HUMAN VACCINES & IMMUNOTHERAPEUTICS
2025, VOL. 21, NO. 1, 2578089
https://doi.org/10.1080/21645515.2025.2578089

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RESEARCH ARTICLE

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Access to a protected setting vaccination for allergic patients: Evaluation of appropriateness. The experience of Bari Policlinico University Hospital

Antonio Di Lorenzo, Paola De Petro, Felice Leone, Cinzia Annatea Germinario, Silvio Tafuri, and Pasquale Stefanizzi

Interdisciplinary Department of Medicine, University of Bari Aldo Moro, Bari, Italy

ABSTRACT

Vaccination in a protected setting (VPS) ensures the immediate response to potential serious adverse events following immunization (AEFIs). It is effective in both reducing anxiety levels of allergic patients accessing vaccination services and increasing vaccine safety. This paper describes the activities of a VPS clinic in Bari Policlinico General Hospital (Southern Italy) and evaluates the appropriateness of VPS prescription. This is a cross-sectional population-based study. The study population was recruited from January 1, 2022, to December 31, 2024. The study outcome was represented by the appropriateness of VPS access. Accesses were defined as "appropriate" if they were justified by mastocytosis, uncontrolled asthma, allergy to vaccine components, repeated anaphylaxis episodes, or other conditions with increased risk of serious AEFIs. Differences in variable distributions were studied either via the Chi-square or Mann–Whitney test. The impact of each independent variable on the outcome was studied via multivariable logistic regression. Three-hundred-thirteen patients were enrolled, mainly undergoing SARS-CoV-2 vaccination (90.1%, 282/313). Actual VPS appropriateness was verified only for 11 patients (3.5%), and three cases of post-immunization allergic reactions were observed (reporting rate: 1.0%). All three were effectively treated and did not result in either long-lasting or permanent impairment. No anaphylaxis events occurred. None of the considered variables significantly impacted the odds of appropriate access to VPS, and no significant differences were observed between the appropriate and inappropriate access groups. In our analysis, neither sex nor age was associated with greater appropriateness, suggesting that the perceived need for VPS was related to different not sufficiently known factors.

SUMMARY BOX

- ***What is already known on this topic:*** Vaccine hesitancy is subject-specific. In allergic patients, anxiety may increase both hesitancy and the risk of allergy-like adverse events following immunization (AEFIs). Vaccination in a protected setting (VPS) was proven effective in lowering anxiety levels and increasing compliance with vaccination.
- ***What this study adds:*** This study focused on the recent experience of a large Southern Italian hospital which activated a VPS service in 2022. We identified a significant proportion of inappropriate VPS accesses. Since most subjects accessed our clinic via their general practitioners (GPs), inadequate training of healthcare providers may have caused an overload of VPS evaluation requests.
- ***How this study might affect research, practice or policy:*** This study highlights the need for strengthening GP training, health communication, and healthcare access policies. However, it also shows how VPS services are often requested to lower anxiety and are therefore effective in increasing vaccination uptake.

ARTICLE HISTORY
Received 5 June 2025
Revised 22 September 2025
Accepted 17 October 2025

KEYWORDS
SARS-CoV-2; allergy; autoimmune disease

Introduction

Concerns regarding vaccine safety are a determinant of vaccine hesitancy.[1] Despite the availability of strong evidence supporting the excellent safety profile of currently marketed vaccines, doubts persist among the general population.[2–5] During the Severe Acute Respiratory Syndrome Coronavirus 2 (SARS-CoV-2) pandemic, SARS-CoV-2 vaccines were regarded with special concern. Their rapid development, the lack

CONTACT Pasquale Stefanizzi pasquale.stefanizzi@uniba.it Interdisciplinary Department of Medicine, University of Bari Aldo Moro, Piazza G. Cesare 11, Bari 70124, Italy.

