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Severe Acute Respiratory Syndrome Coronavirus 2 Vaccination in Children with a History of Multisystem Inflammatory Syndrome in Children: An International Survey

Levi Hoste, MD[1,2], MIS-C researchers*, Antoni Soriano-Arandes, MD, PhD[3], Emilie Pauline Buddingh, MD, PhD[4], Elizabeth Whittaker, MD, PhD[5,6], Alexandre Belot, MD, PhD[7], Rolando Ulloa-Gutierrez, MD[8], Peter Olbrich, MD, PhD[9,10,†], and Filomeen Haerynck, MD, PhD[1,2,†]

The optimal severe acute respiratory syndrome coronavirus 2 vaccine strategy for patients with a history of multisystem inflammatory syndrome in children (MIS-C) is unclear. We performed an international survey (32 countries) and found substantial variations in vaccine policies. Respondents did not report relapses of MIS-C or other severe inflammatory side effects after severe acute respiratory syndrome coronavirus 2 vaccination in 273 patients with a history of MIS-C. *(J Pediatr 2022;248:114-8).*

In approximately 1 in 3000 to 5000 severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) infections, multisystem inflammatory syndrome in children (MIS-C) occurs with a severe and potentially life-threatening disease course (1%-2% mortality).[1-3] MIS-C primarily affects previously healthy children between 6 and 10 years of age.[2,3] Besides high-grade fever, the clinical spectrum includes gastrointestinal, cardiovascular, dermatologic, and neurologic symptoms.[3,4] In addition to supportive care, most patients are treated with immunomodulatory therapies, including 1 or more of intravenous immunoglobulin, systemic corticosteroid, and a biologic response–modifying agent.[5] Pediatric SARS-CoV-2–related hospitalizations increased during the more recent omicron surge, both in relative (18% of hospitalizations in South Africa were children)[6] and absolute numbers (4-5 times as many children hospitalized in the US compared with delta surge).[7] To date, it is unclear how the incidence of MIS-C evolves with different SARS-CoV-2 variants, although a recent preprint suggests a lower risk for MIS-C when delta and omicron were dominant compared with alpha lineage.[8]

Although the pathophysiology of MIS-C remains enigmatic, data show activation of oligoclonally expanded T lymphocytes, reminiscent of disease driven by superantigen exposure such as in toxic shock syndrome. In MIS-C, however, upregulated T lymphocytes associated with MIS-C harbor the *TRBV11-2* gene, encoding for the T-cell receptor Vβ 21.3, which appears to be a highly sensitive and specific feature.[9-12] Although the exact source of superantigen in MIS-C remains unknown, persistence of viral exposure is one of the possibilities, given that widespread replication of SARS-CoV-2 has been demonstrated in deceased patients with MIS-C[13] and SARS-CoV-2 spike, S1, and nucleocapsid antigens have been detected in plasma of patients with MIS-C.[14]

Currently approved pediatric vaccines against coronavirus disease 2019 are mRNA-based and encode for the SARS-CoV-2 spike protein.[15-17] SARS-CoV-2 vaccination generally is well tolerated, even in young children.[18] Nevertheless, rare but severe inflammatory events have been documented after SARS-CoV-2 vaccination, such as myocarditis in young (male) adults,[19] or broader multisystem inflammation (MIS after SARS-CoV-2 vaccination) in adolescents or adults.[20-26] In children who previously experienced MIS-C, re-exposure to the viral protein could trigger a relapse of hyperinflammation, especially with a presumed superantigen underlying the pathophysiology of MIS-C. To date, limited data are available in children receiving SARS-CoV-2 vaccination after MIS-C. We performed an international survey

AE	Adverse event
MIS-C	Multisystem inflammatory syndrome in children
SARS-CoV-2	Severe acute respiratory syndrome coronavirus 2

