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Review

COVID-19 vaccines and autoimmune disorders: A scoping review

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Abstract: Background: Upon the global COVID-19 vaccination campaign, unprecedented in the history of public health, concerns have emerged regarding potential associations between vaccination and autoimmune disorders. Historical research has long identified mechanisms by which vaccines might trigger or unmask autoimmune processes. However, systematic synthesis of evidence concerning COVID-19 vaccines and autoimmunity remains limited. Objective: To review the literature on associations between COVID-19 vaccination and autoimmunity, focusing on six conditions: Graves' disease, Hashimoto's thyroiditis, multiple sclerosis, rheumatoid arthritis, systemic lupus erythematosus, and type 1 diabetes mellitus. Methods: We conducted a scoping review of 109 studies published in 2022, retrieved from PubMed and the WHO COVID-19 databases. Inclusion criteria encompassed English-language articles reporting empirically verifiable clinical manifestations of autoimmune disease associated with any COVID-19 vaccine, without restrictions by population, geography, or study type. Results: Across 109 included studies, relapses or flares in patients with autoimmune disorders were reported in nearly 60% of studies, while about one-quarter described new-onset autoimmune disorders in persons without prior autoimmunity. Several mechanisms of action linking COVID-19 vaccination and autoimmune disorders were reported, such as autoimmune inflammatory syndrome induced by adjuvants, molecular mimicry, bystander immune activation, and interactions with immunosuppressive and disease modifying therapies. Serious adverse events, though less common than mild or moderate ones, were also reported. General and population-specific vaccine efficacy were claimed but empirical support was often lacking. Conclusions: This review highlights the substantial patterns of reported associations of autoimmune disorders following COVID-19 vaccination, in patients with and without prior autoimmunity. The

general and population-specific benefits of vaccination are claimed, but evidence for them is lacking. A proper evaluation of risks and benefits is needed to support vaccination recommendations given the reported associations between it and autoimmune disorders.

Keywords: COVID-19 vaccines; adverse events post-vaccination; autoimmune disease flare and onset; autoimmune disorders; type 1 diabetes mellitus; rheumatoid arthritis; multiple sclerosis; systemic lupus erythematosus; Graves' disease; Hashimoto's thyroiditis; scoping reviews

1. Introduction

The global COVID-19 vaccination campaign, launched in late 2020, has been the largest inoculation effort in human history, widely credited with curbing infection rates and reducing morbidity and mortality across populations [1–3]. However, such claims often rely on general assumptions or complex epidemiological modeling, with limited direct evidence, especially regarding specific subpopulations such as those affected by autoimmune disorders [4]. As a result, alongside its widespread uptake, the scale of this campaign has intensified scrutiny of vaccine safety, including concerns about possible associations with autoimmune disorders, even among researchers otherwise strongly supportive of COVID vaccination [5,6].

These concerns have emerged upon reports of exacerbated or new-onset autoimmune disorders following vaccination, which have raised questions about the safety, efficacy, and immunogenicity of COVID-19 vaccines, such as whether COVID-19 vaccines might trigger autoimmune processes in certain individuals [7,8]. Observational studies, pharmacovigilance reports, and case series have documented associations across a range of disorders—Graves' disease, Hashimoto's thyroiditis, multiple sclerosis, rheumatoid arthritis, systemic lupus erythematosus, and type 1 diabetes mellitus, among others [5,9]. A particularly concerning condition, acute transverse myelitis, has also been reported in temporal association with COVID-19 vaccination. For example, one population-based study in Korea identified a significantly elevated incidence rate ratio for acute transverse myelitis within 42 days post-vaccination across both viral vector and mRNA-based vaccines [10].

Such findings are not without precedent, nor limited to COVID-19 vaccines. Vaccine safety researchers have long acknowledged that while vaccines are designed to prevent infectious diseases, they may also act as environmental triggers of autoimmune phenomena via immune cross-reactivity and adjuvant effects, and a decades-long body of research has examined the relationship between vaccines and autoimmune phenomena. Pioneering contributions include those of Yehuda Shoenfeld and colleagues, who identified patterns of vaccine-induced autoimmunity across various vaccines, including hepatitis B, influenza, and measles-mumps-rubella [11–13]. These investigations have highlighted mechanisms such as molecular mimicry, bystander activation, and the role of adjuvants in breaking immune tolerance—the latter a constellation of factors that may lead to what in 2011 Shoenfeld termed "autoimmune inflammatory syndrome induced by adjuvants" or ASIA [14].

The COVID-19 vaccine experience, however, provides an unprecedented opportunity to explore these questions at scale, given the massive exposure of diverse populations to relatively new vaccine technologies, especially the novel mRNA platform. Therefore, we undertook this scoping review to

investigate the evidence for associations between COVID-19 vaccines and six major autoimmune disorders: Graves' disease, Hashimoto's thyroiditis, multiple sclerosis, rheumatoid arthritis, systemic lupus erythematosus, and type 1 diabetes mellitus. These conditions were selected based on their clinical relevance and the significant number of individuals affected, as identified by prior research categorizing the most consequential autoimmune diseases in terms of prevalence and severity [15–17].

Building on our previously published protocol [18], the goal of this scoping review was to synthesize data from peer-reviewed and preprint sources reporting on autoimmune phenomena following COVID-19 vaccination, in individuals with pre-existing autoimmune disorders—whether in the form of flares or of new autoimmune disorders—or as de novo autoimmune conditions in individuals with no prior autoimmunity.

2. Methods

2.1. Study design and search strategy

We conducted a scoping review as per Arksey and O'Malley's framework [19]. These authors proposed that, in contrast to systematic reviews that "typically focus on a well-defined question where appropriate study designs can be identified in advance [and] provide answers to questions from a relatively narrow range of quality assessed studies", scoping reviews help to "address broader topics where many different study designs might be applicable [and are] less likely to seek to address very specific research questions nor, consequently, to assess the quality of included studies" [19], thus our choice of this approach. Our analysis was enhanced by Levac et al.'s team-based approach, which proposes that throughout the review, from articulating a research question, identifying and selecting relevant studies, charting the data and collating, summarizing, and reporting results, the process should be iterative and cooperative, i.e., "team-based" [20]. This approach helps research teams address unforeseen practical challenges, such as the need to refine inclusion/exclusion criteria during the screening and selection process.