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of long-term safety data, and the novelty of the mRNA platform employed by various products were some of the main reasons for hesitancy.[6–8]

In 2022, Italy made SARS-CoV-2 vaccination mandatory in order to access workplaces, thus requiring all subjects to either undergo vaccination or acquiring a certificate stating that the vaccine was contraindicated for underlying medical conditions.[9,10] Many subjects required specialistic evaluation in order to avoid vaccination, and even after a positive opinion by clinicians often maintained a skeptical attitude toward SARS-CoV-2 vaccines.[11–13] Subjects with a history of severe allergies were observed to have especially high anxiety levels associated with vaccination, leading to a higher probability of allergy-like symptoms after immunization.[14,15]

Vaccination in an *ad hoc* hospital clinic, also named protected setting (VPS), is known to lower anxiety levels in allergic subjects and was therefore recommended by Italian and international guidelines.[16,17] A protected setting can be defined as an outpatient vaccination clinic equipped with emergency instrumentation and directly connected with an intensive care unit (ICU), allowing for timely intervention in case of serious adverse events following immunization (AEFIs). It involves multiple specialists, including vaccinologists, allergologists, and ICU staff, performing a thorough evaluation of the patient before vaccination and a systematic causality approach after immunization.[18,19]

Due to the significant request of pre-vaccination evaluation of both allergic patients and subjects with other conditions, Bari Policlinico General Hospital started a VPS service on January 1, 2022. This paper describes the activities of this clinic while also evaluating the appropriateness of VPS prescription. Our aim is to identify the determinants of appropriateness, drawing insights regarding future developments of VPS activities.

Materials and methods

Setting description

Bari Policlinico (Apulia Region) is the largest hospital in Southern Italy, with 1,550 beds and hosting, among other facilities, a vaccination clinic, three ICU wards (including a pediatric one) and an allergology specialistic center. Patients may require VPS via their general practitioner (GP) or hospital physicians, who contact the hospital's booking center prescribing a vaccinology evaluation. VPS evaluation may be required for both SARS-CoV-2 and other vaccines. GPs may refer patients for VPS evaluation by contacting Policlinico's University Hygiene Unit, either sending relevant healthcare documentation via e-mail or letting the patient consign their own documentation to the hospital's staff. Patients may ask for referral even if their GP does not deem it necessary, but the decision is ultimately the healthcare provider's.

The University Hygiene Unit's medical staff collects the subject's pathological, pharmacological, familiar and occupational anamnesis, as well as their vaccination history. Specific conditions exposing to an increased risk of allergic AEFIs (e.g., mastocytosis) and previous allergic reactions to vaccines are investigated with special attention. Although the sole condition requiring VPS is previous allergic reactions to the needed vaccine or diagnosed allergy to one or more components of the vaccine itself, VPS is still offered to all subjects requiring evaluation, aiming to lower anxiety and encourage vaccination.[20,21]

Specialistic consultation is always required for dubious cases, involving different branch specialists according to the subjects' health conditions. Allergologists are generally consulted in order to identify hypersensitivity to one or more vaccine and/or vaccine components, and a different product is offered for vaccination if available. Total IgE and tryptase are not routinely considered, but they might be assessed in case the allergology consultant deems necessary.[22] After immunization, patients are required to wait for an hour in an adjacent room, in order to monitor potential adverse events of anaphylaxis and promptly treat them.

Study design

This is a cross-sectional population-based study. The study population is represented by all patients who accessed Bari Policlinico General Hospital's VPS service from January 1, 2022, to December 31, 2024.

Subjects were adequately informed about the data they would have been required to provide, and written consent to study participation was required.

No information regarding sexual orientation, gender identity, religious or political beliefs was collected. Only routinely needed data was collected. Since all personal information was anonymized before analysis, neither body liquid nor tissue samples were collected. Study was approved by the Policlinico University Hospital – Regional Ethics Committee (study protocol code: 51/2022). The study was conducted in agreement with the principles of the Declaration of Helsinki. No exclusion criteria were set.

Evaluation of appropriateness of VPS access

The study outcome was represented by the appropriateness of VPS access (yes/no). VPS was deemed appropriate for the following conditions, as provided by current guidelines:

- Mastocytosis;[23,24]
- Uncontrolled asthma;[25,26]
- Allergy to one or more vaccine components;[25]
- Repeated episodes of either allergic or idiopathic anaphylaxis;[27]
- Other conditions for which a specialist identified an increased risk of serious AEFIs.[2,25,27]

On the other hand, allergies to respiratory antigens, food, non-vaccine drugs, latex, *Hymenoptera* venom, previous non-serious allergic AEFIs to the needed vaccine, allergic AEFIs to other vaccines were not deemed appropriate conditions for VPS recommendation. The type of vaccination and the subjects' age and sex were used as independent variables. It is relevant to mention that immune depression represents a contraindication to live attenuated vaccines' administration but does not necessarily contraindicate vaccination with other, non-live products.[28,29]

Statistical analysis

Quantitative variables were described as mean ± standard deviation. Qualitative variables were described as percentages and proportions.

