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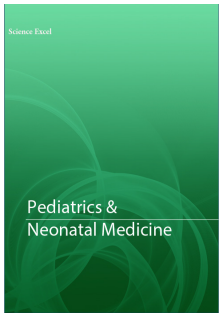

Multisystem Inflammatory Syndrome in Children Before and After COVID-19 Vaccination: No Change in Incidence

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Abstract

Objective: Multisystem Inflammatory Syndrome in Children (MIS-C) was identified as a rare but serious hyperinflammatory condition temporally associated with SARS-CoV-2 infection. Pediatric COVID-19 vaccination has been promoted based on the assumption that vaccination reduces the risk of MIS-C; however, population-level evidence supporting this assumption remains limited.

To assess whether pediatric COVID-19 vaccination was associated with reduced MIS-C incidence.

Methods: Epidemiologic review across three periods: (1) pre–COVID-19 baseline Kawasaki disease and Toxic Shock Syndrome (TSS), immunologically similar hyperinflammatory condition to MIS-C (before March 2019); (2) pre-vaccine COVID-19 MIS-C incidence (March 2019–May 2021); and (3) post–vaccine rollout MIS-C incidence (June 2021–December 2022) was conducted.

Results: The baseline pre-pandemic Kawasaki disease (KD) and pediatric TSS incidence ranged from 0.23 to 15.8 and from 0.15 to 0.25 per 100000 person-years, respectively. During the pre-vaccine COVID-19 period, annualized MIS-C incidence ranged from 0.95 to 6.1 per 100,000 person-years, with substantial geographic and temporal variability. The incidence of MIS-C after the enrollment of vaccines slightly declined but this may be attributed to the emergence of Delta and later Omicron subvariants. Extrapolation from the Moderna's 3d PSUR (Periodic Safety Update Report) suggests 42 MIS-C cases following Moderna vaccination and 504 cases annually across all products in 2022.

Conclusion: Available data do not demonstrate a clear association between pediatric COVID-19 vaccination and prevention of MIS-C at the population level. Interpretation is limited by reliance on passive surveillance systems, inconsistent denominators, diagnostic overlap, and restricted access to manufacturer safety data.

Introduction

In the aftermath of the COVID-19 pandemic, critical reassessment of public health decision-making is necessary to prevent future systemic failures. During the early pandemic period, mRNA-based COVID-19 vaccines were authorized for emergency use, including for pediatric populations as young as six months of age. Emergency Use Authorization (EUA) permits earlier access to medical products but does not require the same duration of safety and efficacy evaluation as full licensure [1].

Initially, the CDC recommended vaccination as protection of vulnerable populations through reduced transmission [2]. Justification for parents to vaccinate their children as young as 6 months of age and older was published as a tutorial document that emphasized that COVID-19 vaccines are safe, will protect children against infection, that the possible side effects are mild, and that the vaccines may be injected concurrently with other children's vaccines [3]. As evidence accumulated that vaccination did not reliably prevent SARS-CoV-2 transmission, the rationale increasingly emphasized prevention of severe disease, medically significant illness, and hospitalization in children [4].

Before the COVID-19 pandemic, a clinically similar pediatric hyperinflammatory syndrome was recognized, namely toxic shock syndrome (TSS), most commonly associated with staphylococcal or streptococcal (group A) infections [5-7].

Abbreviations

CDC: Centers for Disease Control and Prevention; COVID-19: Coronavirus disease 2019; EUA: Emergency Use Authorization; MIS-C: Multisystem Inflammatory Syndrome in Children; MMWR: Morbidity and Mortality Weekly Report; mRNA: Messenger ribonucleic acid; PSUR: Periodic Safety Update Report; SARS-CoV-2: Severe acute respiratory syndrome coronavirus 2; TSS – Toxic shock syndrome; VAERS: Vaccine Adverse Event Reporting System

