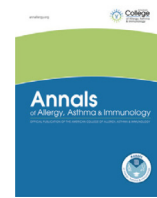




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The Role of the Allergist in Coronavirus Disease 2019 Vaccine Allergy Safety



A Pilot Study on a “Hub-and-Spoke” Model for Population-Wide Allergy Service

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ABSTRACT

Background: Hong Kong started its coronavirus disease 2019 (COVID-19) vaccination program in February 2021. A territory-wide Vaccine Allergy Safety (VAS) clinic was set up to assess individuals deemed at “higher risk” of COVID-19 vaccine-associated allergies. A novel “hub-and-spoke” model was piloted to tackle the overwhelming demand of services by allowing nonallergists to conduct assessment.

Objective: To evaluate the outcomes of the VAS hub-and-spoke model for allergy assessment.

Methods: Records of patients attending the VAS hub-and-spoke Clinics between March and August 2021 were reviewed (n = 2725). We studied the overall results between the Hub (allergist led) and Spoke (nonallergist led) Clinics. The Hub and the Hong Kong West Cluster Spoke Clinic were selected for subgroup analysis as they saw the largest number of patients (n = 1411).

Results: A total of 2725 patients were assessed under the VAS hub-and-spoke model. Overall, 2324 patients (85.3%) were recommended to proceed with vaccination. Allergists recommended significantly more patients for vaccination than nonallergists (odds ratio = 21.58; $P < .001$). Subgroup analysis revealed that 881 of 1055 (83.5%) patients received their first dose of COVID-19 vaccination safely after assessment. Among those recommended vaccination, more patients assessed by allergists received their first dose of vaccination (odds ratio = 4.18; $P < .001$).

Conclusion: The hub-and-spoke model has proven to be successful for the vaccination campaign. This study has illustrated the crucial role of allergists in countering vaccine hesitancy. Results from the study revealed considerable differences in outcomes between allergist-led and nonallergist-led clinics. Precise reasons for these differences warrant further evaluation. We are hopeful that the hub-and-spoke model can be similarly adapted for other allergist-integrative services in the future.

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Introduction

Vaccination remains the most promising strategy to end the coronavirus disease 2019 (COVID-19) pandemic. Hong Kong started its territory-wide COVID-19 vaccination program in February 2021, providing its citizens with the following 2 vaccine options: CoronaVac (Sinovac, Beijing, People’s Republic of China) and Comirnaty (BioNTech, Germany). Hong Kong citizens can freely choose between the 2 vaccines for

their primary inoculations, with surplus doses purchased for both formulations of vaccines. Both vaccines became available around the same time (within a month) of each other. Although vaccine-associated allergic reactions and anaphylaxis are extremely rare, the overall vaccine acceptance rate by the public was below 40% even before the commencement of COVID-19 vaccinations in Hong Kong, largely attributed to the lack of trust in novel vaccine platforms and manufacturers.^{1,2}

Given the novel nature of messenger RNA vaccines and initial global concerns over vaccine-related allergic reactions, worldwide health authorities took a conservative approach in protecting individuals who may be at higher risk of COVID-19 vaccine-associated allergy.^{3,4} Similarly, the Hong Kong Institute of Allergy (HKIA) established its first territory-based COVID-19 Vaccine Allergy Safety (VAS) Consensus Statements to define individuals at higher risk of potential COVID-19

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vaccine-related allergies. Owing to the initial fear of potential excipient-associated allergies, patients with history of anaphylaxis or severe, immediate-type allergic reactions to multiple classes of drugs or foods were cautioned and may require allergist assessment before COVID-19 vaccination.⁵ A territory-wide VAS Clinic was set up for prevaccination evaluation of these at-risk individuals. However, this VAS Clinic had limited capacity as there was only 1 specialist in Immunology and Allergy working in Hong Kong's public health care system.

Despite clear guidance for vaccination, many patients were inappropriately referred for specialist assessment because of anxiety or misdiagnosis of previous allergic history.⁶ Given Hong Kong's extreme shortage of allergists, the VAS Clinic was quickly overwhelmed by an exponential increase in referrals that reached more than 2500 new referrals per month.^{6,7} Coupled with growing concerns of vaccine safety amid media reports of suspected COVID-19 vaccine-associated anaphylaxis, these long waiting times for VAS assessment led to delayed vaccinations and growing vaccine hesitancy among the general population.⁸ To tackle the overwhelming demand for vaccine allergy services, a novel VAS "Hub-and-Spoke" model was piloted to allow nonallergist doctors to conduct prevaccination allergy assessment.