From the [1]Primary Immune Deficiency Research Laboratory, Department of Internal Diseases and Pediatrics, Centre for Primary Immunodeficiency Ghent, Jeffrey Modell Diagnosis and Research Centre, and [2]Department of Internal Medicine and Pediatrics, Division of Pediatric Pulmonology, Infectious Diseases and Inborn Errors of Immunity, Ghent University Hospital, Ghent, Belgium; [3]Pediatric Infectious Diseases and Immunodeficiencies Unit, Hospital Universitari Vall d'Hebron (HUVH), Barcelona, Spain; [4]Department of Pediatrics, Leiden University Medical Centre, Leiden, The Netherlands; [5]Paediatric Infectious Diseases, Imperial College Healthcare NHS Trust, London, United Kingdom; [6]Section of Paediatric Infectious Diseases, Imperial College, London, United Kingdom; [7]Pediatric Nephrology Rheumatology and Dermatology, CHU Lyon, Lyon, France; [8]Servicio de Infectología Pediátrica, Hospital Nacional de Niños "Dr Carlos Sáenz Herrera," Centro de Ciencias Médicas, Caja Costarricense de Seguro Social (C.C.S.S.), San José, Costa Rica; [9]Pediatric Infectious Diseases, Rheumatology and Immunology Unit, Hospital Universitario Virgen del Rocío, Instituto de Biomedicina de Sevilla, IBiS/Universidad de Sevilla/CSIC, Red de Investigación Traslacional en Infectología Pediátrica RITIP, Sevilla, Spain; and [10]Departamento de Farmacología, Pediatría y Radiología, Facultad de Medicina, Universidad de Sevilla, Spain

*List of MIS-C researchers is available at www.jpeds.com (**Appendix 1**).
†Contributed equally.

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among health care professionals to assess experience with tolerability of SARS-CoV-2 vaccine in children with a history of MIS-C.

Methods

Our cross-sectional electronic survey (**Appendix 2**; available at www.jpeds.com) was composed of 24 questions covering vaccination policies used for children with previous MIS-C (local, regional, and/or national guidelines); number of children with a history of MIS-C who were or were not (yet) vaccinated against SARS-CoV-2; and identification of uncommon adverse events (AEs), codified as possible, probable, or certain, occurring after SARS-CoV-2 vaccination in these children. Respondents were asked to specify whether the entered cases were counted accurately (eg, registered as cases) or as estimated numbers. The survey link was distributed globally through personal communication by the authors and through email invitations by multiple professional (inter)national societies of pediatrics, infectious diseases, intensive care medicine, inborn errors of immunity, Kawasaki disease/MIS-C networks, and clinical trials networks. Participants also were asked to distribute the survey invitation to other colleagues involved in MIS-C care. The professional background of respondents was evaluated to confirm relevant roles in care and/or policymaking regarding patients with MIS-C. IP addresses were verified to ensure the uniqueness of each participant. Possible overlapping data (eg, national data that included regional counts) were excluded after personal communication with the involved respondents. Given the study design, overall survey response rates and subsequently any comparisons between survey respondents with nonrespondents could not be performed. On an individual patient level, no identifiable information was collected. Data were collected from November 1, 2021, to December 15, 2021.

Results

Health care professionals (n = 132) involved in the care of patients with MIS-C initiated the survey. After excluding incomplete entries, we collected complete data from 83 health care professionals from 32 different countries (**Figure 1**). Most respondents were clinicians (79/83) and/or clinical researchers (21/83). Medical specialties included pediatrics (53/83), pediatric infectious diseases (23/83), cardiology (13/83), immunology (8/83), intensive care and emergency medicine (8/83), rheumatology (7/83), and dermatology (1/83). Four entries were excluded because of probable or confirmed overlapping data. After we excluded these cases, information from 5673 patients with MIS-C was analyzed (**Figure 2**). In total, 3465 of these cases were accurately counted and 2208 were reported as estimated case numbers of patients with MIS-C; 44% of the patients had been admitted to intensive care units during their MIS-C episode. Of the eligible cohort only 15.6% (273/1750) were confirmed to have been vaccinated (24.0% [420/1750]).

