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Review Article

Clinical adverse events following COVID-19 vaccination: a scoping review of observational studies

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ABSTRACT

COVID-19 vaccination has been a central strategy to reduce severe disease and death during the pandemic. Although clinical trials demonstrated favorable safety profiles, real-world monitoring remains necessary to understand adverse reactions across diverse populations. Continuous post-authorization surveillance is essential to address concerns regarding vaccine safety and hesitancy. Objective of this study was to summarize observational evidence describing adverse reactions associated with COVID-19 vaccines in routine clinical and community environments. A scoping review was conducted following a structured methodological approach, including observational studies that evaluated post-vaccination adverse reactions. Eligible designs comprised cohort, registry-based and cross-sectional studies. Main outcomes included frequency, type, onset, severity and functional impact of adverse reactions. Eleven observational studies were included. The vaccines most frequently evaluated were Pfizer-BioNTech, Oxford-AstraZeneca, Moderna and Sinopharm. The most common reactions were local symptoms at the injection site, such as pain, tenderness and swelling, followed by systemic manifestations including fever, fatigue, headache, myalgia and chills. Most reactions appeared within the first 24 to 48 hours after vaccination, were mild or moderate in intensity and resolved spontaneously without medical intervention. Serious adverse events and fatal outcomes were uncommon, although isolated cardiovascular, neurological and allergic reactions were reported. Evidence from observational studies indicates that COVID-19 vaccines have a favorable real-world safety profile. Adverse reactions are predominantly mild, temporary and non-disabling. Continued transparent communication and post-marketing surveillance are necessary to maintain public confidence and ensure equitable uptake, particularly within vulnerable and underserved populations.

Keywords: COVID-19 vaccines, Adverse reactions, Adverse events, Vaccine safety, Post-vaccination effects, Pharmacovigilance, Real-world evidence

INTRODUCTION

The rapid development and deployment of COVID-19 vaccines represented an unprecedented global effort to curb morbidity, hospitalization and mortality associated with SARS-CoV-2 infection. Although clinical trials demonstrated favorable safety profiles and high immunogenicity across platforms, real-world monitoring remains essential to identify adverse reactions across heterogeneous populations, comorbidities and demographic groups that were underrepresented in pre-authorization research. Continued pharmacovigilance has therefore become a core component of the vaccination era, aiming to detect, characterize and contextualize both common and rare reactions in the post-marketing setting.[1-3]

Different vaccine platforms were developed, including mRNA-based, adenoviral-vector, inactivated virus and protein-subunit vaccines, each exhibiting distinct reactogenicity profiles related to antigen delivery mechanisms, formulation and dosing.[4] Inactivated vaccines tend to induce lower reactogenicity, whereas mRNA platforms such as Pfizer-BioNTech and Moderna have been associated with higher rates of systemic adverse reactions, including fever, fatigue, headache, arthralgia and myalgia.[5-7] Local reactions, including injection-site pain, erythema and swelling, remain the most frequently reported across platforms and typically resolve spontaneously.[8]

Despite overall favorable safety, uncommon but clinically significant adverse effects have generated considerable medical and public concern. Cardiovascular complications, including myocarditis, pericarditis and thromboembolic events, have been documented following vaccination, predominantly with mRNA vaccines, although causality and incidence remain under investigation.[9-11] Similarly, recent literature has proposed the existence of post-acute COVID-19 vaccination syndrome (PACVS), characterized by prolonged symptoms such as fatigue, dysautonomia, peripheral neuropathy and cognitive dysfunction lasting months after vaccination, though evidence remains preliminary and heterogeneous.[12-14]

Vulnerable populations present an additional dimension of safety concern. Cancer patients, for example, often exhibit altered immune responses due to their underlying disease and immunosuppressive treatment. Current observational data indicate that COVID-19 vaccines are generally well tolerated in oncology cohorts, with most adverse effects classified as mild, while severe vaccine-related events requiring hospitalization are infrequent.[15] Moreover, patients with hematologic malignancies may demonstrate reduced antibody responses compared with healthy individuals, although vaccination still reduces the risk of hospitalization, intensive care admission and death associated with COVID-19 infection.[16]

Understanding the real-world safety profile of COVID-19 vaccines is essential for clinical decision-making, reinforcing public confidence and ensuring equitable uptake. Synthesizing observational evidence provides a meaningful framework to contextualize adverse reactions, recognize clinically significant signals, and strengthen communication strategies aimed at addressing concerns regarding post-vaccination events.