The proportion of cases in which VPS was appropriate was confronted between males and females and among different vaccine types via the chi-squared test. The mean age of subjects was confronted between the appropriate VPS and inappropriate VPS group via the Mann–Whitney test, since the age distribution was non-normal. Finally, a multivariable logistic regression model was fitted evaluating the impact of each independent variable on the outcome.

A two-sided p-value < .05 was considered indicative of statistical significance. The database was built via software Microsoft Excel®. All statistical elaborations were performed via software STATA MP17®.

Results

Descriptive statistics

During the study period, 313 patients accessed the Bari Policlinico VPS service. All subjects consented to participate, and following specialist's evaluation all of them were vaccinated. Female subjects were predominant over males, representing 71.9% of the study population (225/313). The study population's mean age was 55.7 ± 19.7 years. Only 18 pediatric patients were included, 17 of whom were evaluated for SARS-CoV-2 vaccination; the remaining subject was evaluated for the diphtheria-tetanus-pertussis (dTap) vaccine (to be administered in adult formulation due to the subject being over 15).

As far as vaccines are concerned, SARS-CoV-2 vaccination was the most commonly dispensed (90.1%, 282/313), followed by the flu vaccine (3.8%, 12/313), the dTap vaccine (3.2%, 10/313) and the human papillomavirus (HPV) vaccine (2.9%, 9/313). In a small percentage of cases, the measles-mumps-rubella-varicella (MMRV) vaccine (0.3%, 1/313), the meningococcal B vaccine (0.3%, 1/313) and the pneumococcal 20-valent conjugated vaccine (0.3%, 1/313) were administered.

Table 1. Study population characteristics.

	Sex		Age (years)		Administered vaccine						
	M	F	Mean	SD	SARS-CoV-2	Flu	HPV	MMRV	MenB	Pneumo	dTap
Appropriate	5	6	50.0	14.2	9	/	/	1	/	/	1
Inappropriate	83	219	55.9	19.9	273	12	9	/	1	1	9
Total	88	225	55.7	19.7	282	12	9	1	1	1	10

In most cases, patients accessing VPS were not at a higher risk of AEFIs than the general population, with 96.5% of subjects suffering from seasonal, food or non-vaccine drugs allergies, (302/313). A single patient reported systemic mastocytosis (0.3%) and two subjects had a diagnosis of allergies to vaccine components (0.7%). In addition to these cases, six patients (1.9%) reporting non-serious allergic reactions to previous doses of the same vaccine, one patient (0.3%) suffering from food allergies, and one patient (0.3%) reporting allergic reactions to other vaccinations were recommended to undergo VPS due to specific concerns by the specialists evaluating them. Overall, VPS was really indicated only for 11 patients (3.5%). Table 1 describes the study population characteristics.

A single case of angioedema was observed during the post-immunization observation period (reporting rate: 0.3%). The subject was treated via adrenalin administration. Two cases of urticaria were observed, both in patients who had reported previous allergic reactions to the same vaccine (reporting rate: 0.7%). Both subjects were administered intramuscular antihistaminic. VPS access was appropriate for all these three patients. In particular, the subject experiencing angioedema suffered from allergies to multiple substances, and had been evaluated by an allergologist who identified an actually increased risk for reactions to the SARS-CoV-2 vaccine's components. Both subjects manifesting urticaria had been referred for VPS due to known AEFIs to previous doses of the same vaccine (the SARS-CoV-2 one). All reactions were effectively controlled and underwent resolution in less than 30 min following drug administration. The overall reporting rate of allergic reactions is 1.0% (3/313). No patients manifested anaphylaxis.

