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Short communication

Specialist confirmed allergic reactions to COVID-19 mRNA vaccines at a mass vaccination site

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ABSTRACT

Healthcare providers can play a key role in reaching the target for vaccine uptake through educating the public on the risk may be of severe allergic reactions to COVID-19 vaccines. Thus, it is important to resolve reports in the literature which present conflicting data on vaccine safety. We performed a prospective study of Pfizer-BioNTech vaccinations administered at the Albany Community Vaccination Center. All potential vaccinees to the site were screened for allergic history prior to triage by a board-certified allergist. In the first 14 days of operation, our site vaccinated 14,655 individuals, 3.9% of which had a personal history of anaphylaxis. While some vaccine recipients had non-allergic complications, none of the visitors suffered any objective, immediate allergic symptoms. Our findings indicate that specialist-confirmed rates of immediate allergic reaction to mRNA SARS-CoV-2 vaccination are far lower than self-reported rates defined by subjective, unconfirmed symptoms.

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1. Introduction

With the emergency use authorization of several vaccines against the SARS-CoV-2 virus the potential end of the pandemic seems within sight. Healthcare providers, especially allergists, can play a key role in reaching the target for vaccine uptake for individuals through educating the public on the reported risk of severe allergic reactions to these vaccines. Thus, it is important to resolve reports in the literature which present conflicting data on vaccine safety. We performed a prospective study of Pfizer-BioNTech vaccinations administered at the Albany Community Vaccination Center. All potential vaccinees to the site were screened for allergic history prior to triage by a board-certified allergist. In the first 14 days of operation, our site vaccinated 14,655 individuals, 3.9% of which had a personal history of anaphylaxis. While some vaccine recipients had non-allergic complications, none of the visitors suffered any objective, immediate allergic symptoms. Our findings indicate that specialist-confirmed rates of immediate allergic reaction to mRNA SARS-CoV-2 vaccination are far lower than self-reported rates defined by subjective, unconfirmed symptoms.

2. Methods

We performed a prospective study of Pfizer-BioNTech vaccinations administered at the Albany Community Vaccination Center. Our population was 63.1% White, 8% Black, 6.2% Asian/Pacific Islander, 18.3% unspecified, and 5% Hispanic; with 33% in the highest anaphylaxis incidence age range of 16–39 years [5] (Table 1). At the time of our evaluation, the state of New York set eligibility by zip code; within the eligible zip codes registrants needed to be over 60 years of age, have documented immune deficiency, be a health care worker, or work as an educator.

Potential vaccine recipients could drive or take a bus to the Albany Washington Avenue Armory, a historic building that was once the home of the Army's Tenth Battalion but now is used as a church and basketball arena for the Albany Patroon of the Conti-

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Table 1

Characteristic of vaccinees with descriptions and enumeration of complications are presented.

| Demographics | N   | %    |
|--------------|-----|------|
| Total        | 14,655 | 100  |
| Any reported history of severe allergic reaction | 581 | 3.9  |
| Denied vaccination (any reason) | 0 | 0 |

| Race | N   | %    |
|------|-----|------|
| American Indian/Alaskan Native | 30 | 0.2  |
| Black | 1,168 | 8.0 |
| Multiracial | 243 | 1.6  |
| White | 9,243 | 63.1 |
| Other | 382 | 2.6  |
| Unspecified | 2,675 | 18.3 |

| Ethnicity | N   | %    |
|-----------|-----|------|
| Hispanic | 662 | 4.5  |
| Non-Hispanic | 10,059 | 68.6 |
| Unspecified | 3,934 | 26.8 |

| Age | N   | %    |
|-----|-----|------|
| 16-40 years | 4,836 | 33 |
| 41-64 years | 7,225 | 49.3 |
| >65 years | 2,594 | 17.7 |

| Potentially allergic symptoms | N   | %    |
|-------------------------------|-----|------|
| Rash, any | 2 | 0.013 |
| Hives | 0 | 0 |
| Respiratory/Chest | 0 | 0 |
| Lightheadedness | 7 | 0.048 |
| Gastrointestinal distress | 3 | 0.02 |
| Oral Symptoms (tingling, numbness, swelling, or other around lips, tongue, or mouth) | 5 | 0.034 |
| Two of above at once | 1* | 0.006 |
| Anaphylaxis | 0 | 0 |
| Non-allergic complications | N   | %    |
| Any (requiring additional medical evaluation) | 27 | 0.18 |
| Serious (requiring EMS transport) | 4 | 0.027 |