METHODS

This scoping review was conducted following a structured methodological approach to identify observational evidence regarding adverse reactions to COVID-19 vaccines. A comprehensive search strategy was applied across PubMed, Scopus and Web of Science using predefined terms related to COVID-19 vaccination and adverse events. A total of approximately 100 sources were initially identified, from which 35 studies were selected for final inclusion based on relevance and eligibility.

Eligible studies consisted exclusively of observational designs, including cohort, cross-sectional, and registry-based analyses reporting adverse reactions after COVID-19 vaccination in any population group. Titles and abstracts were screened, followed by full-text review. Data were extracted using a standardized form including study characteristics, population details, vaccine platform, type of adverse reactions and reported severity.

Due to heterogeneity in study methods and outcome definitions, results were synthesized narratively rather than statistically. Subgroup considerations were included for vulnerable populations such as cancer patients and immunocompromised individuals.

RESULTS

A total of 35 observational studies met the inclusion criteria and were incorporated into this review. These studies represent a heterogeneous spectrum of methodologies, populations and vaccine platforms, reflecting real-world administration across multiple clinical settings.[1-3] The majority of evidence derived from mRNA vaccines, followed by adenoviral-vector and inactivated platforms, consistent with global distribution and authorization patterns.[4,5]

Across studies, populations included healthy community participants as well as medically complex groups, such as cancer patients, autoimmune populations and older adults.[6-8]Reported symptom profiles varied according to vaccine type, age group, prior COVID-19 infection, immune status and dose number.[9,10]

Overall, the most frequent adverse reactions were mild and self-limited, with onset typically within 24 to 48 hours and spontaneous resolution.[11-13] This trend was consistent

across both healthy and vulnerable populations, supporting a favorable short-term reactogenicity profile.[14,15]

Interpretatively, early-onset reactogenicity was more pronounced following mRNA vaccination and among younger age groups, reflecting stronger innate immune activation.[16,17]In contrast, inactivated vaccines exhibited markedly lower reactogenicity.[18,19] Several studies also documented differences between doses: second doses were associated with increased systemic symptoms, while boosters in immunocompromised patients demonstrated altered immunogenicity and selective late-onset manifestations.[20-22]

Collectively, the extracted findings confirm a cohesive pattern in real-world evidence: common short-term reactions predominate, while clinically significant or persistent adverse events represent a smaller but relevant proportion within observational data.

Across the included studies, local adverse reactions represented the most frequently documented category of post-vaccination effects. Injection-site pain was consistently the dominant manifestation, followed by erythema, induration and localized swelling.[1-3] These symptoms typically appeared within the first 24 hours and demonstrated rapid spontaneous resolution, rarely requiring medical evaluation.[3-5] Local reactions were most pronounced following mRNA vaccines and least frequent in inactivated platforms, a trend consistently reported across population-based and healthcare-worker cohorts.[6-8]

Systemic reactions were the second most prevalent group of adverse events. Fever, fatigue, headache, myalgia and chills were repeatedly identified as common systemic manifestations across studies.[9-13] Most systemic symptoms were classified as mild to moderate in severity, transient and self-limiting, with return to baseline functioning reported in one to three days.[14,15] Notably, systemic reactogenicity demonstrated strong dose-response patterns: higher prevalence was observed following second doses when compared with first doses, particularly in younger age groups.[16-18]

Severe reactions were infrequent but clinically relevant. Across studies, reported serious events included myocarditis, pericarditis, thromboembolic complications, anaphylaxis and prolonged autonomic dysfunction.[19-23] Although these were rare relative to total doses administered, their clinical significance warranted post marketing surveillance reinforcement.[24-26]

Table 1: Summary of eligible studies included in the review

Variable	Summary of findings
Total studies screened	~100
Studies included in synthesis	35
Predominant study design	Observational cohort & cross-sectional
Most evaluated platform	mRNA vaccines
Secondary platforms	Adenoviral-vector
Least evaluated platform	Inactivated vaccines
Geographic distribution	North America, Europe, Middle East, Asia
Most common population	General adult population
Special populations included	Cancer and immunocompromised patients
Primary outcome reported	Post-vaccination adverse reactions

Table 2: Distribution of predominant adverse reactions identified across included studies.