Under this Hub-and-Spoke model, 7 new individual "Spoke" Clinics were set up across Hong Kong. These individual "Spoke" Clinics were run by nonallergists, who were trained and supervised by the allergist-led "Hub." The Hub continued to see patients for prevaccination allergy assessment, but patients with excessive waiting times were redirected to their respective Spokes based on the patients' geographic location (Fig 1). The primary objective was to empower individual Spoke Clinics to independently provide prevaccination assessment with support from the Hub.

This study aims to evaluate the outcomes and effectiveness of the VAS Hub-and-Spoke model for prevaccination allergy assessment. We studied the overall rate of vaccination and comparative rates between the Hub (allergist led) and Spoke (nonallergist led) Clinics. We also conducted a subgroup analysis to compare the actual rate of COVID-19 vaccination and allergic reactions after assessment at Hub and Spoke Clinics.

Methods

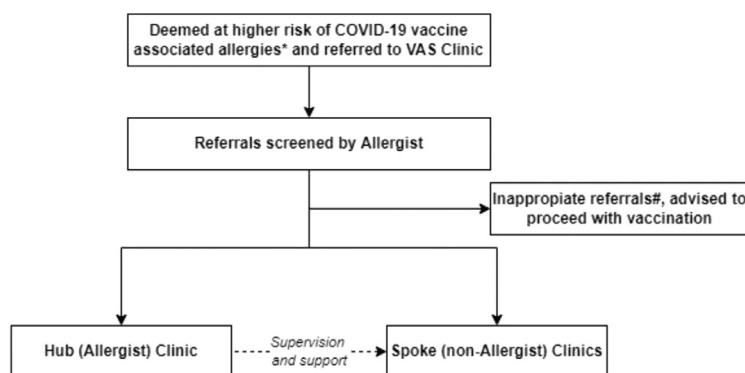
The Hospital Authority is the sole publicly funded health care provider in Hong Kong with its services organized into the following 7 geographic clusters: Hong Kong West Cluster (HKWC), Hong Kong East Cluster, Kowloon Central Cluster, Kowloon West Cluster, Kowloon East Cluster, New Territories West Cluster, and New Territories East Cluster. A Spoke Clinic was established at each of the 7 clusters. The Hub was the Department of Medicine of Queen Mary Hospital and The University of Hong Kong, led by a specialist in

Immunology and Allergy and remains the only referral center with recognized immunology or allergy under the Hospital Authority. Nonallergist doctors from the Departments of Internal Medicine and Family Medicine and Primary Healthcare were openly recruited to participate in their respective Spoke Clinics. All doctors attended dedicated training seminars regarding COVID-19 VAS conducted by the Hub. Each Spoke Clinic was led by at least 1 senior consultant in Family Medicine who could contact the Hub at any time. Training material was available as on-demand videos, including suggested protocol-driven algorithms in accordance with HKIA recommendations. On-site vaccine challenges were not made available at the time of this study; hence, Hub and Spoke clinics all referred recommended patients back to the community for vaccinations. All vaccine centers are equipped with facilities and trained personnel to treat anaphylaxis. Patients attending the Spoke Clinics could also be diverted back to the Hub Clinic at the Spoke's discretion after communication with the Hub. Patients were only recommended to proceed with vaccinations or not. No recommendations regarding vaccine formulation were given.

Medical records of patients attending the Hub and Spoke Clinics between March 2021 and August 2021 were retrieved and reviewed. Only complete patient records were included for analysis, and all data were anonymized after data extraction. Extracted clinic data included age, sex, indicators for referral, allergy investigations performed, and outcome of allergist evaluation (if deemed at higher risk of COVID-19 vaccine-associated allergic reactions and whether to proceed with vaccination or not). Individuals at higher risk of potential COVID-19 vaccine-related allergies were defined as those with history of anaphylaxis or severe, immediate-type allergic reactions to multiple classes of drugs or foods were cautioned and may require allergist assessment before COVID-19 vaccination.⁵ Inappropriate referrals were defined as insufficient information or absence of such criteria.