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Multisystem Inflammatory Syndrome in Children (MIS-C) was described in early 2020 as a novel pediatric condition associated with SARS-CoV-2 infection [8,9]. The same disease was earlier termed Pediatric Multisystem Inflammatory Syndrome Temporally Associated with SARS-CoV-2 (PIMS-TS) [10]. MIS-C is characterized by fever, systemic inflammation, and multiorgan involvement, frequently affecting the cardiovascular, gastrointestinal, hematologic, mucocutaneous, and respiratory systems. It was reported that, besides organ dysfunction, some children with PIMS-TS may develop circulatory shock and meet diagnostic criteria for Kawasaki disease with coronary artery dilatation or aneurysms. In some cases, MIS-C may overlap with symptoms of Kawasaki disease (Kawasaki-like disease) or resemble toxic shock syndrome (TSS), but in other cases clinical and laboratory characteristics were considerably different [8-10].

Later, MIS-C was reported as sporadic cases without prior infection with SARS-CoV-2 after receiving two doses of the Pfizer-BioNTech COVID-19 vaccine 12 weeks apart. It was suspected that the vaccines could be a potential trigger for MIS-C in patients with no history of infection [11]. According to my understanding, the actual incidence of vaccine-induced MIS-C is unknown because no prospective active surveillance has ever been carried out.

According to Moderna's Third Periodic Safety Update Report (PSUR) [12], MIS-C is defined as illness in individuals younger than 21 years presenting with fever for at least one day, requiring hospitalization, with laboratory evidence of inflammation and involvement of two or more organ systems, in the absence of alternative diagnoses, and with evidence of recent SARS-CoV-2 infection or exposure. Children affected are generally previously healthy, and antecedent SARS-CoV-2 infection is typically mild or asymptomatic.

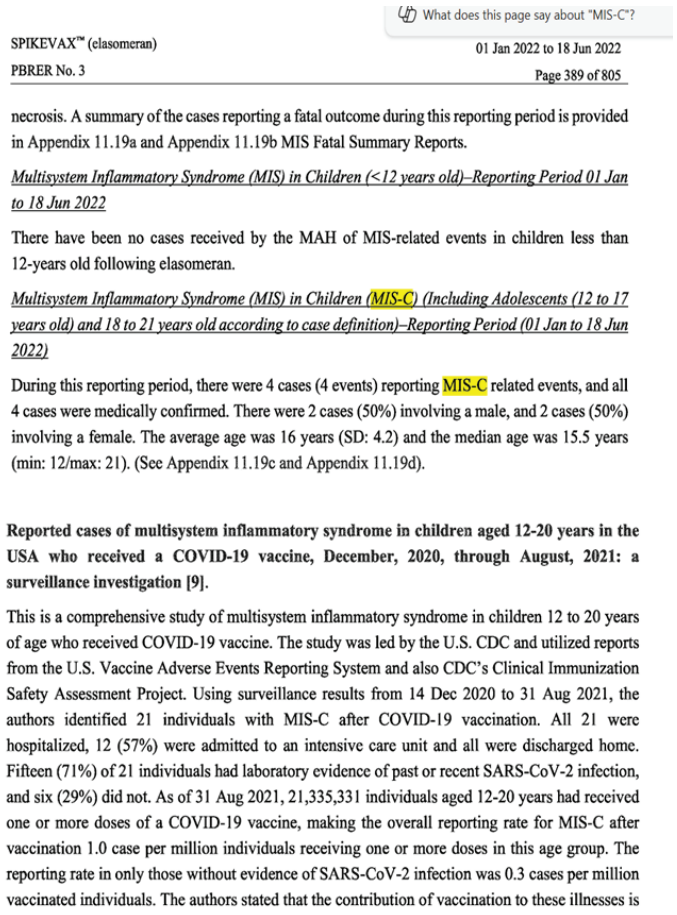
The objective of this study was to assess whether pediatric COVID-19 vaccination was associated with reduced MIS-C incidence by comparing MIS-C rates before and after vaccine rollout and contextualizing these findings against baseline Kawasaki disease and pediatric TSS incidences. Regulatory safety data from Moderna's 3rd PSUR were also reviewed to identify reported MIS-C cases following vaccination. Estimation of vaccine-induced MIS-C was attempted based on the reviewed incidence and Moderna's 3rd PSUR documentation.