Adverse reaction category	Most frequent manifestations	Typical onset	Clinical course	Relative frequency
Local reactions	Pain, erythema, swelling, induration	≤ 24 hours	Transient, self-limited	Most frequent
Systemic reactions	Fever, fatigue, headache, myalgia, chills	24–48 hours	Resolves spontaneously	Second most frequent
Severe reactions	Myocarditis, pericarditis, thrombosis, anaphylaxis	Variable	Requires clinical evaluation	Rare

Interpretatively, standardized reporting across studies demonstrated marked variability, limiting comparative quantification. Nonetheless, aggregated trends revealed internal consistency across observational cohorts, reinforcing that mild local and systemic reactions constitute the overwhelming majority of adverse events,

while severe complications remain uncommon within real-world datasets.[27-30]

Several studies included in this review examined adverse reactions among medically vulnerable subgroups, particularly cancer patients and individuals with compromised immunity.[1-3] In oncology cohorts, adverse reactions were predominantly mild and localized, mirroring trends in the general population.[4,5] However, systemic symptoms were less frequently reported among patients receiving active chemotherapy, likely reflecting attenuated inflammatory responses associated with immunosuppressive regimens.[6,7] Despite reduced reactogenicity in this subgroup, no increased rate of severe post-vaccination events was observed across included studies.[8,9]

Among immunocompromised individuals, emerging evidence demonstrated variable reactogenicity profiles following booster doses.[10,11] Patients with hematologic malignancies, in particular, exhibited reduced antibody responses yet did not display disproportionately severe vaccine-related adverse effects.[12,13] These findings support vaccination safety in high-risk clinical cohorts, despite limited immunogenicity in certain settings.[14]

Older adults showed lower rates of systemic reactions compared with younger adults across multiple reports.[15,16] This pattern was consistently attributed to diminished innate immune activation with aging.[17] Younger populations demonstrated more robust inflammatory responses, resulting in higher systemic symptom frequency, particularly following mRNA vaccination.[18-20]

Table 3: Comparative adverse effects associated with major COVID-19 vaccine platforms.

Vaccine platform	Most frequent local adverse effects	Most frequent systemic adverse effects	Less frequent but clinically relevant adverse effects
Pfizer-biontech (mrna)	Injection-site pain, swelling, erythema	Fever, fatigue, headache, myalgia, chills	Myocarditis, pericarditis, anaphylaxis
Moderna (mrna)	Injection-site pain, swelling, warmth	Fever, chills, fatigue, arthralgia, myalgia	Myocarditis, pericarditis, delayed hypersensitivity
Oxford-astrazeneca (adenoviral vector)	Pain, tenderness, swelling	Fever, fatigue, headache, malaise	Thrombosis with thrombocytopenia syndrome (tts)
Johnson & johnson (adenoviral vector)	Injection-site pain, redness	Fatigue, fever, headache	Tts, guillain-barré syndrome
Sinopharm (inactivated virus)	Mild pain, tenderness	Mild fatigue, low-grade fever	Rare hypersensitivity reactions
Sinovac (inactivated virus)	Mild pain, swelling	Headache, fatigue	Rare neurologic symptoms (reported)

Collectively, subgroup findings reinforce that adverse-event severity is not disproportionately elevated in high-risk or medically complex populations.[21-23] Nonetheless, several studies underscored the need for continued post-marketing monitoring, particularly for delayed and immune-mediated complications in fragile populations.[24-26]

Integrating subgroup trends with global findings, a cohesive pattern emerges: while reactogenicity varies by clinical vulnerability, severe adverse reactions remain uncommon across all groups evaluated, further supporting vaccination safety in diverse populations.[27-30]

DISCUSSION

The findings of this review demonstrate that the safety profile of COVID-19 vaccines in real-world settings remains consistently favorable across healthy and vulnerable populations. Evidence from observational studies confirms that the majority of adverse reactions are mild, short-lived, and consistent with anticipated immunologic responses to vaccination. In healthy individuals, local reactions such as pain, erythema and swelling at the injection site represent the dominant symptom cluster, followed by self-limited systemic manifestations including fever, fatigue, headache and musculoskeletal discomfort[1-3]. These reactions occur most frequently within the first 48 hours and generally do not interfere significantly with routine daily functioning[4]. The elevated rate of systemic reactions following second doses in healthy adults reported across multiple sources suggests stimulus-dependent amplification of immune activation[5].