The Hub and the HKWC Spoke Clinic were selected for subgroup analysis as they saw the largest number of patients. All patients who attended these 2 clinics were followed-up by telephone at least 1 month after Hub or Spoke Clinic assessment and had their vaccination records confirmed by the Hospital Authority's Computer Management System. For subgroup analysis, additional information was collected by telephone interview, including other existing medical comorbidities, smoking status, history of urticaria, history of drug allergy, and any allergic reactions after COVID-19 vaccination. Rates of COVID-19 vaccination were compared between patients attending the Hub and HKWC Spoke Clinic.

Categorical variables were expressed as number (percentage) and continuous variables as median (range) where appropriate. Logistic regression was used to calculate the odds ratios (ORs) of vaccine recommendation and actual vaccination respectively associated with



* Patients with history of anaphylaxis; or severe, immediate-type allergic reactions to multiple classes of drugs/foods

Referrals with insufficient information or did not meet criteria for "higher risk of COVID-19 vaccine associated allergies"

Figure 1. Flowchart of referral pathway of VAS hub-and-spoke model. COVID-19, coronavirus disease 2019; VAS, Vaccine Allergy Safety.

Table 1
Characteristics of Study Participants by Hub and Spoke Clinics

Variables	Overall	Hub	HKWC spoke	KCC spoke	NTWC spoke	KWC spoke	NTEC spoke	HKEC spoke	KEC spoke
Number of patients	2725	654	757	241	226	223	240	204	180
Age, median (range)	52 (17-97)	52 (18-97)	53 (18-90)	52 (19-81)	50 (19-83)	53 (21-83)	49.5 (17-74)	53 (18-85)	49 (19-89)
Female (%)	2016 (74%)	452 (69.1%)	570 (75.3%)	177 (73.4%)	180 (79.6%)	154 (69.1%)	190 (79.2%)	159 (77.9%)	134 (74.4%)
Reasons for referrals (n, %)									
Anaphylaxis	818 (30%)	144 (22%)	192 (25.4%)	55 (22.8%)	57 (25.2%)	105 (47.1%)	141 (58.7%)	64 (31.4%)	60 (33.3%)
Multiple allergies	1732 (63.6%)	408 (62.4%)	515 (68%)	173 (71.8%)	168 (74.3%)	118 (52.9%)	99 (41.3%)	137 (67.2%)	114 (63.3%)
Others ^a	175 (6.4%)	102 (15.6%)	50 (6.6%)	13 (5.4%)	1 (0.4%)	0 (0%)	0 (0%)	3 (1.5%)	6 (3.3%)

Abbreviations: Hong Kong West Cluster (HKWC), Hong Kong East Cluster (HKEC), Kowloon Central Cluster (KCC), Kowloon West Cluster (KWC), Kowloon East Cluster (KEC), New Territories West Cluster (NTWC), and New Territories East Cluster (NTEC).

^aOther precautions, for example, prior suspected excipient allergies, mastocytosis and idiopathic anaphylaxis.

the Hub and Spoke Clinics. A *P* value of less than .05 was considered statistically significant. STATA version 16 (StataCorp LLC, College Station, Texas) was used for all analyses.

Informed consent was waived (because all data were anonymized and collected retrospectively) and approved by the institutional review board of the University of Hong Kong and Hospital Authority HKWC.

Results

More Than 85% of Assessed Patients Were Recommended Coronavirus Disease 2019 Vaccination

A total of 2725 patients were assessed under the VAS Hub-and-Spoke model. Approximately one-quarter (654 patients [24%]) were assessed at the Hub, whereas the remaining 2071 patients were assessed at Spoke Clinics. The overall median age was 52 (17-97) years, and the female-to-male ratio was 2.8:1. Overall, 2324 of 2725 patients (85.3%) were deemed to be not at higher risk of COVID-19 vaccine-associated allergy and thus recommended to proceed with vaccination. Detailed breakdown of the number of patients assessed, demographics, reasons for referral, and recommendation rates for COVID-19 vaccination of Hub and Spoke Clinics is found in Table 1 and Figure 2. There were no marked demographic differences between patients seen at the Hub or any Spokes Clinics.

Allergists Recommended Significantly More Patients for Coronavirus Disease 2019 Vaccination Than Nonallergists

After prevaccine assessment, 98.9% (647 of 654) of patients assessed by the Hub (allergist led) were recommended for vaccination, whereas 81% (1677 of 2071) of patients assessed at a Spoke (nonallergist led) Clinic were recommended for vaccination. Results of recommendation rates of individual clinics are found in Figure 2. The Hub recommended significantly more patients for vaccination

than the Spoke Clinics (OR, 21.58 [95% confidence interval, 10.16-45.82]; *P* < .001) (eTable 1). This finding was consistent when comparing the Hub with individual Spoke Clinics (data not found).