Scoping reviews, like systematic reviews, often evaluate interventions, but they can also be designed to appraise broader phenomena, i.e., "phenomena of interest" [21]—in our case, the evidence for associations and underlying mechanisms between COVID-19 vaccination and autoimmune disorders. Given the exploratory purpose of our review and the emerging, heterogeneous nature of the literature, this framework was particularly well suited to our objectives. As the project evolved, we made several pragmatic adjustments to refine scope and focus, recognizing that a full mapping of the rapidly expanding COVID-19 vaccine literature was not feasible. Our final design therefore reflects both methodological appropriateness and practical responsiveness to the characteristics of the evidence base.

Our search strategy was deliberately designed to align with the objectives of a scoping review—mapping and characterizing the available evidence rather than conducting an exhaustive systematic synthesis. Accordingly, we selected two complementary, high-yield databases—PubMed and the WHO COVID-19 Global Database—that together provide extensive coverage of the biomedical and public-health literature relevant to our topic. Following the PRISMA-ScR guidelines [22], on June 15th, 2023, we searched the two databases to identify studies that reported clinical manifestations of

autoimmune diseases occurring after COVID-19 vaccination and had been published between December 2020 and the search date.

For PubMed, we searched MeSH Major Topic terms ["Graves disease" OR Hashimoto's thyroiditis" OR "multiple sclerosis" OR "rheumatoid arthritis" OR "systemic lupus erythematosus" OR "type 1 diabetes" OR "autoimmunity" OR "autoimmune diseases" OR "autoimmune disorders"] combined with ["COVID-19 vaccines"]. For the WHO search, the same terms were searched as [Title, abstract, subject]. Initial eligibility criteria included: (i) publication between 2000 and 2023, (ii) English language, and (iii) preprint or published status. Reports by leading national and international health agencies—for example, the Centers for Disease Control and Prevention and the World Health Organization—were consulted to contextualize the study findings but were not included in the data set unless they met all eligibility criteria.

2.2. Eligibility criteria

We included articles in English that referred to the association between any type of COVID-19 vaccine and an autoimmune disorder, and that reported empirically verifiable clinical manifestations of autoimmunity. There were no temporal or geographic restrictions, and all populations were eligible regardless of age, sex/gender, race/ethnicity, socioeconomic status, or national origin. Articles had to be accessible through the libraries of the authors' academic or professional affiliations. To capture the broadest range of perspectives on the association between COVID-19 vaccines and autoimmune disorders, we included all article types provided that they met these inclusion criteria.

2.3. Search methods for identifying data

Before selecting articles for assessment, we conducted a preliminary screening of the search results to discard irrelevant material. One reviewer initially scanned titles and retained only those that met the inclusion criteria: (1) articles reporting on the association between any type of COVID-19 vaccine and an autoimmune disorder; (2) focus on empirically verifiable clinical manifestations of autoimmune disorders; (3) availability through any of the library websites of the authors' affiliated universities; and (4) in English. Next, two reviewers independently screened the remaining abstracts according to the review objectives and excluded studies based on the following criteria: (1) not focused on COVID-19, (2) not focused on vaccines, (3) not focused on autoimmunity, (4) no identifiable clinical outcome, (5) no original or primary data, or (6) not in English. In cases of uncertainty about the relevance of an abstract, a third reviewer broke the tie, and full-text retrieval was undertaken if needed.

2.4. Data selection process

We identified a total of $n = 4385$ articles; $n = 1673$ duplicates were removed, resulting in $n = 2712$ articles for screening. An additional $n = 1265$ articles were excluded after title and abstract review, leaving $n = 1447$ articles for further screening. For substantive and logistical reasons, we further limited the dataset to articles published in the 12 months following the peak COVID-19 vaccination period in 2021: substantively, this was the period when both primary series vaccines and boosters

became broadly available to general populations for whom access had been formerly limited, and when booster acceptance was high, around 79% [23]; logistically, our team's resources were limited; upon reflection, however, this adjustment allowed us to capture the phase of maximum vaccine uptake and most intensive global surveillance of post-vaccination outcomes. This decision further restricted inclusion to articles published in 2022, reducing the dataset to $n = 498$. Two reviewers independently determined whether the abstracts met the inclusion criteria, with disagreements resolved through full team discussion. After full-text review, $n = 109$ articles were included for data charting (Appendix, Figure A.1).

We monitored inter-rater reliability throughout the screening process, assessing agreement after approximately one-fourth of the retrieved articles were screened, and took corrective measures if reliability fell below 80% [24]. Throughout the screening process, we used Rayyan literature review management software (https://www.rayyan.ai/), which facilitated double-blind screening, recorded inclusion and exclusion decisions, and flagged disagreements between reviewers.

2.5. Data charting and synthesis

Data charting was assisted by a codebook, performed using a Microsoft Excel spreadsheet, conducted by two researchers, and tailored to capture the phenomenon of interest. Before initiating full data charting, two reviewers independently charted a sample of studies, and the team met to calibrate the approach and discuss results. Charting categories included the following: details about article type (e.g., study methodology and population demographics); data informing our phenomenon of interest (e.g., autoimmune manifestation, vaccine type, adverse events, causal relationships, mechanism of action, authors' support of vaccination for patients with autoimmune disorders); and contextual factors (e.g., country where study was reported, author affiliations, reported funding sources, and conflicts of interest) (Appendix, Table A.1).

3. Results

3.1. Article characteristics

The studies included in this scoping review were methodologically diverse—they comprised case reports (52/109; 47.7%), case series (15/109; 13.7%), cohort studies (28/109; 25.7%), cross-sectional studies (12/109; 11.1%), and randomized trials (2/109; 1.8%). First, authors were affiliated with institutions located primarily in the United States (21/109; 19.2%), Italy (15/109; 13.8%), and Japan (13/109; 11.9%), with additional contributions from researchers based in China, India, Iran, Germany, Brazil, France, Israel, Poland, Austria, Kuwait, Thailand, Hong Kong, Taiwan, Saudi Arabia, Turkey, South Korea, Norway, the United Kingdom, Tunisia, Malaysia, Egypt, Belgium, Puerto Rico, Chile, Colombia, Spain, Peru, Greece, Singapore, and Austria.

