Safety Platform for Emergency vACcines

D2.3 Priority List of Adverse Events of Special Interest: COVID-19

Work Package: WP2 Standards and tools

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1. Background

To maximize the value of vaccine safety data in clinical trials given their relatively limited sample size, it is essential to standardize their collection, presentation and analysis when possible.

Given serious adverse events following immunization (AEFIs) are fortuitously rare, this need for globally accepted standard case definitions that allow for valid comparisons extend to individual case reports, surveillance systems, and retrospective epidemiologic studies.

This need for standardization was recognized by Dr. Robert Chen at a vaccine conference in Brighton, England in 1999. Harald Heijbel, Ulrich Heininger, Tom Jefferson, and Elisabeth Loupi joined his call one year later to launch the Brighton Collaboration as an international voluntary organization, now with more than 750 scientific experts. It aims to facilitate the development, evaluation and dissemination of high-quality information about the safety of human vaccines.[1]

The goals of the Brighton Collaboration in the domain of case definitions have been to:

1. Develop standardized case definitions for specific AEFI's
2. Prepare guidelines for their data collection, analysis and presentation for global use
3. Develop and implement study protocols for evaluation of case definitions and guidelines in clinical trials and surveillance systems.
4. Raise global awareness of their availability and to educate about their benefit, monitor their global use, and facilitate access.

Safety monitoring during clinical trials is a crucial component for vaccine development. Before a vaccine can receive regulatory approval for marketing, rigorous safety monitoring and reporting is required. In the CEPI funded vaccine development programs, the CEPI funded developers are the sponsors and responsible for safety monitoring of their products and have the responsibility to comply with regulatory requirements. Since CEPI funds several developers that develop vaccines for the same target, using different vaccines and platforms, harmonization of safety monitoring is essential to allow for meaningful analysis and interpretation of the safety profiles of CEPI funded vaccines.

CEPI has contracted with the Brighton Collaboration, through the Task Force for Global Health, to harmonize the safety assessment of CEPI-funded vaccines via its Safety Platform for Emergency vACcines(SPEAC) Project. As part of its landscape analysis of COVID-19, this document describes the methods and results SPEAC used to arrive at the list of adverse events of special interest (AESI).

Adverse events of special interest

An adverse event following immunization (AEFI) is defined as 'any untoward medical occurrence which follows immunization, and which does not necessarily have a causal relationship with the usage of the vaccine. The adverse event may be any unfavorable or unintended sign, abnormal laboratory finding, symptom or disease.'[2]

'Adverse Event of Special Interest' (AESI) is further defined in Council for International Organizations of Medical Sciences (CIOMS) VII[3] as:

"An adverse event of special interest (serious or non-serious) is one of scientific and medical concern specific to the sponsor's product or program, for which ongoing monitoring and rapid communication by the investigator to the sponsor could be appropriate. Such an event might require further investigation in order to characterize and

understand it. Depending on the nature of the event, rapid communication by the trial sponsor to other parties (e.g., regulators) might also be warranted."

AESI can be specified in the Program Safety Analysis plan (PSAP) early in product development for safety planning, data collection, analysis and reporting on AESI data, and eventually form the base of AESI analysis in Reporting and Analysis Plan.

While the current CEPI vaccine development focus is primarily on phase 1 and 2 clinical trials, which will have very small total sample sizes (likely N < 1000), the ultimate goal is to have vaccines ready for use against emerging, epidemic diseases. Vaccine safety assessment needs therefore to be conducted 1) across the entire life cycle of vaccine development, approval and use, and 2) in a harmonized and standardized manner so that data are comparable across different trials and populations. Many if not most of the AESI identified as relevant to CEPI vaccine programs are likely to be rare events and may never occur in the context of a given trial. Nevertheless, we have to be prepared to maximize the utility of vaccine safety data in case they do occur.

