process.

After the multidisciplinary analysis through open meetings and focus groups, some implementation strategies were identified: revision of the flows to optimize the intermediate waiting lines (especially between admission and history, and between history and inoculation), modular design development to allow scalability, and revision of the layout to rationalize the use of space.

#### Literature Review

The literature survey, as highlighted above, has not produced appreciable results regarding evidence of the creation and testing of MVC to cope with Covid-19. Among the few significant studies, one is about a drivethrough simulations (5); this approach could be very useful in certain situations and countries but in this study, it has not been considered as a possible implementation methodology. Other available examples mostly concern seasonal influenza and are experiences carried out in the USA; some of them also provide examples of MVC layout realized in a building not normally used for healthcare purposes, like schools (16), clubs (17), shopping malls (18). The main aspects taken into consideration were: parking, entrance, registration area, triage, waiting rooms (where people stay both before and after vaccination), educational area, medical evaluation rooms, vaccine storage, vaccination station, post-vaccination area, and exit.

# Regional and national regulations and case studies

The analysis of Italian and regional indications about MVC highlighted a lack of indications about

the functional distribution and layout, instead of the definition of the process (reception, anamnesis, inoculation, observation, and stock areas) (Table 1).

On the contrary, the case studies analysis allows to compare different process and configuration of macro areas and spaces (Table 2). Functional analysis and needs of different spaces for a MVC

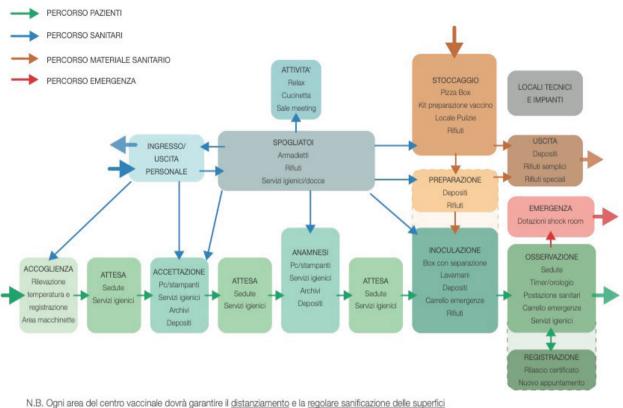
Finally, an additional analysis was conducted, identifying for each environmental unit the minimum necessary equipment, the appropriate size for correct

Italian Regions Regulations							
Region	Date	General Indications Functional Scheme		Layout			
Veneto	22/12/20	Yes	No	No			
Molise	27/12/20	Yes	No	No			
Lazio	29/12/20	Yes	Yes	No			
Sardegna	30/12/20	Yes	Yes	No			
Marche	31/12/20	Yes	No	No			
Valle D'Aosta	01/01/21	Yes	No	No			
Abruzzo	05/01/21	Yes	No	No			
Calabria	11/01/21	Yes	No	No			
Umbria	13/01/21	Yes	No	No			
Lombardia	24/02/21	Yes	Yes	Yes			

Table 1. Italian regulations for MVC at 15/01/2021

Table 2. Case Studies of MVC active before 15/02/2021

	USA		Germany		UK	
	<i>Disneyland</i> , California	Super Vaccine Station, San Diego	Velodrom – Prenzlauer Berg, Berlino	<i>Arena</i> , Berlino	Cattedrale di Salisbury	<i>Millennium</i> <i>Point</i> , Birmingham
Location	Park	Parking	Sports centre	Fair	Church	Cultural centre
Туре	Temporary	Drive-in	/	80 stands	/	/
Dimentions	40 ha (400.000 m <sup>2</sup> )	/	/	/	/	/
Vaccine/day	7.000	5.000	2.200	5.000	400	2.500
Time	1	total 15 minutes	1 h	1 h	30 minutes	less than 1 h
Parking	300	/	/	/	/	Multilevel parking
Accessibility	Metro, highways and tram	/	Train, metro and strategic connection between three districts	/	/	1
Furniture	1	1	/	1	/	/
Emergency	1	1	1	1	/	/
Services	/	/	Free taxi for over 80 yo	/	/	Hand sanitizer
Storage	/	/	/		/	/



N.D. Ogni alea dei centro vaccinale dovra garantine il <u>distanzinento</u> e la <u>regulare saminozzone delle si</u>

#### Figure 3. Functional plan

and comfortable use, the proximity between one environment and another, and the waiting areas necessary to ensure the distancing in the moments of maximum peak (Figure 3).