Most study authors did not declare any conflicts of interest (64/109; 58.7%), a minority did not mention them (18/109; 16.5%), and slightly over one quarter (27/109; 24.8%) provided explicit conflict-of-interest statements. The latter predominantly involved ties to pharmaceutical companies, including AstraZeneca, Bayer, Biogen, Eli Lilly, Genentech, GlaxoSmithKline, Merck, Novartis,

Pfizer, Sanofi, Takeda, Teva, and others. Funding sources were declared by about one-third of the authors (33/109; 30.3%), with funding coming from a range of institutional or governmental granting agencies, non-profit organizations, and/or pharmaceutical companies (Appendix, Table A.2).

All included articles focused on at least one of the six autoimmune disorders of interest—about one-third on multiple sclerosis (36/109; 33.1%), followed by systemic lupus erythematosus (31/109; 28.4%), type 1 diabetes (16/109; 14.7%), Graves' disease (13/109; 11.9%), and rheumatoid arthritis (13/109; 11.9%)—with a few (11/109; 10.1%) mentioning more than one disorder. Virtually all studies focused on adult patients (106/109; 97.2%), only two (2/109; 1.9%) researched pediatric patients, while one study (1/109; 0.9%) did not include patients but surveyed physicians. For most studies, the research objective was to report individual cases or case series documenting the relationship between autoimmune disorders and COVID-19 vaccination—including adverse events and COVID-19 infection (88/109; 80.8%)—while the remainder focused on immunological responses and vaccine safety analyses (21/109; 19.2%). Nearly half of the studies (52/109; 47.7%) explicitly mentioned outcomes of interest, including humoral responses (21/52; 40.4%), adverse events and flares (13/52; 25%), clinical assessments such as hospitalization or COVID-19 infection (8/52; 15.4%), vaccine safety (6/52; 11.6%), and disease relapses (4/52; 7.6%).

3.2. Relationship between COVID-19 vaccines and autoimmune disorders

Associations between COVID-19 vaccination and one of the selected six major autoimmune diseases—Graves' disease, Hashimoto's thyroiditis, multiple sclerosis, rheumatoid arthritis, systemic lupus erythematosus, and type 1 diabetes mellitus—were reported across all included articles. Over half of the studies (61/109; 56%) suggested a causal direction for these associations, while the rest reported either an unclear causal direction (22/109; 20.2%) or no causal direction (26/109; 23.9%). Articles suggesting a causal relationship included those reporting: 1) relapses, flares, or complications of pre-existing autoimmune disorders attributed to COVID-19 vaccination (e.g., [25]), 2) new autoimmune disorders diagnosed post-vaccination in patients with existing autoimmune disorders [26,27] and 3) new autoimmune disorders diagnosed post-vaccination in individuals without a prior history of autoimmune disorder (e.g., [28,29]).

Some authors described cases in which patients were presumed to have had undiagnosed autoimmune disorders becoming clinically apparent following vaccination, yet generally the assertion that vaccines "triggered" a previously unknown disorder was not supported by evidence. For instance, Mele et al. reported the case of a patient who "before receiving the vaccine […] did not know he had multiple sclerosis"—i.e., had never experienced symptoms—asserting that the disorder predated vaccination based on "older regions of demyelination in the left frontal horn" revealed by magnetic resonance imaging and interpreted as "chronic" lesions [30]. However, because no pre-vaccination imaging was cited providing evidence of such "older regions", it could not have been possible for the authors to determine if these regions indeed predated vaccination or instead developed after it and in close succession to the acute episode.

Several studies, such as Barbhaiya et al. (2022), highlighted the difficulty of distinguishing between relapses or flares in autoimmune disease and adverse events from vaccination, underscoring the risk of misclassifying vaccine-induced adverse events as disease flares or relapses, particularly in

the absence of laboratory-based confirmation [31]. Others, such as Al-Midfai et al. (2022) described new or worsening disease after vaccination, while also reporting the lack of sufficient evidence to establish causality [32]. Finally, almost half of the articles described potential mechanisms of action connecting COVID-19 vaccination and autoimmune phenomena. These discussions addressed either autoimmune symptomatology in general or the six autoimmune conditions of focus. We further elaborate on the relationship between vaccination and autoimmune processes—including causal direction and mechanisms of action—in the Discussion section.

3.3. Relapses or flares in individuals already experiencing specific autoimmune disorders

Over half of the articles (65/109; 59.6%) reported relapses or flares in patients with autoimmune disorders following COVID-19 vaccination. Within this group, multiple sclerosis was the most frequently reported autoimmune condition associated with such events. No relapses or flares post-vaccination were reported in patients with Hashimoto's thyroiditis. We present information about the six selected disorders in alphabetical order.

3.3.1. Relapses or flares in Graves' disease

Patrizio et al. (2022) reported two cases of acute relapse in patients with Graves' disease occurring within days of receiving the Pfizer BNT162B2 mRNA vaccine (hereafter "Pfizer vaccine") [33]. Ruggeri et al. (2022) reported a case of a Graves' disease relapse in a 61-year-old man after a third dose of the Pfizer vaccine [34].

3.3.2. Relapses or flares in Hashimoto's thyroiditis

As noted earlier, no articles reported relapses or flares in patients with Hashimoto's thyroiditis following COVID-19 vaccination.

3.3.3. Relapses or flares in multiple sclerosis

Al-Midfai et al. (2022) reported a case of worsening multiple sclerosis symptoms within two weeks of a second dose of the Johnson & Johnson COVID-19 vaccine, noting that this was the first reported case of a multiple sclerosis flare associated with this particular vaccine, whereas previous reports involved Pfizer, Moderna mRNA-1273 (hereafter "Moderna"), and AstraZeneca ChAdOx1 (hereafter "AstraZeneca") vaccines [32]. Lohmann et al. (2022) described a case of "severe" and "progressive" worsening multiple sclerosis symptoms within 23 days of a first dose of the Pfizer vaccine, including sensorimotor paraparesis, longitudinal extensive transverse myelitis, incontinence, and optic neuritis [35]. The patient had also experienced worsening paraparesis less than one month earlier following tetanus and pneumococcal vaccinations, after a lengthy history of stabilization without disease-modifying therapies. Kataria et al. (2022) reported multiple sclerosis relapse within three weeks of the second dose of the Pfizer vaccine [36], citing other researchers who suggested that vaccines may overstimulate the immune system, precipitating the transition from subclinical to clinical

disease within 30 days [37,38]. Giossi et al. (2022) reported two, out of 39, cases of multiple sclerosis relapse in patients on disease modifying therapies after a second dose of the Pfizer vaccine [39].