To this end SPEAC has chosen to identify AESI that have been previously identified with immunization in general (e.g. anaphylaxis, Guillain Barré Syndrome) or vaccine platforms in particular (e.g., arthritis following recombinant vesicular stomatitis virus vectored vaccine). In addition, it is important to consider events that may occur during the clinical course or as a complication of the chosen target pathogen. Depending on the platform, a vaccine targeting that pathogen may induce an adverse event with a similar immunopathogenic mechanism; whether this occurs or not can only be assessed by studying this specific AESI (e.g., sensorineural hearing loss after Lassa Fever).

2. Objective of this deliverable

The primary objective is to create and provide lists of potential AESI relevant to development of COVID-19 vaccines recognizing that our understanding of this virus is not fully developed and that this document may need to be updated or changed.

The secondary objective is to harmonize their safety assessment (monitoring, investigation and analysis) by having standard case definitions, tools and informational aides, developing them as needed.

3. Methods

Methods to obtain initial list of AESI

Initially, SPEAC vaccine safety experts used their expertise and experience to identify which existing Brighton Collaboration defined adverse events were most likely to be of relevance to CEPI vaccine candidates.

Subsequently, we developed the following scoring system to characterize the nature of evidence linking a given AESI to immunization:

1. Proven association with immunization.
2. Proven association with a vaccine platform and/or adjuvant relevant to CEPI vaccine development.
3. Theoretical concern based on immunopathogenesis.
4. Theoretical concern related to viral replication during wild type disease.
5. Theoretical concern because it has been demonstrated in an animal model with one or more candidate vaccine platforms.

A given AESI could have more than one rationale. For example, convulsion could be associated with 1, 2 and 4.

It was decided for clarity to present the AESI in 3 separate tables:

1. AESI relevant to a broad range of vaccines.
2. AESI relevant to one or more specific vaccine platforms.
3. AESI relevant to a specific target disease.

One or more of these tables may be amended once the vaccine safety templates are developed for each of the CEPI vaccine platforms or should new evidence for a possible or proven vaccine safety signal be published.

The SPEAC approach to identifying AESIs associated with one of the CEPI target disease has been described in detail for Lassa Fever and MERS (see SPEAC-D2.2). It was necessary to modify this approach for COVID-19 given it only first appeared in December 2019.

Specifically, a PubMed search was performed on 26/01/20 with the terms ("china"[tw] and "coronavirus"[tw]) AND ("2019/01/01"[PDat]: "2021/01/30"[PDat]) in order to pick up all articles published since the beginning of 2019 mentioning both china and coronavirus. There were 65 results. An additional PubMed search was then performed with the terms (("Coronavirus"[Mesh] OR "coronavirus"[tw] OR "coronaviruses"[tw] OR "2019-nCoV"[tw]) AND ("2020/01/26"[PDat] : "2021/01/30"[PDat])) on 2/17/20 to pick up all articles published since the previous search. This new search was then saved and daily email alerts were set up to continuously update the group of any new articles published on the topic.

All articles providing information on the COVID-19 clinical course and complications were selected for expert review as described below.

Evaluation of literature and Decision-Making Process to Finalize initial List of AESI

All retrieved articles were independently reviewed by two medical experts (B Law and WT Huang). Each expert made summary notes on the target disease clinical course and complications.

Each expert then drafted a list of AESI for consideration, independently. Subsequently the lists were reviewed and discussed in order to have an agreed upon list of potential AESI for subsequent review and approval by the SPEAC executive board. Extracted data were summarized in a PowerPoint slide set.

Once developed the preliminary list of AESI was shared with CEPI.

Continuing literature review to update AESI list

Since 17 February 2020 daily PubMed searches have been performed with the terms (("Coronavirus"[Mesh] OR "coronavirus"[tw] OR "coronaviruses"[tw] OR "nCoV"[tw] OR “COVID”[tw]). A term for (OR SARS-CoV-2”[tw]) was added 6 March 2020. Since 12 May 2020 a requirement for English language only was added

A single expert screened the titles of all retrieved citations for articles that addressed the clinical course and complications of COVID-19. Of note, since acute respiratory distress syndrome (ARDS) is a well-known and main feature of severe and critical COVID-19, articles focused on ARDS as a clinical entity were not selected for review. Other respiratory complications were captured as were articles suggesting unique or novel pathogenic mechanisms for ARDS as seen with COVID-19. Appendices 1 through 10, appended to this report, summarize in tabular format, and capture the citations of all articles retrieved for review. Reviews, meta-analyses, studies, case

reports and case series as well as commentaries were captured in an effort to identify and numerate new clinical presentations that would be relevant to the AESI list.