Inferential statistics

The chi-squared test could not highlight any significant differences in terms of VPS appropriateness between males and females (chi2: 1.70; p-value: 0.193). Likewise, subjects vaccinated with different vaccines had no significant differences in VPS appropriateness (p-value > .05), with the exception of the one case of MMRV vaccination, which was at an increased risk of allergic AEFIs (chi2: 27.54; p-value < .001). Mann-Whitney's test did not identify any significant differences in terms of average age between subjects accessing the VPS service appropriately and inappropriately (z: 1.49; p-value: 0.139).

The multivariable logistic regression model (Table 2) did not identify any significant impact on VPS appropriateness by any of the considered variables (p-value > .05). It is relevant to notice that all vaccines except the SARS-CoV-2 one had to be excluded from the model, as they predicted appropriateness (MMRV) or inappropriateness (dTap, HPV, pneumococcus, meningococcus B, flu) perfectly.

Table 2. Multivariable logistic regression.

Covariate	aOR	95% CI	p-value
Male sex	1.56	0.41 – 5.88	0.512
Age	1.00	0.96 – 1.03	0.827
SARS-CoV-2 vaccination	0.34	0.04 – 3.18	0.342
dTap vaccination	Omitted due to collinearity		
HPV vaccination	Omitted due to collinearity		
Anti-pneumococcus vaccination	Omitted due to collinearity		
Anti-meningococcus B vaccination	Omitted due to collinearity		
Influenza vaccination	Omitted due to collinearity		
MMRV vaccination	Omitted due to collinearity		

The outcome is represented by VPS appropriateness.

Discussion

Our study describes the activity of the VPS service of Bari Policlinico General Hospital, a large hospital in Southern Italy, over the course of 2 years. We investigated the appropriateness of VPS requests by patients accessing the clinic, trying to evaluate whether age, sex, or specific vaccines were associated with a higher odd of appropriate access. During the first 2 years of activity, 313 people were evaluated and vaccinated in a protected setting, but this approach was only deemed appropriate in 11 cases. These figures are consistent with existing literature, with a pre-pandemic paper highlighting an overwhelming prevalence of vaccination eligibility in a larger sample.[30]

In our analysis, neither sex nor age were associated with greater appropriateness, suggesting that the perceived need for VPS was related to different factors. As already stated, anxiety plays an important role in increasing the risk of AEFIs. It is therefore possible that fear of adverse events was the main driver for people accessing our clinic.[31]

Risk communication is an important moment of vaccination practices, both in allergic and non-allergic patients.[32–34] Allergies are known to be often associated with anxiety which may determine or exacerbate vaccine hesitancy. Moreover, anxiety itself may be responsible for psychosomatic phenomena such as hyperventilation, gastroenteric distress, and subjective dyspnea. Patients may perceive these events as adverse reactions, thus increasing their own vaccine hesitancy toward future vaccination. VPS represents a resource to encourage vaccination of these patients, therefore ensuring their access to vaccination itself.[35–38]

The significant disproportion of appropriate and inappropriate accesses in our population highlights that conditions requiring VPS are rare, but also suggests that GPs tend to over-recommend this kind of practice to their patients. This excessively cautious behavior might stem from inadequate GP training, but also from medico-legal concerns related to vaccination, leading healthcare professionals to refer allergic subjects to highly qualified vaccination hubs. In fact, it has been highlighted that GPs tend to be especially cautious when vaccinations are involved, looking for external consultation due to the concern that patients may resort to lawsuits following AEFIs.[39–41] This is especially noteworthy, as inappropriate accesses may determine a depletion of human resources, as well as time, that could be otherwise differently allocated.[42]

Even inappropriate accesses, however, represented an occasion to vaccinate potentially hesitant patients [e.g. frail patients under immunosuppressive treatments or patients who had reported previous allergic reactions], who might have refused vaccination altogether had they not be given the chance to access a VPS service: it is noteworthy that no vaccine refusals were registered in our study population, confirming that VPS was appreciated by patients.[22,43,44]

Since most subjects accessed our clinic to undergo SARS-CoV-2 vaccination, confrontation with other vaccines did not offer any insights. On the other hand, this data suggests a greater degree of concern regarding this specific vaccine, probably related to the law about mandatory vaccination. Since the beginning of the SARS-CoV-2 vaccination campaign, in fact, fear of unforeseen allergic reactions was identified as a reason for hesitancy even by healthcare providers.[45,46] Products based on mRNA platforms were especially researched into, with complement-mediated mechanisms being currently suspected of determining basophile activation in predisposed subjects.[47]

To our knowledge, this is the first study to describe the activities of a vaccination clinic dedicated to high-risk patients in Italy. Despite the scarcity of data, the fact that 313 people were vaccinated confirms that this kind of service is able to promote vaccination among allergic subjects.

