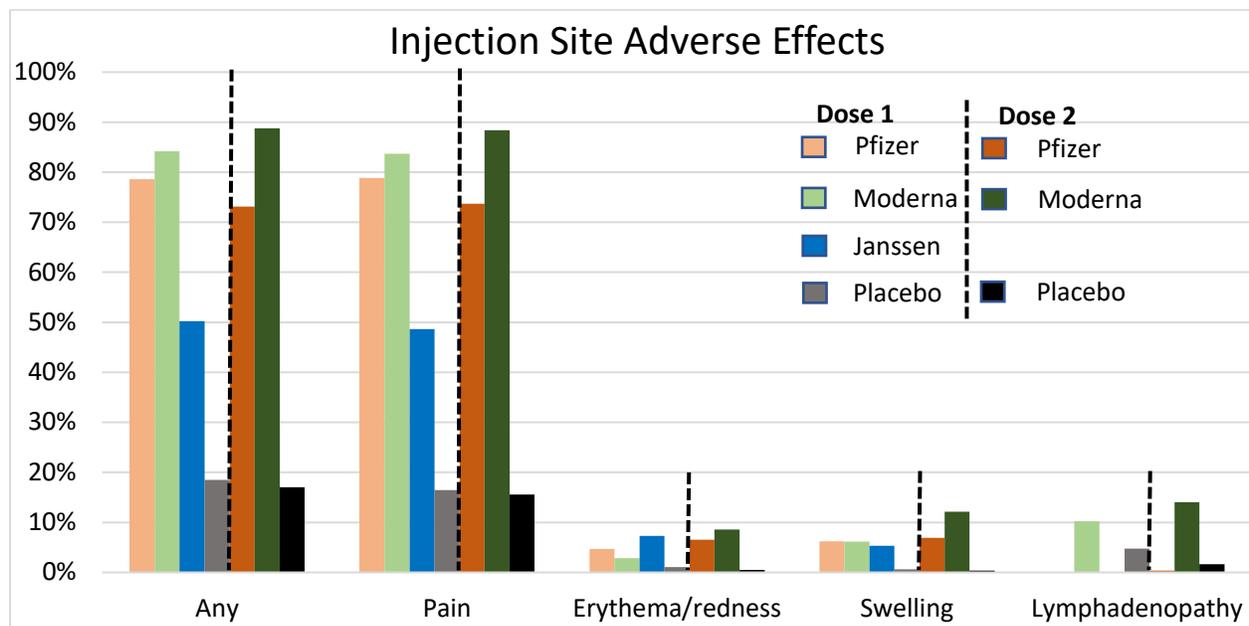


Common adverse effects to expect following the currently available COVID-19 vaccines

Adverse effects are common following administration of the COVID-19 vaccines. Approximately 80 – 90% of patients experience some adverse effect after the Pfizer and Moderna vaccines while 50 – 60% experience one or more adverse effects from the Janssen vaccine. Most adverse effects tend to be more common among younger patients. For the Pfizer and Moderna vaccines, adverse effects occur with a higher frequency after the 2nd dose. However, the overwhelming majority of adverse effects are minor and self-limited, resolving within 1 – 3 days. In clinical trials, serious adverse events occurred with similar frequency to patients treated with placebo (less than or equal to 1% of all patients).

The most common adverse effects experienced by patients are local, injection site reactions (Figure 1). Pain at the injection site is, by far, most common, occurring in more than 70% of patients administered the Pfizer and Moderna vaccines and 50% of those given the Janssen vaccine. Swelling and lymphadenopathy may be more common with the Moderna vaccine compared to the Pfizer vaccine, but the lack of head-to-head comparisons limits this observation.