4. Results

Table 1 lists AESIs considered potentially applicable to COVID-19 vaccines based on known association with vaccination in general. The rationale for including the AESI is further delineated in the last column of table 1.

Adverse events of special interest applicable to COVID-19 vaccines

TABLE 1. AESI RELEVANT TO VACCINATION IN GENERAL (EVENTS LISTED IN RED HAVE EXISTING BC CASE DEFINITIONS) IN THE TOOLBOX.)

BODY SYSTEM	AESI TYPE	RATIONALE FOR INCLUSION AS AN AESI (SEE FOOTNOTE)
Neurologic	Generalized convulsion	1, 2, 4
	Guillain-Barré Syndrome (GBS)	2
	Acute disseminated encephalomyelitis (ADEM)	3
Hematologic	Thrombocytopenia	1, 2
Immunologic	Anaphylaxis	1, 2
	Vasculitides	3, 4
Other	Serious local/systemic AEFI	1, 2

1. Proven association with immunization encompassing several different vaccines
2. Proven association with vaccine that could theoretically be true for CEPI vaccines under development
3. Theoretical concern based on immunopathogenesis.
4. Theoretical concern related to viral replication during wild type disease.
5. Theoretical concern because it has been demonstrated in an animal model with one or more candidate vaccine platforms.

Table 2 focuses on AESIs relevant to particular vaccine platforms that are being considered in the COVID-19 vaccine development programs.

TABLE 2. AESI RELEVANT TO SPECIFIC VACCINE PLATFORMS FOR COVID-19 VACCINES

BODY SYSTEM	VACCINE PLATFORM SPECIFIC AESIs*	KNOWN/POSSIBLE ASSOCIATION WITH
Neurologic	Aseptic meningitis Encephalitis / Encephalomyelitis	Live viral vaccines including measles
Immunologic	Arthritis	r-VSV platform
Other	Myocarditis	MVA platform

*Review of nucleic acid platforms, and protein platforms has not been conducted since these are novel

AESIs Related to Specific Target Disease of COVID-19

Five articles on the clinical picture and epidemiology of COVID-19 were available for inclusion in the first review for relevant AESIs. [5-9]

Appendices 1 through 10 capture newly reviewed citations retrieved as part of the daily updated PubMed searches. The appendices are organized by body system (1. Cardiovascular, 2. Central nervous system, 3. Dermatologic, 4. Gastrointestinal, 5. Hematologic, 6. Kidney, 7. Multisystem Hyperinflammatory Syndromes, 8. Musculoskeletal, 9. Ocular and 10. Respiratory).

Each Appendix provides a tabular summary that organizes the citations into sections as follows: 1. Reviews; 2. Meta-analyses; 3. Pathogenesis / Hypothesis; 4. Guidelines or reviews focused on management; 5. Studies; 6. Case Reports / Series. Section 6 is further subdivided to provide separate rows for the key unique clinical presentations that have been identified in the literature as associated with COVID-19. The source of each citation by geographic region is captured in the tabular summary along with lead author and a brief title.

The full citation for all articles in the tabular summary is provided below the tabular summary. The citation list includes an additional section with relevant commentaries, editorials and letters to the editor.

The AESI identified for COVID-19 are shown in Table 3 along with the respective specific rationales for their inclusion.