In contrast, adverse reactions in cancer patients present distinct characteristics. Studies evaluating vaccine tolerance among oncology populations indicate that side-effects are predominantly mild and do not appear to elevate acute toxicity risk.[6] Importantly, patients undergoing chemotherapy or immune-modulating therapy

experienced fewer systemic reactions than healthy controls, which has been attributed to reduced immunoinflammatory activation under therapy-induced immunosuppression.[7] Although concerns regarding safety in immunocompromised individuals exist, current real-world evidence suggests that vaccination remains clinically safe in these groups, with no disproportionate incidence of severe acute toxicity.[8] Pediatric oncology studies also reported favorable tolerability, further reinforcing the applicability of vaccination across cancer subgroups.[9]

Cardiovascular complications represent the most clinically significant category of adverse reactions described within the literature. Rare cases of myocarditis, pericarditis, arrhythmias and thromboembolic phenomena have been observed, particularly after mRNA and adenoviral-vector vaccines.[10] These events, however, occur at low absolute frequency compared to the rate of serious cardiovascular complications associated with SARS-CoV-2 infection.[11] Studies emphasize the importance of distinguishing temporal association from causality, especially in young adults and adolescents in which myocarditis risk is highest post-vaccination but remains significantly lower than that associated with acute COVID-19 infection.[12]

Beyond acute reactions, several sources report long-term, persistent post-vaccination symptoms in a subset of individuals. These include prolonged fatigue, neuropathic pain, paresthesias, dysautonomia, cognitive impairment, microvascular symptoms and exercise intolerance.[13] The absence of standard diagnostic criteria complicates the interpretation of such presentations, although emerging immunologic models propose dysregulated post-vaccinal cytokine activity or aberrant immune persistence as possible mechanisms.[14] While these findings remain preliminary, they highlight areas in need of rigorous prospective monitoring.

Platform-specific variation represents a central theme. mRNA vaccines demonstrated the highest rate of short-term systemic reactivity across included datasets, particularly in younger age groups.[15] Adenoviral-vector vaccines presented moderate reactogenicity, with thrombotic complications uniquely described in association with this platform.[16] Inactivated vaccines consistently demonstrated lower rates of systemic reactions across healthy and oncology populations[17], though several studies noted weaker antibody responses in parallel. This trade-off illustrates the immunologic variability inherent to vaccine platform design.

Age also influences reactogenicity patterns. Younger adults demonstrate higher systemic symptom frequency, plausibly reflecting stronger innate immune responses and heightened cytokine activation.[18] Conversely, older adults exhibit predominantly local reactions and lower systemic reactogenicity.[19] These observations align with established immunosenescence principles and have implications for post-vaccination counseling.

Taken collectively, the findings of this review confirm the convergence between trial-derived and real-world evidence: adverse reactions to COVID-19 vaccines are predominantly mild and self-limited; severe reactions are rare; and the benefit-risk balance continues to favor vaccination across all demographic and clinical contexts. Nonetheless, vigilance remains essential. Continued post-marketing surveillance is critical to detect delayed effects, identify population-specific vulnerabilities and refine risk-benefit frameworks in immunocompromised and chronically ill patients[20]. Expanding prospective observational cohorts, increasing follow-up duration and harmonizing adverse event reporting tools will be necessary to enhance long-term safety characterization.

CONCLUSION

This scoping review demonstrates that COVID-19 vaccines exhibit a consistent and favorable safety profile across observational evidence. The majority of post-vaccination reactions reported in healthy and medically vulnerable populations were mild, short-lived and self-limiting, predominantly characterized by local and systemic reactogenicity. Severe adverse events were rare in real-world cohorts and did not outweigh the public health benefits associated with immunization. Platform-specific variation was evident, with mRNA vaccines showing higher systemic reactogenicity compared with adenoviral-vector and inactivated platforms. Cancer patients and immunocompromised individuals tolerated vaccination well, despite attenuated immunogenicity in some subgroups. These findings underscore the importance of continued transparent communication, sustained post-marketing surveillance and expanded observational research to further characterize long-term safety outcomes and reinforce vaccine confidence across diverse global populations.

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