More Than 83% of Followed-Up Patients Proceeded and Received First-Dose Coronavirus Disease 2019 Vaccination

For subgroup analysis, 1055 of 1411 patients (74.8%) had complete follow-up data available for analysis. Detailed breakdown of recommendation and first-dose COVID-19 vaccination rates after assessment is found in Figure 3. In this cohort, 881 of 1055 (83.5%) of patients confirmed to have received their first dose of COVID-19 vaccination after assessment. The remaining patients were either waiting for their vaccination appointment or declined vaccination for nonmedical reasons. Among those who received their first dose of COVID-19 vaccination, no patient reported any subsequent allergic reactions, and all patients were eligible for subsequent doses of COVID-19 vaccination.

Patients Assessed by Allergists Were Significantly More Likely to Receive Coronavirus Disease 2019 Vaccination Than Patients Assessed by Nonallergists

Among those recommended vaccination, significantly more patients attending the Hub received their first dose of COVID-19 vaccination (OR, 4.18 [95% confidence interval, 2.81-6.21]; *P* < .001) (Table 2).

Discussion

Establishing the COVID-19 VAS program was paramount to boosting public confidence in vaccination and kickstart the vaccination campaign in Hong Kong. The recommendations set out by HKIA in early 2021 were successful at keeping a low incidence of allergic events to counter local vaccine hesitancy, largely driven by fears of

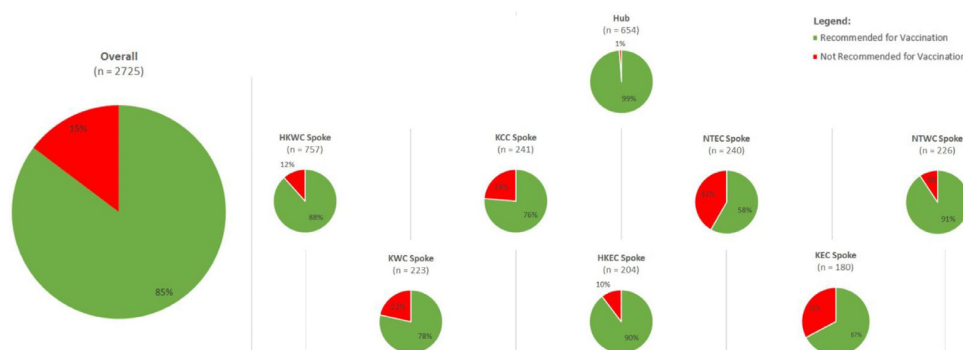


Figure 2. Recommendation rates for COVID-19 vaccination of Hub and Spoke clinics. COVID-19, coronavirus disease 2019; HKEC, Hong Kong East Cluster; HKWC, Hong Kong West Cluster; KCC, Kowloon Central Cluster; KEC, Kowloon East Cluster; KWC, Kowloon West Cluster; NTEC, New Territories East Cluster; NTWC, New Territories West Cluster.

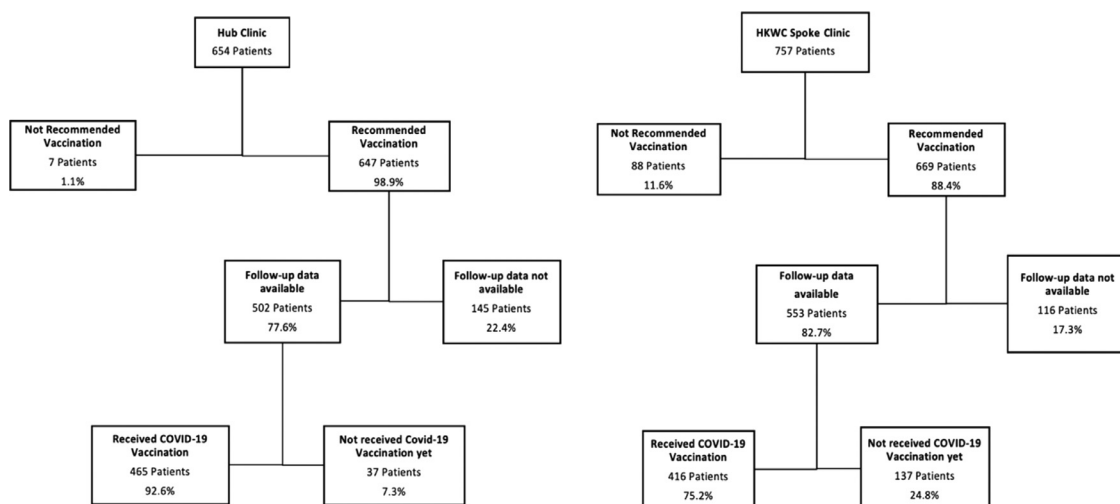


Figure 3. Recommendation and first-dose COVID-19 vaccination rates after assessment. COVID-19, coronavirus disease 2019; HKWC, Hong Kong West Cluster.