TABLE 3. AESI RELEVANT TO COVID-19

BODY SYSTEM	COVID-19 (red font identifies AESI with existing published Brighton Case Definitions)	RATIONALE FOR INCLUSION AS AN AESI (SEE FOOTNOTE)
Immunologic	Enhanced disease following immunization	1 formalin-inactivated measles/RSV vaccines; HIV vaccine 2 Chimeric Yellow Fever Dengue vaccine 5 mouse models SARS/MERS-CoVs
	Multisystem inflammatory syndrome in children	3, 4
Respiratory	Acute respiratory distress syndrome (ARDS)	3, 4
Cardiac	Acute cardiac injury including: • Microangiopathy • Heart failure and cardiogenic shock • Stress cardiomyopathy • Coronary artery disease • Arrhythmia • Myocarditis, pericarditis	3, 4
Hematologic	Coagulation disorder • Deep vein thrombosis • Pulmonary embolus • Cerebrovascular stroke • Limb ischemia • Hemorrhagic disease	3, 4

Renal	Acute kidney injury	3, 4
Gastrointestinal	Liver injury	3, 4
Neurologic	Guillain Barré Syndrome	4
	Anosmia, ageusia	3, 4
	Meningoencephalitis	1, 4
Dermatologic	Chilblain-like lesions	3, 4
	Single organ cutaneous vasculitis	3, 4
	Erythema multiforme	3, 4

1. Proven association with immunization encompassing several different vaccines
2. Proven association with vaccine that could theoretically be true for CEPI vaccines under development
3. Theoretical concern based on immunopathogenesis.
4. Theoretical concern related to viral replication during wild type disease.
5. Theoretical concern because it has been demonstrated in an animal model with one or more candidate vaccine platforms.

While the tables above are the main output for this deliverable, this document including the appendices will be available in the SPEAC toolbox along with a teaching PowerPoint slide set.

5. Recommendations & discussion

SPEAC recommends CEPI and the COVID-19 vaccine developers adopt the list of AESI. SPEAC further recommends that the developers take a uniform approach to the identification, assessment, investigation, analysis and reporting of any AESI should it occur during a clinical trial.

The AESI in Table 3 are listed in order of priority and this is being used to guide development of new Brighton case definitions. It is notable that the majority of COVID-19 AESI do not yet have a Brighton case definition. A working group to develop one for Enhanced disease following immunization has been working since March 2020 and it is anticipated that a publication will be ready for submission in June 2020. New working groups to develop Brighton case definitions will be initiated in coming months as follows:

June: Multisystem inflammatory syndrome in children and ARDS;
July: acute cardiac injury and coagulation disorder;
August: acute kidney injury and liver injury.

It is anticipated that the remainder on the list that need a case definition (Anosmia/ageusia, chilblain-like lesions, erythema multiforme) will be initiated in October. However, it is possible that new conditions may emerge with higher priority for case definition development, and the intent is to maintain flexibility to add and prioritize new events based on the evolving nature of COVID-19.

SPEAC will develop an action plan for each prioritized AESI, in concert with CEPI & vaccine developers to identify specific approaches vis-a-vis planned clinical trials. These could include one or more of:

1. Prioritize development of new Brighton Case Definitions for those AESI that do not yet have one.
2. Prepare tools (tabular checklists and decision trees) that will facilitate standard, harmonized application of Brighton CDs
3. Conduct systematic literature reviews to describe background rates within the target populations.

4. Work with developers to modify or map existing Case Report Forms (CRF)/outcome definitions or draft new ones if desired to achieve, to the extent possible, harmonized and standardized approaches to each AESI.

