



## Short communication

# Relationship between pre-existing allergies and anaphylactic reactions post mRNA COVID-19 vaccine administration

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## ABSTRACT

Two mRNA vaccines for COVID-19, Pfizer-BioNTech and Moderna, are approved for emergency use in the United States. After their approval and dosing in millions of recipients, reports of anaphylaxis began to appear in the Vaccine Adverse Reporting System (VAERS). Here we provide an analysis of the relationship between prior history of allergy and/or anaphylaxis and anaphylaxis rates following the administration of mRNA COVID-19 vaccines. Overall reported incidence of anaphylaxis was estimated to be rare at 4.2 cases per million doses. It appeared that the *relative* incidence of anaphylaxis following administration of these COVID-19 vaccines was two and seven times higher for recipients with a prior history of allergies and/or anaphylaxis, respectively. This report provides valuable metrics to make evidence-based decisions for subjects with pre-existing allergic conditions receiving a COVID-19 mRNA vaccine.

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## 1. Introduction

Two mRNA COVID-19 vaccines are currently approved in the United States by Emergency Use Authorization (EUA). The Pfizer-BioNTech mRNA vaccine has been approved since December 11, 2020 by EUA in the United States for individuals 16 years of age and older [1]. The other mRNA vaccine, from Moderna, received EUA on December 18, 2020 for individuals 18 years of age and older [1]. During the clinical trial for the Pfizer-BioNTech COVID-19 mRNA vaccine, the majority of the adverse effects were short-term, mild-to-moderate pain at the injection site, fatigue, and headache [2]. No serious adverse events were specifically attributed to the vaccine group. Similarly, serious adverse events were rare during the clinical assessment of the Moderna COVID-19 mRNA vaccine [3]. The Moderna study reported hypersensitivity reactions in 1.5% of participants in the vaccine group and 1.1% of participants in the placebo group. The study indicated that the ability to detect rare events like hypersensitivity was limited given the vaccine group sample size of 15,210.

Since the EUA for the two mRNA vaccines, as of February 5th, 2021, the Centers for Disease Control and Prevention (CDC) reported that approximately 19.5 million individuals received at least one dose of the Pfizer-BioNTech vaccine and approximately 17 million individuals received at least one dose of the Moderna

vaccine [4]. The CDC conducts passive post-approval vaccine safety monitoring utilizing the Vaccine Adverse Reporting System (VAERS) [5]. The VAERS database relies on spontaneous reporting by recipients and/or healthcare providers of adverse events after vaccination and includes notifications and reports of suspected anaphylaxis. With regards to COVID-19 vaccine related adverse events, reports of anaphylaxis following administration of the two mRNA vaccines began to appear in the VAERS database post EUA [6,7]. Anaphylaxis is an acute life-threatening condition caused by the systemic release of mast cell mediators that can cause asphyxiation and cardiovascular collapse [8]. Most anaphylaxis is IgE-mediated but can also be caused by non-IgE-mediated mast cell degranulation. Some non-IgE-mediated reactions, referred to as anaphylactoid reactions, resemble the clinical presentation of anaphylaxis and respond similarly to epinephrine.

Shimabukuro et al. reported a preliminary analysis of VAERS data for COVID-19 mRNA vaccine-related anaphylaxis [9]. This study was based on nationwide VAERS data as of January 18, 2021, and it reported anaphylaxis rates of 4.7 and 2.5 cases/million doses post Pfizer-BioNTech and Moderna vaccine administration, respectively. In a recent publication by Blumenthal et al., an analysis of acute adverse reactions to mRNA COVID-19 vaccines among the employees of the Mass General Brigham system was reported [10]. In that study, anaphylaxis events following administration of the Pfizer-BioNTech and Moderna vaccines were observed in 0.027% and 0.023% of recipients, respectively and overall incidence rate of anaphylaxis was 2.47 per 10,000 COVID-19 vaccinations.

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