Dreyer-Alster et al. (2022) reported mild to severe flares or acute relapses in 3.8% (8/211) of multiple sclerosis patients after a booster dose of the Pfizer vaccine, compared to 4.8% of patients reporting such incidents after their second dose [40]. They also reported that symptoms resolved spontaneously or were treated with intravenous high-dose methylprednisolone. Gad et al. (2022) reported multiple sclerosis relapses in 33.3% of 65 vaccinated patients within a sample of 160 patients, compared to 12.8% (5/39) of relapses after confirmed COVID-19 infection in 39 of a 160-patient sample [41]. They also noted that most unvaccinated patients—42 in addition to the confirmed 39—had reported symptoms compatible with COVID infection that they had not communicated to their doctors, a finding that, they observe, could indicate an infection rate as high as "50% of total MS patients" [41]. It is worth noting that if this were the case, then it would mean that the total number of COVID infected, unvaccinated patients was in fact 81—higher than the 39 recorded—and as a result, the rate of relapses among unvaccinated cases was significantly lower—under 1%, rather than the 12.8% reported by the authors. Nevertheless, the authors did not elaborate on the difference, concluding that the "risk of relapse [was comparably] low *either* with infection *or* vaccination" (emphasis added) [41].

3.3.4. Relapses or flares in rheumatoid arthritis

Nakamura et al. (2022) documented a severe flare of rheumatoid arthritis occurring within 10 days of receiving the Moderna vaccine in a patient who had been in remission for 20 years [42]. The flare was accompanied by fever, arthralgia, and Epstein-Barr virus reactivation. The authors "speculated" (p. 2075) that mRNA vaccine components may activate innate immune receptors, thereby triggering downstream immune responses and possibly contributing to both Epstein-Barr virus reactivation and rheumatoid arthritis relapse; they also noted that while the exact mechanism remains unclear, the case illustrates how post-vaccination immune activation may exacerbate autoimmune phenomena in some individuals [42]. Other authors like Zhao et al. (2022) reported that 4.8% (2/42) of the rheumatoid arthritis patients developed significant joint pain, knee effusion, and hand and foot swelling after receiving two doses of the Sinovac inactivated vaccine, while noting that "it is undetermined whether the adverse events are related to the vaccination" [43] (p. 6).

3.3.5. Relapses or flares in systemic lupus erythematosus

In patients with systemic lupus erythematosus, several studies reported flares following vaccination. Sugimoto et al. (2022) documented exacerbations of cutaneous lupus symptoms after the first dose of the Moderna vaccine [44]. Other studies indicated increases in autoantibody levels and mild disease flares post-vaccination [45].

3.3.6. Relapses or flares in type 1 diabetes mellitus

A limited number of articles addressed type 1 diabetes mellitus, noting worsening glycemic control following COVID-19 vaccination—for instance, transient hyperglycemia and episodes of

diabetic ketoacidosis [46]. However, such articles also asserted that adverse events were rare and that they did not outweigh the benefits of vaccination in this population.

3.4. Vaccination associated with new autoimmune disease in autoimmune patients

In addition to relapses or flares of existing autoimmune disorders, several studies (12/109; 11%) also reported the emergence of new autoimmune conditions in patients who were already diagnosed with an autoimmune disease at the time of vaccination. These new-onset diseases were distinct from the patients' original autoimmune conditions and most study authors remained cautious about their conclusions. For example, Bleve et al. (2022) reported the case of a 61-year-old woman with a history of hypothyroidism who, several days after receiving her second dose of the Pfizer vaccine, developed what authors referred to as "autoimmune diabetes" [47]. However, the authors emphasized that although the diabetes appeared after vaccination, causality could not be confirmed.

Similarly, several studies explicitly stated that while their case reports contributed to the growing body of literature on potential autoimmune sequelae of COVID-19 vaccination, the small sample sizes and the lack of mechanistic studies limited their ability to draw firm conclusions regarding causality (e.g., [27,48]). No reports were identified describing the development of new autoimmune diseases post-vaccination in patients originally diagnosed with Graves' disease, Hashimoto's thyroiditis, or multiple sclerosis—only in patients with rheumatoid arthritis, systemic lupus erythematosus, or type 1 diabetes mellitus.

3.5. Vaccination associated with new autoimmune disorders in persons without prior history of autoimmunity

About one fourth of the articles (27/109; 24.8%) reported cases of new autoimmune disease following COVID-19 vaccination in individuals without a prior history of autoimmune disorders. These reports included a variety of autoimmune disorders, such as Graves' disease, Hashimoto's thyroiditis, multiple sclerosis, rheumatoid arthritis, systemic lupus erythematosus, and type 1 diabetes mellitus, as well as other conditions not within our study focus—Guillain-Barré syndrome, vasculitis, and autoimmune hepatitis. While these reports described a temporal relationship between vaccination and new-onset autoimmune symptoms, the authors generally noted that causality could not be confirmed given their study design.

3.5.1. Graves' disease as a new autoimmune disorder

A total of seven case reports documented new-onset Graves' disease following COVID-19 vaccination. The vaccines implicated included Pfizer, Moderna, and AstraZeneca. For example, Shih & Wang (2022) reported a case of Graves' disease diagnosed four weeks after administration of the AstraZeneca vaccine [49]. The patient, a previously healthy individual, developed symptoms including palpitations, heat intolerance, and weight loss, which led to testing that confirmed the diagnosis of Graves' disease. di Filippo et al. (2022) reported that 20 (of 64, or 31%) of new-onset Graves' disease patients seen at their clinic had their first episode within four weeks of a COVID-19 vaccination [29].

Mechanisms suggested were ASIA triggered by adjuvant or excipients such as polyethylene glycols or polysorbate 80 oil-in-water emulsions, and cross-reactive antigen molecular mimicry between proteins with high amino acid sequence similarity, such as the vaccine-induced viral spike proteins and thyroid peroxidase antigens [29].