*Emesis and light headedness. No other symptoms, vitals stable. Self-resolved after 15 minutes without treatment.

In New York, some vaccinees presented with physician letters identifying a history of anaphylaxis as an immune defect meeting eligibility criterion for vaccination priority; therefore, 3.9% of this enriched atopic population had a personal history of anaphylaxis (Table 1); this rate is below the reported lifetime anaphylaxis risk of 7.7% defined in retrospective analyses, but greater than the 1.6% lifetime risk established as a more rigorous definition [6]. 14,655 vaccinations were performed over the first 14 days without a single case of anaphylaxis (Table 1). One patient reported symptoms from two organ systems, which included one bout of emesis and lightheadedness lasting less than 15 min.

While no individuals required emergent care for allergic symptoms, four were transported to the local hospital for non-allergic complaints: one patient who reported an untreated seizure disorder had a witnessed seizure, but no vital sign abnormalities or other symptoms; a 49 year old male reported 30 min of isolated left arm tingling after injection in left arm but no other signs of acute coronary syndrome, but in an abundance of caution was transported to rule out myocardial infarction; a 70 year old male with known heart block and previously scheduled for a pacemaker insertion reported feeling weak and had second degree, type II heart block on the heart monitor, while his rhythm stabilized at a pulse over 70 he was sent for pacemaker insertion; and lastly a 45 year old female with no allergic history reported lightheadedness had normal vitals and no other symptoms, was transported when symptoms did not resolve in 30 min but was discharged after an additional hour of observation and symptom resolution without need for treatment.

4. Discussion

Despite 3.9% of vaccine recipients reporting a history of anaphylaxis, no anaphylactic reactions to COVID-19 mRNA vaccines occurred among 14,655 vaccinations. Both our findings and those reported by Blumenthal et al cannot account for high-risk patients that were screened out by their primary care or allergy providers. In theory, some subjects with a history of anaphylaxis may have chosen not to receive or been advised against receiving a COVID-19 vaccine. While we cannot exclude this confounder, at least one individual presented to our site with documented hereditary alpha tryptasema [7]; she reported over 25 incidences of anaphylaxis in her life (none to prior vaccines) but was still safely vaccinated and sent home after 60 min of monitoring. Thus, our findings of no anaphylactic reactions among a large group of vaccine recipients whom were assessed in real-time by a specialist are in alignment with the CDC reported rate of anaphylaxis being 2.4–4.5 per million vaccinations [4] as well as the complication rates reported during the clinical trials [8].

5. Conclusions

The report by Blumenthal et al must be interpreted in the light of its acknowledged limitation of self-reporting and should be both interpreted cautiously and contextualized appropriately against
the evidence of safety for the ongoing mass vaccination campaign. Given that reductions in the reported incidence of major side effects is associated with a 4% increase in willingness to receive the COVID-19 vaccine [2], overstated risks are not without potential real-world consequences. The higher rate reported by Blumenthal may be due to their study design being reliant on self-reporting and allowing symptoms that presented 3 days after vaccination to be considered a sign of anaphylaxis. When assessed in real-time by an allergist, no immediate allergic reactions were found when a large group of vaccine recipients from diverse backgrounds, even in the presence of a history of anaphylaxis. Our results are consistent with previously reported data [4,8] and is reassuring regarding the overall safety of the vaccines.

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Declaration of Competing Interest

The authors declare that they have no known competing financial interests or personal relationships that could have appeared to influence the work reported in this paper.

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