Figure 1. Local, injection Site Adverse Effects

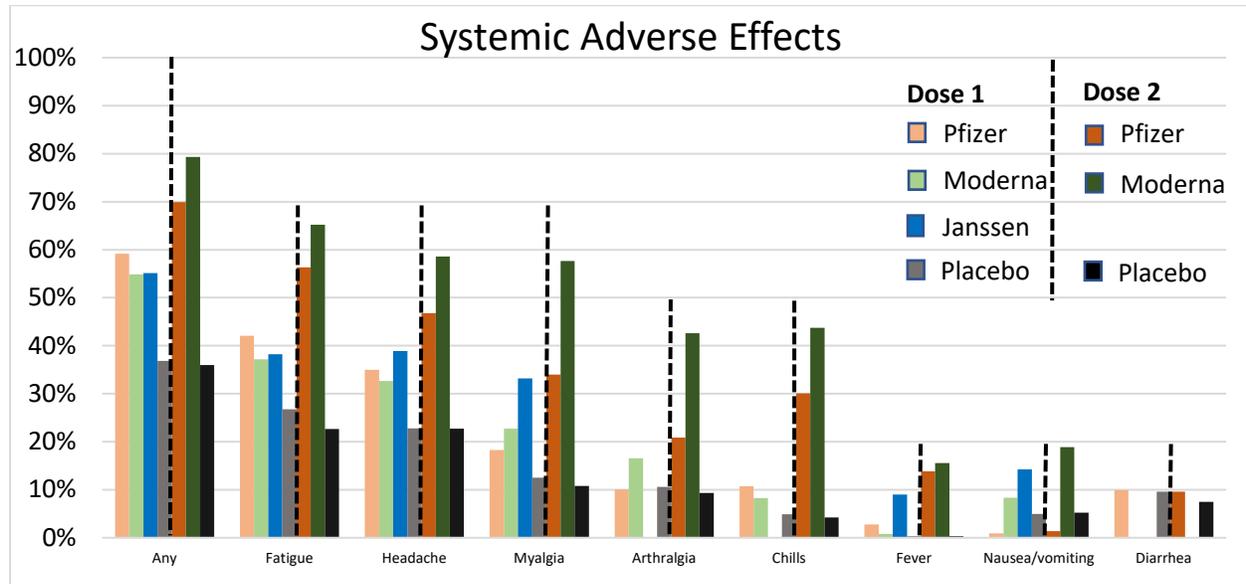


Placebo data pooled from FDA briefing documents for Pfizer, Moderna, & Janssen vaccines.

Systemic adverse effects occur in the majority of patients (Figure 2) but their overall frequency is less than injection site reactions. Like injection site reactions, systemic adverse effects are more common after the 2nd dose of the Pfizer and Moderna vaccines. Between 70 – 80% of patients experience systemic adverse effects following the 2nd dose of the Pfizer and Moderna COVID-19 vaccines while the frequency

appears lower (55%) with the Janssen vaccine. Fatigue, headache, myalgias, arthralgias, and chills are the most common systemic adverse effects experienced overall and are consistent with systemic reactogenicity associated with other vaccines. Although direct comparisons between the mRNA COVID-19 vaccines have not been made, the frequency of systemic adverse effects appear higher with the Moderna vaccine compared to the Pfizer vaccine, particularly after the 2nd dose.

Figure 2. Systemic Adverse Effects



Placebo data pooled from FDA briefing documents for Pfizer, Moderna, & Janssen vaccines.

Serious adverse effects are a common concern among vaccine recipients. Hypersensitivity reactions were uncommon but appeared more common in patients receiving the vaccines compared to placebo. In clinical trials, hypersensitivity reactions occurred in 0.6%, 1.5%, and 0.2% of patients given the Pfizer, Moderna, and Janssen vaccines, respectively. The most common hypersensitivity reactions were rash and urticaria at the injection site. Anaphylaxis was not observed in any of the trials. Among the first 1,893,360 doses of the Pfizer vaccine administered, there were 107 reports of severe allergic reactions including 21 with anaphylaxis (rate of 11.1 per million doses administered); 61 additional cases were reported but considered nonallergic reactions while 7 remain under investigation. Bells palsy, a frequent concern voiced among patients, was not reported in the Pfizer study and occurred more than 28 days after the injection in 4 patients in the Moderna trial (3 treated with the vaccine, 1 treated with placebo). Serious adverse events assessed as related to the vaccine were observed in 7 patients administered the Janssen vaccine, including 2 cases of facial paralysis and 1 case of Guillian-Barre Syndrome.

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