Chee et al. (2022) published a correspondence reporting six cases of post-vaccination Graves' disease, although detailed clinical information was limited [50]. Taieb et al. (2022) documented a case of Graves' disease after the second dose of the Pfizer vaccine in a 43-year-old woman with no prior autoimmune history [51]. Symptoms included palpitations, heat intolerance, and weight loss, with laboratory findings confirming the diagnosis. Vera-Lastra et al. (2021) reported Graves' disease in a previously healthy 34-year-old woman two weeks after receiving the AstraZeneca vaccine; the diagnosis was confirmed based on clinical and laboratory findings consistent with Graves' disease [52]. Although these cases reported a temporal association between vaccination and the onset of Graves' disease, most authors cautioned that causality could not be definitively established.

3.5.2. Hashimoto's thyroiditis as a new autoimmune disorder

Lioulios et al. (2022) reported cases of new-onset Hashimoto's thyroiditis and Graves' disease within two and four months, respectively, post-vaccination with the Pfizer vaccine in patients without autoimmune disease, albeit on dialysis [53]. Subsequent to vaccination, the Graves' disease patient experienced mild COVID-19 symptoms—"mainly low-grade fever and malaise—followed by relapse— "deterioration of thyroid hormone levels"—two months later. The authors concluded that "both natural infection and vaccination elicit a weak yet extended immune response, with a tendency to cross-reactivity to non-pathogenic antigens, thus leading to autoimmunity" [53].

3.5.3. Multiple sclerosis as a new autoimmune disorder

Havla et al. (2022) reported a case of new-onset multiple sclerosis within six days of a first dose of the Pfizer vaccine, but stated that it was not possible to determine causality based on this one case [54]. Toljan et al. (2022) reported five new cases of multiple sclerosis in previously healthy patients within one to five weeks of receiving mRNA COVID-19 vaccines—Pfizer in three cases and Moderna in two cases [55]. Cases included individuals who developed optic neuritis, sensory disturbances, motor weakness, and other demyelinating symptoms, consistent with magnetic resonance imaging-confirmed multiple sclerosis.

3.5.4. Rheumatoid arthritis as a new autoimmune disorder

Yonezawa et al. (2022) reported a case of new-onset rheumatoid arthritis within days of the second dose of the Pfizer vaccine in a patient with no prior history of autoimmune disorders, albeit with a diagnosis of combined pulmonary fibrosis and emphysema related to a 30-year history of smoking [56]. Watanabe et al. (2022) described a case of new-onset rheumatoid arthritis in a previously healthy individual after the second dose of the Pfizer vaccine [57]. Singh et al. (2022)

reported a case of new-onset rheumatoid arthritis within two weeks of an inactivated COVID-19 vaccine (COVAXIN) [58].

3.5.5. Systemic lupus erythematosus as a new autoimmune disorder

Nelson et al. (2022) reported a case of severe systemic lupus erythematosus in a pediatric patient within two days of a third dose of the Pfizer vaccine [59]. The patient presented with facial and body rash, bilateral arthralgias in the shoulders, hands, and knees, progressive hair loss, pleuritic chest pain, and photophobia. Molina-Rios et al. (2022) described new-onset systemic lupus in a previously healthy patient within two weeks of the first dose of the Pfizer vaccine [60]. The patient was also diagnosed with inflammatory arthralgias, dyspnea, hypoxemia, pulmonary thromboembolism, and suspected secondary antiphospholipid syndrome and required hospitalization in an Intensive Care Unit for life-threatening conditions.

Sogbe et al. (2022) reported a case of new-onset systemic lupus erythematosus with myopericarditis in a patient within one week of receiving a third dose of the Pfizer vaccine [61]. Lemoine et al. (2022) described a case of new-onset systemic lupus erythematosus and polymyalgia rheumatica within two days of the first dose of the Pfizer vaccine, with symptoms including headache, upper and lower limb muscle weakness, stiffness, and pain [62]. The patient required hospitalization by day seven and subsequently chose not to receive a second dose. Nelson et al. (2022) reported new-onset systemic lupus erythematosus with acute pancreatitis and vasculitic skin rash within seven days of the first dose of the Pfizer vaccine [59]. The authors suggested that a possible mechanism for the induction of autoimmune pathophysiology could involve vaccine adjuvants triggering the nucleotide-binding oligomerization domain.

Gamonal et al. (2022) reported a case of new-onset systemic lupus erythematosus in a previously healthy patient within three weeks of a second dose of the AstraZeneca vaccine [63]. Wang et al. (2022) also reported a case of new-onset systemic lupus erythematosus with acrocyanosis within two weeks of a first dose of the AstraZeneca vaccine, suggesting a potential mechanism involving type 1 interferon and proinflammatory cytokine pathways [64]. Raviv et al. (2022) described a case of new-onset systemic lupus erythematosus in a healthy patient with no family history of autoimmune disorders, occurring within two days of a first dose of the Pfizer vaccine [65]. Symptoms were initially diagnosed as an allergic rash but worsened and evolved into psoriasiform-papulosquamous plaques on the face, neck, and arms, nonscarring hair loss across the scalp, persistent and numerous joint pains, and ultimately a diagnosis of systemic lupus erythematosus.

Sagy et al. (2022) reported a case series of three patients developing new-onset systemic lupus erythematosus within three days to one month after receiving the Pfizer vaccine [66]. Kim et al. (2022) described a case of lupus with multi-organ involvement after a second dose of the AstraZeneca vaccine, suggesting that vaccination triggered an autoimmune response through the stimulation of CD8+ T cells, increased cytokine production, and cross-reactivity between spike protein antibodies and various tissue antigens [67]. Kreuter et al. (2022) reported a case of subacute cutaneous lupus erythematosus within ten days of a first dose of the Pfizer vaccine [45]. After ruling out other triggering factors, such as recent infection, sun exposure, or new drug exposures, a diagnosis of vaccine-induced subacute

cutaneous lupus erythematosus was determined and treated with hydroxychloroquine and glucocorticoids, with full remission achieved within four weeks.