vaccine-related allergic reactions. Despite these recommendations, there remained an overwhelming number of referrals which the VAS Clinic could not handle.⁶ This novel VAS Hub-and-Spoke model was therefore established and allowed for nonspecialists to participate in evaluating patients who were deemed “higher risk” for developing COVID-19 vaccine-associated allergies. This study found that the Hub-and-Spoke model was safe and effective for prevaccine allergy assessment, but there were significant differences between the Hub and Spoke Clinics.

Overall, our Hub-and-Spoke model enabled 2725 patients to be assessed and 2324 (85%) were recommended for vaccination. The longest waiting appointment time for prevaccine assessment fell from more than 5 years (scheduled before establishment of the Hub-and-Spoke model) to less than 3 months. Were it not for this VAS initiative, these patients would have been ineligible for COVID-19 vaccination under local guidance. More importantly, from our subgroup analysis, more than 83% of these recommended patients successfully received their first dose of COVID-19 vaccines. Given the severe shortage of allergists in Hong Kong, it is evident that our Hub-and-Spoke model was both safe and effective in improving vaccination rates, with no patients reporting any subsequent allergic reactions and all remaining eligible for subsequent COVID-19 vaccinations. Furthermore, the effects of this successful Hub-and-Spoke model were considerably more far reaching than just the 2725 patients assessed. By ensuring low incidences of vaccine-related allergic events, we were able to bolster public confidence in the safety of COVID-19 vaccines.

This study specifically highlights the impact of specialist-level expertise, particularly in Immunology and Allergy. Hong Kong’s experience in COVID-19 VAS exemplifies yet another aspect of Immunology and Allergy in which specialist-level input is necessary. Allergists

are often thought to manage only rare and highly specialized diseases, but this study highlights their role in tackling population health such as widespread vaccine hesitancy during an urgent global vaccination campaign. Our results also reveal the importance of multidisciplinary collaboration, especially between internists and family physicians, and highlight the feasibility of further Hub-and-Spoke or allergist-integrative models in the future.

When comparing outcomes between the Hub (allergist led) and Spoke (nonallergist led) Clinics, we identified that the Hub Clinic recommended significantly more patients for vaccination. Several factors may have contributed to this difference. First, before the establishment of the Hub-and-Spoke model, the existing VAS service at the Hub was already evaluating prevaccination patients who were deemed at “higher risk.” In our previous published experience, 98% of these initial patients were recommended vaccination and subsequently completed their COVID-19 vaccinations safely.⁶ This initial experience likely allowed doctors at the Hub to become familiar and more confident with the safety of COVID-19 vaccines. Second, allergists at the Hub Clinic may have been less conservative in their recommendations. Patients in Hong Kong with a previous history of suspected “anaphylaxis” or severe, immediate-type allergic reactions to multiple classes of drugs or foods were deemed at possible risk of undiagnosed excipient allergy and cautioned against COVID-19 vaccination before allergist evaluation. Despite having allergist support and freedom to redirect patients back to the Hub, nonallergists may have felt less confident in excluding possible excipient allergy and adopted a relatively cautious approach, thus recommending fewer patients for vaccination.

However, our follow-up analysis also identified that patients assessed at the Hub (allergist led) clinic were significantly more likely

Table 2
Logistic Regression of First-Dose COVID-19 Vaccination Status

Variables	Odds ratio	95% confidence interval	P value
Hub Clinic (allergist) vs Spoke Clinic (nonallergist)	4.18	2.81-6.21	<.001
Age	1.03	0.90-1.17	.68
Female	0.81	0.54-1.21	.30
Smoking	0.64	0.31-1.32	.22
Hypertension	0.53	0.34-0.82	.005
Diabetes mellitus	1.04	0.58-1.86	.89
Chronic obstructive pulmonary disease or asthma	1.19	0.61-2.32	.60
History of urticaria	0.91	0.61-1.38	.66