Methods

Publicly available baseline epidemiologic data on hyperimmune conditions in children such as Kawasaki disease and pediatric TSS (pre–COVID-19) and MIS-C (pre- and post–vaccine rollout) were identified through PubMed-indexed peer-reviewed literature, insurance-based epidemiologic analyses, and national public health surveillance reports. The reviewed periods were arbitrarily chosen to identify the impact of COVID-19 vaccination on MIS-C incidence.

- Period I: Pre-COVID-19, before March 2019
- Period II: Pre-vaccine rollout (March 2019 – May 2021)
- Period III: Post-vaccine rollout (June 2021 – December 2022)

In addition, Moderna's 3rd PSUR, released by the European Medicines Agency following a Freedom of Information request, was reviewed with particular attention to reported MIS-C cases following vaccination.



What does this page say about "MIS-C"?

SPIKEVAX™ (elasomeran) 01 Jan 2022 to 18 Jun 2022

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necrosis. A summary of the cases reporting a fatal outcome during this reporting period is provided in Appendix 11.19a and Appendix 11.19b MIS Fatal Summary Reports.

Multisystem Inflammatory Syndrome (MIS) in Children (<12 years old)–Reporting Period 01 Jan to 18 Jun 2022

There have been no cases received by the MAH of MIS-related events in children less than 12-years old following elasomeran.

Multisystem Inflammatory Syndrome (MIS) in Children (MIS-C) (Including Adolescents (12 to 17 years old) and 18 to 21 years old according to case definition)–Reporting Period (01 Jan to 18 Jun 2022)

During this reporting period, there were 4 cases (4 events) reporting MIS-C related events, and all 4 cases were medically confirmed. There were 2 cases (50%) involving a male, and 2 cases (50%) involving a female. The average age was 16 years (SD: 4.2) and the median age was 15.5 years (min: 12/max: 21). (See Appendix 11.19c and Appendix 11.19d).

Reported cases of multisystem inflammatory syndrome in children aged 12-20 years in the USA who received a COVID-19 vaccine, December, 2020, through August, 2021: a surveillance investigation [9].

This is a comprehensive study of multisystem inflammatory syndrome in children 12 to 20 years of age who received COVID-19 vaccine. The study was led by the U.S. CDC and utilized reports from the U.S. Vaccine Adverse Events Reporting System and also CDC's Clinical Immunization Safety Assessment Project. Using surveillance results from 14 Dec 2020 to 31 Aug 2021, the authors identified 21 individuals with MIS-C after COVID-19 vaccination. All 21 were hospitalized, 12 (57%) were admitted to an intensive care unit and all were discharged home. Fifteen (71%) of 21 individuals had laboratory evidence of past or recent SARS-CoV-2 infection, and six (29%) did not. As of 31 Aug 2021, 21,335,331 individuals aged 12-20 years had received one or more doses of a COVID-19 vaccine, making the overall reporting rate for MIS-C after vaccination 1.0 case per million individuals receiving one or more doses in this age group. The reporting rate in only those without evidence of SARS-CoV-2 infection was 0.3 cases per million vaccinated individuals. The authors stated that the contribution of vaccination to these illnesses is

For comparison, the incidence rates were annualized and standardized per 100,000 population-years. Where necessary, estimates were extrapolated using publicly available vaccination coverage data to facilitate retrospective estimation of the role of vaccines in MIS-C incidence.

Results

Table 1 summarizes pediatric hyperinflammatory syndrome incidence across the three study periods. The baseline pre-pandemic pediatric Kawasaki disease (KD) and TSS incidence ranged from 0.23 to 15.8 and from 0.15 to 0.25 per 100000 person-years, respectively.

During the pre-vaccine COVID-19 period, reported MIS-C incidence varied substantially by geography and surveillance methodology, ranging from 0.95 to 6.1 per 100,000 person-years. The spike incidence of MIS-C as 27.6/100000/y in New York reported by Dufort [18] is an outlier because at the same period and in the same area the estimated incidence was 8/100000/y [19]. These incidences were in the same range as the baseline reported hyperinflammatory conditions such as KD and TSS.