3.5.6. Type 1 diabetes mellitus as a new autoimmune disorder

Sakurai et al. (2022) reported a case of new-onset type 1 diabetes mellitus within three days of a first dose of the Pfizer vaccine in a patient with no prior history of autoimmune disease [68]. Tang et al. (2022) described a case of sudden and severe new-onset type 1 diabetes mellitus within five days of vaccination with the inactivated CoronaVac vaccine [69]. The patient was hospitalized and treated for diabetic ketoacidosis and continued to show nearly complete loss of islet function at the four-week follow-up, although no islet-associated autoantibodies were observed. Sasaki et al. (2022) reported a case of new-onset type 1 diabetes mellitus within eight days of a first dose of the Pfizer vaccine [70]. Yano et al. (2022) described a case of new-onset type 1 diabetes mellitus and latent thyroid autoimmunity in a previously healthy patient within six weeks of the first dose of the Moderna vaccine [71]. Bleve et al. (2022) reported two cases of new-onset autoimmune diabetes: one following the first dose of the AstraZeneca vaccine, and the other after the second dose of the Pfizer vaccine [47]. Sasaki et al. (2022) documented a case of new-onset type 1 diabetes mellitus within four to eight weeks of a second dose of the Moderna vaccine [72]. Sato et al. (2022) reported a case of new-onset type 1 diabetes mellitus in a cancer patient undergoing treatment with nivolumab, an immune checkpoint inhibitor, within weeks of receiving a second dose of an mRNA-based SARS-CoV-2 vaccine (no brand was reported) [73].

3.6. Adverse events after COVID-19 vaccination

Most articles (101/109; 93%) documented adverse events following the administration of COVID-19 vaccines. Although the timing of these events varied among studies, adverse events were generally classified as vaccine-related only if they occurred within 28 days of vaccination [74]. The eight articles (8/109; 7%) that did not report adverse events either focused on serologic responses as their primary research question or stated that adverse events were outside the scope of their study. Half of the studies that mentioned adverse events (53/101; 52%) reported different categories of events. Articles typically classified these events as mild, moderate, or severe, and described them as either directly or indirectly related to COVID-19 vaccination. The terms “mild” and “minor” were often used interchangeably to describe events that did not require hospitalization or further medical care. These included local injection site pain, fatigue, chills, diarrhea, nausea, vomiting, rashes, fever, myalgia, chest pain, and headaches. Such reactions were frequently described as self-limiting and resolving within a few days. Mild side effects were the most reported.

When severe adverse events were reported, they included anaphylaxis, marked dyspnea, throat closure, severe rashes, and hospitalization. Some authors further categorized adverse events as short-term or long-term and/or as local or systemic [75]. However, most articles did not provide clear definitions for these categories. In the case of adverse events associated with specific autoimmune diseases, the studies often applied their own disease-specific grading systems. Overall, while most articles reported that patients experienced mild and “manageable” side effects, some articles

documented instances of severe reactions post-vaccination that required medical intervention, including hospitalization (e.g., [44,45,60,75–77]). Despite these occurrences, most authors concluded that most adverse events were mild and transient and that the vaccines demonstrated a generally favorable safety profile.

3.7. Efficacy of COVID-19 vaccination

Just over half of the articles (57/109; 52.3%) did not explicitly address the efficacy of COVID-19 vaccination. Among the 52 articles (47.7%) that did, most cited as supporting evidence sources that reported policy / legal positions—global health agencies' statements or regulatory approvals—or clinical trials that excluded their own study populations. Among the articles that mentioned efficacy, most (38/52; 73%) echoed the general assertion that COVID-19 vaccines are effective at reducing disease severity, hospitalization, and mortality, even as some of them acknowledged that immunocompromised and autoimmune patients had been excluded from initial vaccine trials, leaving gaps in efficacy data for these populations. For example, Lemoine et al. (2022) referenced the United States Food and Drug Administration's approval of the Pfizer vaccine [62], citing a Phase 3 trial that reported 95% efficacy in preventing infection [78]—a trial that excluded the population of focus of the authors' study. Similarly, Aydoğan et al. (2022) reported that the two-dose regimen was expected to "confer 95% protection against the virus" [79]. Of note, the authors referenced clinical trial data that did not include their own study population and referred to *relative*, not *absolute*, risk reduction [78]—the latter, as per the US Food and Drug Administration, of greater clinical relevance [80], and independently estimated *at under 1%* [81].

Several authors made broad claims about the role of vaccination in mitigating COVID-19 transmission, disease severity, and mortality, even as their own findings challenged these claims. For example, Chaudhary et al. (2022), upon reporting four cases of Graves' disease following viral vector COVID-19 vaccination, asserted that mass vaccination campaigns were safe and had been highly effective in controlling the pandemic—yet did not provide data supportive of this statement [28]. Similarly, Ghadiri et al. (2022) observed an "absence of vaccine efficacy in controlling severe COVID-19" in a relatively healthy patient population (younger individuals, lower Body Mass Index, nonsmokers, no comorbidities), while still concluding that they "expected more infection over time in the absence of vaccination" and that "vaccines could curb the incidence" [82]. This apparent inconsistency—observing lack of efficacy while simultaneously asserting efficacy unsupported by their own finding—underscores a pattern identified in several studies.

In studies that involved specific populations such as pediatric patients, autoimmune patients, or immuno-compromised individuals, several authors explicitly noted the absence of robust efficacy data. Scaramuzza et al. (2022), for example, conducted a survey of fully vaccinated Italian pediatric diabetologists regarding their vaccine recommendations [83]. While advocating for prioritizing high-risk children for vaccination, respondents acknowledged that "data on COVID-19 vaccine efficacy and antibody responses in children will no doubt emerge over the coming months" [83], reflecting the absence of conclusive efficacy data at the time of their study. Similarly, some studies suggested that inactivated COVID-19 vaccines might offer comparable protective effects with potentially fewer adverse events, particularly among patients with autoimmune disorders [74,84]. However, these conclusions

were typically drawn from small observational cohorts or immunogenicity data rather than from clinical outcomes measuring efficacy against infection or disease severity.

Likewise, Manta et al. (2022) suggested that despite limited direct data in vulnerable groups, the potential benefits of vaccination were expected to outweigh the risks, due to the assumed higher vulnerability to severe infection of these populations [27]. This position was held by several authors who, conversely, did not appear to assume that this higher vulnerability may also apply to vaccine harms. An illustrative example was a study by Toljan et al. (2022), in which authors implied a favorable benefit-versus-risks ratio—suggesting that sudden neurological impairments occurring shortly after mRNA vaccination could indicate the onset of multiple sclerosis yet reaffirming vaccine efficacy in this population [55]. Indeed, the lack of consistent, population-specific benefit-risk assessment was a notable feature across most of the studies that engaged with efficacy claims. Lastly, several authors asserted the critical role that vaccination was playing in facilitating "the societal return to normalcy during the COVID-19 pandemic" [85], without offering specific evidence or arguments to support these claims.