Abbreviation: COVID-19, coronavirus disease 2019.
NOTE: Bold denotes statistical significance ($P < .05$).

to get vaccinated than patients assessed in Spoke Clinics by nonallergists. This is likely a result not only in more effective risk stratification but suggests the role of other contributing factors from both patients and doctors. It is known that health care provider recommendation is paramount for acceptance of various vaccines.⁹ Patients are likely to have a preformed preference for receiving advice from a specialist doctor. The Hong Kong health care system lacks gatekeeping for specialist referrals with relative ease of access to most specialist services. This may have conditioned many patients to always seek “specialist opinion” and be accustomed to receiving such assessments readily.^{10–12} In particular, with vaccine allergy perceived as a highly specialized topic, patients may place less trust and confidence in the advice given by nonallergists. These patient preconceptions are perhaps not unfounded. Factors involving the doctor may include the content of advice, but also the manner in which the advice was conveyed. Doctors in the Hub Clinic are well versed with allergy-related counseling in their line of work. During vaccine allergy assessment, it was pertinent to offer reassurance, similar to the support allergists offer in various clinical scenarios, where they are faced with patient anxiety and skepticism. Hub doctors also likely tend to be more comfortable and confident in their own judgment, which can greatly affect patient perception.^{13,14} In addition, specialist clinics were more able to provide guidance regarding conditions unrelated to COVID-19 vaccine allergies. As mentioned, inappropriately referred patients were often concerned over other immunologic conditions, such as allergic rhinitis, asthma, atopic dermatitis, food allergies, or chronic spontaneous urticaria. These conditions are often misunderstood to be related to vaccine allergy, or falsely attributed to higher risk of allergy in general.^{15–18} It is likely that the Hub Clinic was also able to address these concerns more holistically and provide advice on the management of these conditions where necessary. With better control of various immunologic conditions, this could have also led to more patient confidence and subsequent vaccinations. The specific factors associated with patient confidence and willingness to receive vaccination after consultation warrant dedicated studies in the future.

Limitations of this study include its study design using medical record review and telephone for follow-up interviews. We did not include patients who did not attend their appointments nor calculate the default rates for each clinic. Data for potential confounders (such as coexisting comorbidities or other drug allergies) and complete COVID-19 vaccination status were not available for patients outside the subgroup analysis (ie, the 6 other Spoke Clinics). Further details regarding prior drug allergies could not be analyzed. There may also have been possible referral bias; as the Hub was able to provide additional Immunology and Allergy services, it therefore saw a disproportionately higher number of patients referred for “other” allergy indications (such as prior suspected excipient allergies, idiopathic anaphylaxis). However, we would anticipate that this would have lowered the Hub recommendation rate. In addition, the vaccination rates presented represent only a snapshot of the current vaccination status. Patients who were not vaccinated at the time of data collection (eg, waiting for their vaccine appointments) may have subsequently received vaccination.

In conclusion, vaccine hesitancy is complex and multifaceted, with factors involving health care providers, patients, media, social environment, and health care and political systems. This study has illustrated the crucial role of allergy specialists in reaffirming vaccine safety and countering vaccine hesitancy. Scarcity in allergists in Hong Kong is no new predicament.⁷ Although this pandemic allowed for opportunities for collaboration with other specialties and allied

health services, it reveals a critical need for further development and resources in this area of health care in Hong Kong.

The Hub-and-Spoke model has proven to be successful for the vaccination campaign, and we are hopeful that it can be similarly adapted for other valuable services as allergists across the territory remain scarce. As a result of this pilot, a population-wide active Penicillin Allergy Delabeling Initiative is also being developed using the same model. Results from the study revealed considerable differences in outcomes between allergist-led and nonallergist-led clinics. Precise reasons for these differences warrant further evaluation to develop more effective strategies to tackle future population-wide campaigns and programs.

Supplementary Data

Supplementary material associated with this article can be found in the online version at <https://doi.org/10.1016/j.anai.2022.05.011>.

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Supplementary Data**eTable 1**
Logistic Regression of Recommendation Rates

Variables	Odds ratio	95% Confidence interval	P value
Hub Clinic (allergist) vs Spoke Clinic (nonallergist)	21.58	10.16-45.82	<.001
Age	0.99	0.92-1.07	.85
Female	0.88	0.68-1.14	.33

NOTE. Bold denotes statistical significance ($P < .05$).