MIS-C cases continued to be reported after vaccine rollout, with incidence varying by country and period. Interestingly, the incidence of MIS-C from Chilean data was higher in 2021,

Table 1. Pediatric Hyperinflammatory Conditions and MIS-C Incidence
(Annualized per 100,000 persons/year)

Period	Population / Setting	Age Group	Disease	Incidence	Reference
I – Pre-COVID-19	Japan (2018)	<5 y*	KD	15.80	Ae et al. (13)
	South Korea (2012–2014)	<5 y*	KD	8.60	Kim et al. (14)
	Finland, Norway, Sweden (1998–2009)	<5 y*	KD	0.23–0.50	Salo et al. (15)
	USA (2019)	<18 y**	KD	1.48	CDC (16)
	U.S. National Cohort	Not specified	TSS	0.80–3.40	Ross (5)
	U.S. National Cohort (2006–2018)	<21 y***	TSS	0.25–1.00	Leung (6)
	UK (2008–2012)	≤16 y****	TSS	0.15	Sharma (7)
II – Pre-Vaccine COVID-19#	USA (Apr–Jun 2020)	<20 y	MIS-C	6.10	Payne et al. (17)
	New York (Mar–May 2020)	<21 y*****	MIS-C	27.60	Dufort et al. (18)
	New York (Mar–Jun 2020)	<20 y*****	MIS-C	8.00	Lee et al. (19)
	Italy (Nov 2020–Apr 2021)	<18 y	MIS-C	3.27	La Torre et al. (20)
	Sweden (~May–Dec 2021)	<18 y	MIS-C	6.80	Rhedin et al. (21)
	Chile (2020)	<17 y	MIS-C	0.95	Villena et al. (22)
III – Post-Vaccine CO-VID-19	Chile (2021)	<17 y	MIS-C	1.30	Villena et al. (22)
	Chile (2022)	<17 y	MIS-C	0.42	Villena et al. (22)
	USA, Delta wave (Jul–Dec 2021)	<21 y	MIS-C	5.90	CDC (23)
	USA, Omicron BA.1/BA.1.1 (Jan–Apr 2022)	<21 y	MIS-C	5.00	CDC (23)

No MIS-C data exist before 2020 because the syndrome was first described after in early 2020. Most incidence estimates prior to May 2021 are from early pandemic surveillance (spring–summer 2020) and population studies covering late 2020–early 2021.
*Calculated as a proportion of under 5-years-old of 4.4% of the whole population.
** Calculated for 337 million USA population.
*** Calculated as an average of 25% of the population.
**** Informed are 39% of all cases.
***** Calculated as 83 million New York inhabitants and equal incidence during the year

the year when vaccination started, being 1.3/100,000/year compared to the preceding year with a recalculated incidence of 0.95/100,000/year. The incidence of MIS-C in the USA after the vaccine enrolment was at the level of 5.9/100000/y [23]

The 3rd PSUR reported 21 MIS-C cases among vaccinated individuals aged 12 to 20 years between December 2020 and August 2021. Extrapolation suggests approximately 42 cases annually attributable to Moderna vaccines alone. Assuming proportional distribution across manufacturers, this corresponds to an estimated 504 cases annually across all vaccine products, or approximately 0.24 cases per 100,000 population-years based on U.S. vaccination coverage.

Discussion

This analysis compared pediatric hyperinflammatory syndromes across three periods to assess whether COVID-19 vaccination was associated with reduced MIS-C incidence. The temporal stratification was intended to evaluate population-level trends and the rationale for pediatric vaccination as a strategy to prevent hospitalization [3]. Although MIS-C was coined only in 2020, I examined the second period starting from March 2019 when the COVID-19 pandemic was proclaimed by WHO [24]. The duration of Period II and Period III is equal.