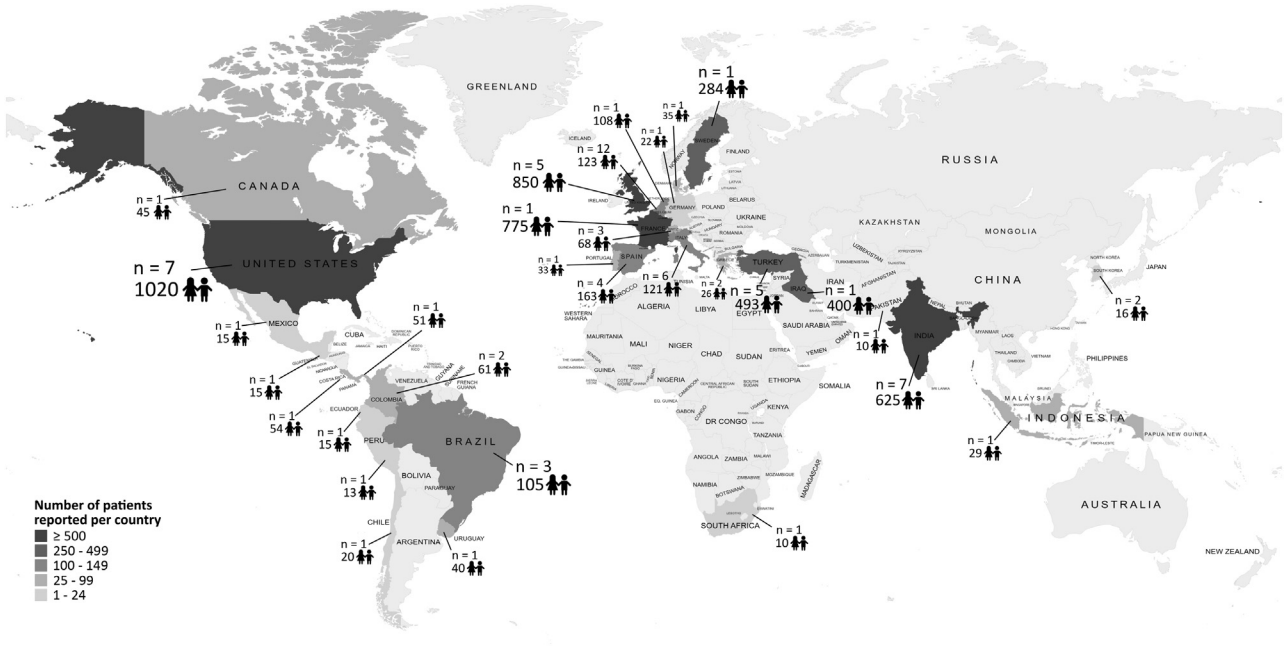

Figure 1. World map with countries colored that are represented in the dataset. For each country, the number of respondents (n) is mentioned as well as the number of patients with MIS-C who were reported. Map created by mapchart.net.