3.8. Authors' perspectives on COVID-19 vaccination for patients with autoimmune disorders

Concerning authors' perspectives on the appropriateness of COVID-19 vaccination for patients with autoimmune disorders, most authors expressed a positive stance toward vaccination vis-à-vis its risks (65/109; 59.6%), about a third maintained a cautious viewpoint (38/109; 34.9%), only a few (6/109; 5.5%) presented a negative assessment of the balance of risks versus benefits, and no author explicitly advised against it. As such, most authors (60/109; 55%) explicitly concluded that COVID-19 vaccines should still be administered to patients with autoimmune disorders, even as they acknowledged the need to remain vigilant about what they described as "rare" side effects.

Illustrative examples included Brès et al. (2022), who asserted that vaccination of this population should proceed, "while being aware of potential rare side effects, with minimal final consequences" [86]. As well, Barbhaiya et al. (2022) stated that vaccines are "important" for patients with lupus, while acknowledging that information on vaccine tolerance in this population remained "unclear" [31]. Similarly, Ganakumar et al. (2022) noted the existence of "rare" but potentially severe adverse events, such as glycemia worsening among diabetic patients, but concluded that this "does not take away from the fact that vaccines are the single most important preventive measure in curbing the spread of COVID-19 and the resultant healthcare costs, and all efforts must be made to continue vaccination" [46]—although the authors did not offer any evidence to support this assertion.

4. Discussion

This scoping review synthesized evidence from 109 published studies regarding associations between COVID-19 vaccination and autoimmune disorders. Our analysis revealed substantial patterns of reported association suggesting: (1) worsening of existing autoimmune conditions upon COVID vaccination in over half of the studies; (2) triggering of new autoimmune disorders in about one-tenth of already affected individuals; and (3) new-onset autoimmune disorders in previously healthy individuals in about one-quarter of the studies. While most studies were case reports, case series, or

small cohort studies not designed to establish causality, the consistency of observed patterns across different study designs and autoimmune conditions supports the case for considering these associations in clinical decision-making and public health policy. Although such designs limit causal inference, they remain essential for early signal detection, particularly in populations excluded from large-scale trials, among whom adverse events may otherwise go unrecognized.

Placed within the broader epidemiological context, these findings align with reports of a rising global burden of autoimmune disease, particularly in industrialized regions. Population-based studies have shown steady increases in autoimmune incidence over recent decades—for example, autoimmune hypothyroidism in the United Kingdom now affects approximately 350 per 100,000 women annually [87]—and global analyses suggest mean annual increases of nearly 20 percent across autoimmune conditions [88]. This upward trend underscores that the emergence of post-vaccination autoimmune signals should be interpreted within an already expanding landscape of immune dysregulation, not dismissed as isolated anomalies. It also highlights the importance of sustained vigilance in evaluating potential iatrogenic contributors to autoimmune morbidity. Notably, the reviewed literature often presented vaccine benefits as established facts while treating adverse associations with greater linguistic and evidentiary caution—a pattern that highlights the need for more balanced standards of inference.

In examining the broader evidence base, adverse events following vaccination—injection site pain, fatigue, and headaches—were reported in over 90% of studies and were most commonly described as mild and self-limiting. However, a notable subset of studies reported serious adverse events such as anaphylaxis, marked dyspnea, hospitalization, and autoimmune-mediated reactions. It should be noted that across these studies, authors consistently acknowledged the difficulty of confirming causality, and emphasized the need for larger, population-based investigations to evaluate whether vaccination may elevate relapse risk, or whether these episodes reflected coincidental timing within a population subgroup already at risk for disease activity. Studies also described the development of new autoimmune disorders post-vaccination in patients with rheumatoid arthritis, systemic lupus erythematosus, and type 1 diabetes, although not among patients with Graves' disease, Hashimoto's thyroiditis, and multiple sclerosis. While the absence of such reports may indicate that patients in those studies do not experience adverse effects postvaccination, they may also reflect underreporting, or the methodological limitations of study designs themselves.

These clinical observations are consistent with established immunological mechanisms that plausibly explain such phenomena, mechanisms long recognized in immunology and well established in the scientific literature: molecular mimicry, including in the context of spike protein vaccines [89], bystander activation [90]; epitope spreading [90]; adjuvant-related immune stimulation via vaccine components such as lipid nanoparticles (used in mRNA vaccines) or viral vectors [91]; and interferon pathway dysregulation, implicated in the pathogenesis of systemic lupus erythematosus and other autoimmune disorders [64]. While the understanding of these mechanisms in the context of COVID-19 vaccination is evolving, the consistency of the reported autoimmune-related adverse events across multiple studies provides clinical support for these pathways. Further, recent studies have explicitly noted the role of mRNA vaccines as possible triggers of autoimmune disorders [4,92,93].

Importantly, while study authors made assertions about the efficacy and benefits of COVID vaccination for the population of interest, they generally offered little supporting evidence. For example, close to half of the studies discussed vaccine effectiveness, but most referred to prior trials,

regulatory approvals, or public health statements rather than their own empirical data, or data relevant to patients with autoimmune disorders, therefore limiting researchers' capacity to properly assess the balance of risks and benefits of COVID-19 vaccination among these patients. Perspectives on the appropriateness of vaccination for this population were divided between positive endorsement, cautious support, and in very rare instances, negative assessment, although no study recommended explicitly against vaccination in light of the risk of exacerbation of autoimmune processes.

Finally, a notable pattern was the inconsistency among the applications of standards of evidence to causal claims regarding benefits versus those regarding risks of COVID vaccination and the emphasis on efficacy and safety claims without population-specific analyses [6]. In sum, in the absence of clear benefit data—particularly for groups excluded from key trials—the continued reliance on generalized claims substitutes assumption for evidence, and the burden of proof remains unmet. This epistemic asymmetry in vaccine research deserves further investigation.