The diagnosis of MIS-C is problematic because it overlaps with other pediatric hyperinflammatory conditions such as Kawasaki disease, toxic shock syndrome, myocarditis, septic shock, and cytokine release syndromes [8-10,17-21]

Annualized incidence comparisons indicate that pre-vaccination MIS-C rates were not orders of magnitude higher than baseline Kawasaki disease and pediatric TSS incidences. MIS-C cases were also reported following vaccination, raising skepticism about the necessity of vaccinating children as a population-level preventive strategy.

The authors of several studies estimated that MIS-C was rare, treatable, and led to mortality only in extremely rare cases. For example, Rhedin et al. [21] wrote that "*Knowing … risk populations might facilitate identification of children with MIS-C and potentially guide targeted public health interventions. Nevertheless, the absolute risks for MIS-C were very low.*" La Torre et al. [20] emphasized "*Early diagnosis and step-up treatment with IVIG, steroids, and anakinra depending on the organ involvement or response to therapy contributed to the good outcomes achieved for our patients: no patient died, no patient was admitted to the PICU, and no cardiac sequelae were seen in echocardiograms taken 8 weeks from onset.*" Payne et al. [17] concluded: "*These findings suggest that MIS-C was a rare complication of SARS-CoV-2 infection; further study is needed to understand why MIS-C incidence varied by race/ethnicity and age group.*". In other words, it could be inferred from these citations that there was no clear justification for the world-wide vaccination of healthy children starting from the

age 6 months. By contrast, population-based vaccination with injectables that received only EUA approval, in retrospect, seems an exaggerated precaution.

Secondly, during population-wide COVID-19 vaccine enrollment, sporadic cases of vaccine-induced MIS-C were reported [11]. More definitive conclusions about vaccine-induced MIS-C would require access to complete manufacturer safety datasets submitted to regulatory agencies.

Comparison of MIS-C incidences was complicated by inconsistent denominators across studies [25]. Some analyses use total population denominators, whereas others restrict denominators to pediatric populations with varying age cutoffs. Accurate recalculation requires demographic data, as the proportion of children varies widely across countries [25]. However, it is evident that the decrease in MIS-C cannot be documented after vaccination enrollment. Replacement of wild-type and alpha variants by Delta and Omicron subvariants over time [24] might have shifted disease severity, including MIS-C, which might have been a confounding factor attributed to the alleged vaccine effectiveness.

Another major limitation of this study is the acknowledged problems with post-marketing surveillance, which relies primarily on passive reporting systems such as the Vaccine Adverse Event Reporting System (VAERS), known to underreport adverse events [26]. In addition, inconsistent classification of vaccination status [27], particularly shortly after vaccination, may bias incidence estimates.

From an immunologic perspective, mRNA vaccines induce systemic and prolonged spike protein expression, which may contribute to immune dysregulation through mechanisms such as molecular mimicry or immune complex formation [28]. MIS-C may represent a systemic manifestation of a type III hypersensitivity reaction, analogous to the Arthus reaction described in 1903 [29] where the organism is first primed (through encounter with the wild virus or the first vaccine dose) and then challenged with the second dose or the third dose called booster. Therefore, the concept of "hybrid immunity," [30] involving prior infection followed by vaccination, seems not immunologically justified and may pose a potential risk for hyperinflammatory responses.

Taken together, although this retrospective analysis of MIS-C incidences across different time periods is limited by inconsistent surveillance systems, diagnostic overlap, reliance on passive adverse-event reporting, inconsistent denominators, and variable pediatric age definitions, it does not support the benefit of children's vaccination with preparations marketed as vaccines. There is no evidence supporting that these preparations reduced severe morbidity including MIS-C and hospitalization of children.

Conclusion

MIS-C was initially described as a post-infectious complication of SARS-CoV-2 in children. An evaluation of publicly available surveillance systems, peer-reviewed epidemiologic studies, and manufacturer safety reports at the population level does not demonstrate a measurable reduction in MIS-C incidence associated with pediatric COVID-19 vaccination. Across aggregated datasets, a consistent protective effect is not evident. Full transparency and access to regulatory safety data are necessary to enable a more rigorous and independent assessment to inform pediatric public health policy.

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Conflict of interest

None

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