6. References

1. Bonhoeffer J, Kohl K, Chen R et al. The Brighton Collaboration – enhancing vaccine safety. Vaccine 2004; 22: 2046.
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7. Guan W, Ni Z, Hu Y et al. Clinical characteristics of 2019 novel coronavirus infection in China. medRxiv prepring doi: https://doi.org/10.1101/2020.02.06.20020974 (not yet peer-reviewed when made available online).
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DOCUMENT INFORMATION

Master Service Agreement		Service order	1
Project acronym	SPEAC	Full project title	Safety Platform for Emergency Vaccines
CEPI Project Lead	Nadia Tornieporth / Jakob Cramer		
CEPI Project Manager	Brett Barnett		
CEPI Contract Manager	Nishat Miah		

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Key words	Toolbox, adverse events of special interest, guidance documents

SIMPLIFIED DOCUMENT HISTORY

NAME	DATE	VERSION	DESCRIPTION
Barbara Law, Matthew Dudley, Wan-Ting Huang	03/02/2020	V1.0 COVID-19	Pertinent articles retrieved, reviewed and AESI list proposed
Barbara Law, Wan-Ting Huang	23/02/2020	V1.1 COVID-19	Revision to AESI list based on Wang-JAMA 2020[8] (arrhythmia added)
Barbara Law	27/02/2020	D2.3 V1.0	Draft deliverable for COVID-19
SPEAC Executive Board	04/03/2020	D2.3 V1.1	Review
Barbara Law	25/05/2020	V2.0	Updated list of AESI including newly available literature

APPENDIX 1. COVID-19 CARDIOVASCULAR MANIFESTATIONS

Type of Reference	# Refs	Author	Country	Focus
1. Reviews	14	1. Akhmerov A	USA	COVID-19 and the heart
		2. Atri D	USA	COVID-19 for the cardiologist: current review
		3. Gupta AK	Multiple	Current perspectives on COVID-19 and CV disease; A white paper by JAHA editors
		4. Matsushita K	France	Impact of COVID-19 on the Cardiovascular System: a review
		5. Larson AS	USA	COVID-19 and Cerbro-Cardiovascular Systems: What do we know so far?
		6. Long B	USA	Cardiovascular complications of COVID-19
		7. Madjiid M	USA	Potential Effects of Coronaviruses on the cardiovascular system: Review
		8. Clerkin KJ	USA	COVID-19 and cardiovascular disease
		9. Bansal M	India	Cardiovascular disease and COVID-19
		10. Basu-Ray I	USA	Cardiac manifestations of COVID-19
		11. Kochi AN	Italy/Switz	Cardiac & arrhythmic complications in COVID-19
		12. Tan W	USA	The cardiovascular burden of COVID-19 (focus on congenital heart disease)
		13. Fried JA	USA	The variety of cardiovascular presentations of COVID-19
		14. Zhao M	China	Advances in relationship between coronavirus infection & cardiovascular diseases
2. Meta- Analyses	3	1. Li JW	China/UK/Aus	Impact of COVID-19 on heart injury: systematic review and meta-analysis
		2. Lippi G	Italy/Spain/US	Cardiac troponin I in patients with COVID-19: Meta-analysis
		3. Krittanawong C	USA/China	COVID-19 & cardiovascular risk: meta-analysis
3. Pathogenesis / hypothesis	7	1. Cheng P	USA	Cardiovascular risks in COVID-19: Potential mechanisms and areas of uncertainty
		2. Lazzerini PE	Italy/USA	Arrhythmic risk and inflammation
		3. Wu	Europe(7)	COVID-19 and inherited arrhythmia syndromes
		4. Nan J	---	Hypoxia in acute cardiac injury of COVID-19. Lessons from pathological studies
		5. South AM	USA	COVID-19, ACE2 and cardiovascular consequences
		6. Giudicessi JR	USA	Genetic susceptibility for COVID-19 associated sudden cardiac death in Afro-Americ.
		7. Thum T	Germany	ACE2 expression in human heart: cause of post-pandemic wave of heart failure?
		8. Cremer PC	USA	SARS-CoV-2 and myocardial injury: Few answers, many questions.
		9. He L	Sweden +multi	Pericyte vascular expression SARS-CoV-2 receptor ACE2 & microvascular inflammation
4. Guidelines or Reviews focused on Management	2	1. NICE	UK	COVID-19 rapid guideline: acute myocardial injury
		2. Siripanthong B	UK/USA	Recognizing COVID-19 related myocarditis: possible pathophysiology, Dx/Rx guideline
		3. Boukhris M	Multiple	Cardiovascular implications of the COVID-19 pandemic
5. Studies	8	1. Zhou B	China	Clinical characteristic of myocardial injury in severe & very severe COVID-19 patients