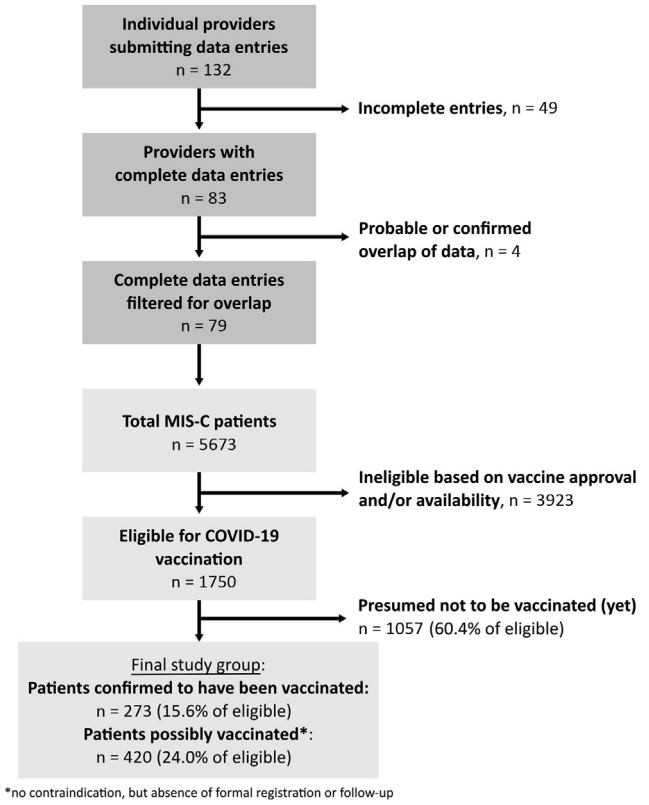

Figure 2. Flowchart representing the selection process of included entries, number of patients with MIS-C reported, and their eligibility for COVID-19 vaccination. *COVID-19*, coronavirus disease 2019.

Patients Who Received the SARS-CoV-2 Vaccine

As stated by the participants at the time of the survey, 1750 patients with MIS-C (30.8% of the study cohort) were eligible by age, vaccine availability, and time since the episode of MIS-C for vaccination. In total, 273 (15.6% of eligible patients) were confirmed to have been vaccinated at the time of the survey. For an additional 420 cases (24.0% of eligible patients), respondents assumed vaccine administration based on the absence of formal contraindication, although no registration or follow-up was performed. This included 81 accurately counted cases and 339 based on estimate numbers.

Policy and Practice

Fourteen of 79 (17.7%) respondents from Belgium, France, India, Italy, Mexico, Pakistan, Turkey, and the US declared MIS-C as a contraindication for SARS-CoV-2 vaccination at the time of the survey, accounting for 1144 patients (20.2% of the cohort). Of note, not all respondents from the same country declared MIS-C as a contraindication (eg, Belgium 7 of 12 respondents, Italy 1/6, Turkey 1/5, US 1/7), suggesting heterogeneous policies or their knowledge on a national level. The participants affirmed that vaccination was contraindicated in their settings due to recommendations of national or regional guidelines (9/14 regions) as well as safety concerns (9/14). Furthermore, 9 participants stated deviation from the standard vaccine regimen for these children compared with previously healthy children without MIS-C or SARS-CoV-2 infection. Recommendations included a minimal interval between MIS-C and administration of the first vaccine dose ranging from 3 months (respondents from Italy, Spain, Sweden, Turkey, United Kingdom, Uruguay, and US) up to 6 months (The Netherlands, United Kingdom). Some respondents declared intent to administer only 1 dose instead of the typical 2-dose regimen (Italy, Spain, and Switzerland).

Most children with previous MIS-C were vaccinated in the same locations as healthy children according to local health authority guidelines, such as vaccination centers or schools (n = 45 respondents), hospitals without admission (n = 3 from India, Italy and Turkey), or hospitals with admission (n = 13 from Belgium, South Korea, Colombia, Indonesia, Spain, Turkey, India, Italy, US). Only 1 respondent from Italy declared that vaccination in a hospital without admission was a specific procedure for MIS-C not applying to healthy children.

Tolerability of SARS-CoV-2 Vaccine

Most respondents (54 of 65 entries without contraindication for vaccination) could not provide specific data on mild or moderate AE, either because there was lack of formal registration and/or that respondents were not at all confronted with these specific AE in patients. Of registered data, mild or moderate AE was reported to a variable extent, including both localized reactions (swelling, redness, pain) and systemic responses (fever, chills, nausea, fatigue, headache, lymphadenopathy). As such, frequencies of AEs for individual entries ranged from 0 to 100% of patients, although importantly, all mild or moderate AEs disappeared after 1-3 days without requiring specific interventions. One 13-year-old male recipient was reported with acute-onset facial nerve palsy (Bell's palsy) 1 week after his second BNT162b2 (Pfizer-BioNTech) vaccine. He was hospitalized and given methylprednisolone (40 mg/d) and recovered without sequelae. No other severe AE was reported by the participants. Importantly, no MIS-C relapse or any other inflammatory conditions were reported after vaccination.