The different functional areas were thus analyzed such as:

- **Pre-acceptance waiting**, the area, external or otherwise, used as an entrance to the facility, in which it is necessary to verify the reservation and body temperature of the user,
- Acceptance, a variable number of workstations equipped with a desk for the operator, a chest of drawers, a printer, a PC and an internet connection,
- Pre-anamnesis waiting area, an area dedicated, in case of need and intense flows, to the waiting before the interview with the doctor, presents both sitting and standing wait,

- Anamnesis, closed or semi-closed box to ensure the privacy of the user, presents the station dedicated to the doctor with desk, PC, printer, internet connection and drawers,
- **Pre-inoculation waiting area**, an area dedicated, in case of need and intense flows, to the waiting before inoculation, presents both sitting and standing waiting,
- Inoculation, open boxes, divided by curtains, for the administration of the vaccine, are equipped with chair, stretcher / chair for administration in a lying position, trolley with drugs, desk, medical supplies, trolley with PC and printing administration,
- **Post-inoculation waiting area**, an area sized according to the daily administration of the center, with seats spaced 1.5 m apart and super-vised by operators,

- **Shock room**, an area dedicated to emergencies, possibly with access to the outside with the arrival of the ambulance in case of emergency, has a stretcher, emergency cart, oxygen cylinders,
- Accessory rooms, such as storage areas, toilets, locker rooms, meeting rooms and refreshment-relaxation areas for staff, technical and control rooms.

According to the actual space and constraints such functional units can be designed as autonomous or merged into common environments.

# Functional and spatial layout

The functional model obtained from the analysis of the spaces was then analyzed, in order to understand which vaccination units were needed to make the environment productive. Therefore, it was configured a basic module of 12 boxes of inoculation, 6 stations of anamnesis and acceptance. This has allowed creating of waiting areas adequate to accommodate the flow of people even in times of greater affluence, avoiding queues. In doing this, the pre-acceptance and post-intake/observation seated waiting areas were then sized. The functional spatial model of the vaccine line was then proposed as reported in Figure 4.

The new model is compact, eliminates queues and intersections, and the user moves in a single direction from entrance to exit, avoiding unnecessary crowds and confusion. Different vaccine lines have been designed, united by the barycentric presentation of the dilution area of the doses, to allow a rapid preparation of the same and speed up the vaccination process. From the usability point of view, the new layout provides resting spaces, short distances, and the necessary equipment for specific activities, sizing the environmental units in such a way as to contain all the necessary devices. One of the features foreseen from the early stages is that the project must be modular with the ability to scale and adapt in real time to needs. This feature is developed according to a principle of block construction with removable units, which is currently the gold standard for healthcare, as it allows for rapid adaptation of spaces to needs (resilience). Fluxes were also analyzed, calculating the times required for each process, in order to avoid queues and provide properly sized waiting areas and buffer zones (Figure 5).

# Scalable model of different MVC sizes

Due to the large geo-demographic differences in the Lombardy region, several hypotheses have been advanced for the deployment of MVCs. Based on population density, the various provinces were divided into very high, high, medium, and low density and vaccination targets were calculated for each (millions of individuals). The optimized utilization profile would be 50% of first doses and 50% of second doses, however it is known that these proportions will be different at the beginning and end of the trial based

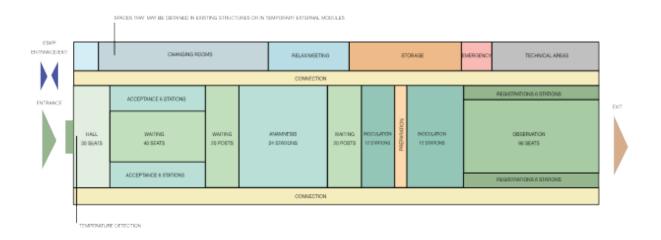


Figure 4. The functional spatial model for the MVC



Figure 5. Fluxes and time analysis

on the proportion of the total vaccinated population. With these issues in mind, the number of vaccines per day (thousands per day) over time (months from the start of mass vaccination) was estimated. The required capacity was also modulated according to the vaccination campaign and vaccine availability, predicting times of vaccine shortages and vaccination peaks. To ensure optimal vaccination capacity at the peak of vaccination, it was projected that about 35 centers in different sizes would be needed: from XXL (12000 m<sup>2</sup>), to XXS (400 m<sup>2</sup>).