5. Limitations and strengths of the study

This review has limitations. First, it included, primarily, case reports, case series, and small observational studies, which are limited in their ability to establish causality or provide population-level risk estimates. However, these designs remain essential for early signal detection, particularly in populations excluded from large-scale trials, where adverse events may otherwise go unrecognized or fail to be captured by broader surveillance systems. Excluding such studies on methodological grounds would risk overlooking the very signals that these studies are capable of capturing, and that this review sought to document.

Second, following standard scoping review methodology, we did not conduct a formal quality assessment or risk-of-bias analysis of the included studies. As noted in the Methods section, the purpose of a scoping review is not to evaluate or quantify, but rather to map the breadth, nature, and characteristics of the existing evidence. Accordingly, formal quality grading would have been inconsistent with our study design and objectives. Indeed, excluding studies based on methodological quality would have eliminated much of the currently available evidence on potential autoimmune sequelae of COVID-19 vaccination, since this evidence derives largely from case reports, case series, and small observational designs. These sources, although limited in statistical inference, are indispensable for early signal detection in populations underrepresented in large-scale trials and therefore central to the purpose of our review. In interpreting findings from these sources, we followed standard epidemiological reasoning for causal inference. As articulated by Bradford Hill [94], temporality is necessary but not sufficient for causation; other criteria such as consistency, biological plausibility, and coherence warrant further investigation. The recurring temporal associations documented here therefore do not constitute definitive causal claims but represent credible clinical signals that merit systematic study. This distinction also motivates our ongoing research on epistemic integrity in vaccine science, which examines how standards of causal reasoning are applied asymmetrically to claims of benefit and harm, as detailed in our recently published study protocol [95].

Third, the search strategy was limited to two major biomedical databases—PubMed and the WHO COVID-19 Global Database—both of which comprehensively index peer-reviewed and preprint literature across clinical, immunological, and public health disciplines. These databases capture the

overwhelming majority of COVID-19–related biomedical research, are frequently used as primary sources for evidence synthesis, and have substantial overlap with other repositories such as EMBASE and Web of Science. The deliberate restriction to these two high-yield databases reflects a pragmatic methodological choice consistent with the exploratory purpose of a scoping review, balancing feasibility with completeness.

Fourth, limiting inclusion criteria to studies published in 2022 excluded reports appearing before or after this window—particularly those emerging later as follow-ups or long-term studies—and should therefore be viewed as a limitation. However, this focus was deliberate and contextually grounded. The year 2022 corresponded to the 12 months following the peak COVID-19 vaccination period in 2021, when both primary series and booster doses became broadly available to general populations and vaccine acceptance reached its highest level, around 79%, as noted in the Methods section. Concentrating on this period strengthened the internal consistency of the review by capturing the phase of maximum vaccine uptake and the most intensive global surveillance of post-vaccination outcomes, thereby enhancing the analytical clarity and contextual relevance of our findings.

Fifth, our search was further limited to English-language publications accessible through the authors' academic affiliations. These restrictions may have excluded relevant earlier or non-English reports, and this should be considered when interpreting our findings. We note, however, that over 80% of study authors were affiliated with institutions not in English-speaking countries, so most likely, their first language was not English, nor were their study populations located in the English-speaking world, facts that jointly help to offset the limitation of including only English language publications.

Sixth, our review excluded data from pharmacovigilance databases, which, while potentially informative, represent primary surveillance systems rather than published research outputs. Incorporating such sources would have required a distinct methodological design and analytical framework beyond the scope of a scoping review, whose purpose is to map the existing scientific and clinical literature. For feasibility reasons, and to maintain methodological coherence, we therefore restricted inclusion to peer-reviewed articles and preprints. This approach aligns with accepted standards for evidence synthesis, ensuring comparability, traceability, and interpretability of the included studies within the established conventions of biomedical review research.

Taken together, the inclusion of case-based and small observational evidence, the use of two comprehensive and internationally recognized databases, the deliberate temporal focus on the peak vaccination period, the English-language corpus representing globally distributed research teams, and the exclusive reliance on peer-reviewed and preprint literature constitute key strengths of this study. These design choices transform practical constraints into methodological coherence, supporting the breadth, internal consistency, and reproducibility of the review despite the inherent challenges of synthesizing emerging evidence on COVID-19 vaccine safety and autoimmunity.

6. Conclusions

In conclusion, while our study design does not provide definitive answers regarding causality or incidence, it has documented substantial patterns of reported associations between COVID-19 vaccination and autoimmune disorders, in both individuals with and without pre-existing autoimmunity—findings that should be of great concern to the clinical community. Our study has also

identified persistent evidentiary and epistemic asymmetries in how vaccine effectiveness and safety claims are framed, a phenomenon that remains largely unexamined in the scientific literature and deserves further scrutiny.

The absence of perfect evidence should not justify the dismissal of credible signals of potential harm, particularly when such signals emerge repeatedly across diverse populations and study designs. Vaccines, like any other pharmacologic intervention, are complex biological products with immunogenic and adjuvant components that warrant the same standards of scrutiny, transparency, and post-market evaluation applied to all medical products. Treating them as exempt from ordinary scientific questioning risks transforming a medical issue into an article of faith rather than one grounded on science.

By synthesizing the available evidence, this review aims to inform clinical decision-making, foster proportionate risk communication, and strengthen surveillance and reporting practices, especially for populations at elevated risk of autoimmune reactions. Its intent is constructive: to promote rigorous, balanced inquiry and to guide future research, practice, and policy concerning the complex relationship between COVID-19 vaccination and autoimmune disorders.

Author contributions

Claudia Chaufan (CC): Conceptualization; Project Administration; Supervision; Investigation; Methodology; Data Curation; Formal Analysis; Writing – Original Draft; Writing – Review and Editing. Laurie Manwell (LM): Investigation; Methodology; Data Curation; Formal Analysis; Writing – Review and Editing. Camila Heredia (CH): Investigation; Methodology; Data Curation; Formal Analysis. Jennifer McDonald (JM): Investigation; Data Curation; Formal Analysis. All authors have read and approved the final version of the manuscript.

Use of AI tools declaration

The authors declare they have not used Artificial Intelligence (AI) tools in the creation of this article.

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Conflict of interest

The authors declare no conflict of interest. Funders and professional / academic affiliations have played no role in the conception, conduct, or decision to conduct this research or submit it for publication.

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