Discussion

The survey documents heterogeneity of vaccine policy as well as limited data on vaccination after recovery from MIS-C. Our data suggest that vaccine recommendations or their understanding or both in the context of MIS-C not only differ between continents and health care systems but also within countries. Potential harms and benefits of SARS-CoV-2 vaccination in children with a history of MIS-C may be weighted differently in each setting. Individual choices or concerns regarding vaccine safety also might exist. Although SARS-CoV-2 vaccination was not contraindicated in patients according to the Centers for Disease Control and Prevention guidelines, we observed a heterogeneous advice within

respondents from the US.[27] Although in most countries AEs of vaccines and drugs are registered centrally by health care agencies, the rarity of MIS-C and the absence of registries documenting follow up of vaccination episodes in affected patients leads to a lack of specific knowledge regarding tolerability of SARS-CoV-2 vaccination in these children.

We found that in most regions around the world, MIS-C is not considered a contraindication for SARS-CoV-2 vaccination. In addition, respondents stated that 273 patients effectively received at least 1 dose of SARS-CoV-2 vaccine after MIS-C. There was no overt experience of increased frequency or severity of AE and no case of MIS-C relapse or other inflammatory conditions after vaccination Our observations are consistent with the overall good safety profile of SARS-CoV-2 vaccines in healthy children. SARS-CoV-2 vaccination is associated with a reduced risk of development of MIS-C after infection.[28,29] It should be noted that Bell's palsy was reported as a severe AE in 1 patient[30] and generally is reversible.[31]

Administration of a SARS-CoV-2 vaccine after MIS-C was assessed by 20% of participants as contraindicated. Furthermore, a substantial number of patients with MIS-C, even if already eligible for vaccination (30% of the cohort), had not been vaccinated or were possibly vaccinated, and 60.4% were not. In addition, some respondents declared to propose longer intervals between MIS-C and vaccination or different dosing schedules than for previously healthy children, potentially exposing patients with MIS-C to a greater risk of reinfection. More detailed information on safety of delayed vaccination or 1- vs 2-dose vaccination will be of value to define the optimal vaccine strategy for this specific group of patients. it will be of interest to document whether occurrence of MIS-C is limited to primary exposure to SARS-CoV-2 or if MIS-C, and with what frequency, follows reinfection.[32]

This analysis is limited by the temporary nature of its data, especially in the midst of an evolving pandemic and vaccine policies. When this survey was initiated, SARS-CoV-2 vaccines were not yet universally accessible for children 5-11 years of age, who represented a substantial proportion of patients with MIS-C.[3] The systematic and prospective collection of additional safety data on younger patients with MIS-C is important to either support or adjust conclusions beyond the current context of predominantly adolescent patients with MIS-C receiving the BNT162b2 (Pfizer-BioNTech) vaccine. A major limitation of the study design is that in only 273 cases vaccine administration has been confirmed, with a potential bias related to recall or notification of AEs. It seems unlikely, however, that attending physicians or health care providers would not have been notified of important inflammatory complications or MIS-C relapses. We did not collect individual data on patients, so information on the demography of those vaccinated, the number of doses administered, or the interval between MIS-C and SARS-CoV-2 vaccination was not documented. Finally, data represent a convenience sample supplied by numerous professionals involved with the care of patients with MIS-C worldwide who chose to participate and should be interpreted as such. ■

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Reprint requests: Filomeen Haerynck, MD, PhD, Department of Pediatric Pulmonology, Infectious Diseases and Immunology, Ghent University Hospital, Corneel Heymanslaan 10, Ghent, Belgium. E-mail: filomeen.haerynck@uzgent.be

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