Finally, an interactive spreadsheet was developed in Microsoft Excel to forecast equipment, space, cost, and a number of operators based on the number of vaccination units desired and the number of daily vaccines, and a checklist for validating vaccination centers, referring to the various criteria related to layout (i.e. general and specific structural requirements).

#### Conclusions

This paper attempts to briefly explain the methods used to optimize processes and space in large vaccination centers in Lombardy. The model in sizes, scalable and replicable, turned out to be extremely functional and adaptable during the period of health emergency to be declined in different scenarios for size and equipment such as fairs, supermarkets, logistic poles, and other buildings for tertiary use. The optimized simulation model has tested the solution of load balancing between history and inoculation, to increase the production capacity of the vaccination unit to optimize the productivity of the vaccination center keeping under control the impacts on the assemblies. The implementation of the new optimized model, theoretically, would allow to scale up the number of daily vaccine administrations from 1250 to 5500 with the same space (in terms of m<sup>2</sup>), with 1.8 times increase

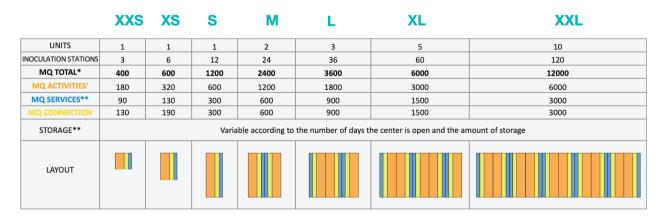


Figure 6. Different sized studied to be applied in different structures

in the number of physicians and maintaining the ratio of other operators. In fact, the evidence acquired from the observation of the first case study, combined with the study of environmental units and analyzed in terms of time for each process and an overall path has made possible the creation of the optimized model able to perform optimally to avoid the formation of queues and assemblages but ensuring a linear path of the maximum duration of 26 minutes entry-exit. The innovativeness, in addition to the model made specifically for the Covid-19 vaccination, is given by the analysis of the logistic process of the system operation used in a preliminary way to the creation of the layout, reflecting the importance and uniqueness of such multidisciplinary team able to investigate both operational and design aspects. In this regard, the analysis carried out thanks to the synergic collaboration between health architecture experts and management engineers on the flows and travel times of the lines, has allowed to obtain a highly efficient and replicable model. The line of 12 stations can in fact be replicated according to specific needs and space availability. This model has turned out extremely functional and effective, suitable to be used on occasions of the emergencies and the periods of vaccines recall.

#### Impacts

The impact of the study has been relevant because it has become the basic model of the regional legislation, disclosed with the DELIBERATION N° XI / 4353 of 24/02/2021. Within the document there are ample space for both indications regarding the vaccination activity (procedures and requirements) and the preparations necessary for the creation of the center, with clear and precise indications regarding size, accessibility, equipment, and minimum facilities. In the same document there are meta-design solutions and functional schemes.

#### Limitations and future developments

The research presents limitations. First, it was carried out in only a month, due to the urgency and the emergency period, with extremely tight deadlines due to the continuous progress of the pandemic. In fact, the model could be adapted to become more suitable to different facilities, like the case of the Novegro Fair, near Milano (Italy), where the layout has been adopted joining anamnesis and inoculation in the same area (19). In the same way, the study could not take into consideration any relevant evidence or precedent of the same type because it was the first event in history in terms of size and demand for mass vaccination and the MVC in other countries was still in the making. The model made for the Lombardy region will be the object of comparison with studies and realizations carried out from other states. Doing so will be a verification of the performance and composition of the model to optimize and adapt it in view of the possible need to recreate the MVC for vaccine recalls.

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**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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