Our study has significant weaknesses. First of all, the population was recruited sequentially, had suboptimal numerosity, and mainly access to VPS looking for SARS-CoV-2 vaccination, therefore limiting the significance of our findings. The exclusion of most vaccines due to collinearity especially highlights the need to expand the sample size, including a more diverse vaccination demand, and sparse data may have impacted the reliability of statistical inference.

Recruiting a larger number of patients could offer further insights but would also require a cooperation of various centers offering VPS, as most conditions for which this approach is recommended are rare in the general population. A multicentric collaboration would optimize the statistical power while also increasing the generalizability of these results. Moreover, more cases of VPS with vaccines other than the SARS-CoV-2

one should be included in future analyses, in order to verify whether the presence of the SARS-CoV-2 vaccination heavily shaped our results or rather represented a good model for other products as well.

Secondly, in order to encourage participation in the study, only routine information was collected. Future studies should evaluate whether anxiety plays a role in increasing (or reducing) inappropriate access to VPS, using validated scales if possible.[48,49] The role of GPs should also be investigated. Finally, it would be interesting to evaluate whether subjects vaccinated in non-protected settings have significantly different characteristics than those accessing VPS, as well as the temporal trends of hypersensitivity reactions before and after the SARS-CoV-2 pandemic.

Conclusion

VPS was often inappropriately recommended by GPs and/or requested by patients. Neither individual nor vaccine-related factors were shown to significantly impact appropriateness, but no episodes of vaccine refusal occurred. VPS represents a valuable asset to decrease vaccine hesitancy and promote vaccination of allergic subjects, thus ensuring their access to vaccine resources. Future research should explore larger, more diverse samples, as well as include a comparison with subjects accessing regular vaccination services as far as AEFI risk is concerned. At the same time, policies should focus on GP-dedicated training programs, in order to reduce inappropriate referrals while also assessing VPS services' cost-effectiveness.

Author contributions

CRediT: **Antonio Di Lorenzo:** Conceptualization, Writing – original draft; **Paola De Petro:** Data curation, Methodology; **Felice Leone:** Formal analysis, Software; **Cinzia Annatea Germinario:** Methodology, Writing – review & editing; **Silvio Tafuri:** Supervision, Writing – review & editing; **Pasquale Stefanizzi:** Conceptualization, Supervision, Writing – original draft, Writing – review & editing.

Disclosure statement

No potential conflict of interest was reported by the author(s).

Funding

The author(s) reported there is no funding associated with the work featured in this article.

Notes on contributor

Stefanizzi qualified in Medicine at the University of Parma in 2014 and he achieved a post degree in Hygiene and Preventive Medicine at the University of Bari in 2019. He is a consultant of the Apulian Observatory for Epidemiology in the field of immunization policies (focus on safety and effectiveness of vaccination programs), surveillance and management of infectious diseases, and health organizations. From July 2020, he has been Assistant Professor of Public Health at the School of Medicine in Bari. He works as a medical doctor at the Bari Policlinico General Hospital – Hygiene Unit, in which he is charged of the management of vaccination activities; since March 2020, he is member of the COVID19 Control Room Unit.

He is a member of the National Group of monitoring safety of vaccines coordinated by the National Drug Agency.

He is author or co-author of 120 indexes scientific papers and over 10 teaching books in the fields of epidemiology and public health.

ORCID

Pasquale Stefanizzi http://orcid.org/0000-0002-3279-0196

Ethical statement

Study was approved by the Policlinico University Hospital – Regional Ethics Committee (study protocol code: 51/2022). The study was conducted in agreement with the principles of the Declaration of Helsinki.

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