		2.	Deng Q	China	Suspected myocardial injury in patients with COVID-19
		3.	Chen L	China	The ACE2 expression in human heart indicates new potential mechanism of injury
		4.	Guo T	China-Wuhan	Cardiovascular implications of fatal COVID-19 outcomes
		5.	Han H	China-Wuhan	Analysis of heart injury lab parameters in 273 COVID-19 patients
		6.	Stefanini GG	Italy	STEMI in patietns with COVID-19: clinical and angiographic outcomes
		7.	Ma L	China	COVID-19 myocarditis and severity factors: an adult cohort study
		8.	Shi S	China	Characteristics_& clinical significance of myocardial injury in severe COVID-19 disease
6. Case Reports/Series					
6.1. Arrhythmias	2	1.	Kir D	USA	AV block in COVID-19
		2.	Seecheran R	Trinidad-Toba	Atrial arrhythmias in a patient presenting with COVID-19
6.2. Endotheliitis	1	1.	Varga Z	Switz	Endothelial cell infection and endotheliitis in COVID-19
6.3. Myocarditis	10	1.	Chen C	China	SARS-CoV-2: A potential etiology of fulminant myocarditis
		2.	Cizgici H	Turkey	COVID-19 myopericarditis
		3.	Doyen D	France	Myocarditis in a patient with COVID-19
		4.	Inciardi RM	Italy	Cardiac involvement in a patient with COVID-19
		5.	Hu	China	Fulminant myocarditis saved with glucocorticoid and human Ig
		6.	Sala S	Italy	Acute myocarditis presenting as a reverse Tako-Tsubo syndrome in SARS-CoV2
		7.	Zeng JH	China	First case of COVID-19 compicated with fulminant myocarditis
		8.	Hua A	China	Life threatening cardiac tamponade complicating myo-pericarditis in COVID-19
		9.	Luetkens JA	Germany	Diffuse myocardial inflammation in COVID19 detectted by Cardiac MRI
		10.	Craver R	--	Fatal eosinophilic myocarditis in a healthy 17yr old male
6.4. Heart Failure and Cardiogenic Shock	2	1.	Tavazzi G	Italy	Myocardial localization of Coronavirus in COVID-19 cardiogenic shock
		2.	Creel-Bulos C	USA	Cor Pulmonale in Critically Ill Patients
6.5. Stress cardio-myopathy	4	1.	Minhas AS	USA	Takostubo syndrome in setting of COVID-19
		2.	Jussela A	USA	COVID-19 related cardiomyopathy in pregnancy
		3.	Roca E	Italy	Takotsubo syndrome associated with COVID-19
		4.	Nguyen D	Belgium	A case of Takotsubo cardiomyopathy with COVID-19
6.6. Acute Coronary Syndrome (ACS)	5	1.	Bangalore S	USA	ST segment elevation in patients with COVID-19: case series
		2.	Fernandez Gasso	Spain	Multivessel spontaneous coronary artery dissection in COVID19
		3.	Dominguez Erquic	Spain	Multivessel coronary thrombosis in patient with COVID-19 pneumonia
		4.	Kumar K	USA	Spontaneous coronary arter dissection in 48 yr old – presenting complaint of COVID
		5.	Salido-tahoces L	Spain	Unusual presentation of ACS (plaque destabilization) in SARS-CoV2 infection

6.7. Other	4	1.	Farina A	Italy	SARS-CoV-2 detection in pericardial fluid of patient with cardiac tamponade
		2.	Zhou C	China	COVID-19 with spontaneous pneumomediastinum
		3.	Kolani S	Morocco	Spontaneous pneumomediastinum in SARS-CoV02 infection 23yo F
		4.	Tape	USA	Syncope as a presenting feature of COVID-19

Full Citations for Table Listings

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APPENDIX 2. COVID-19 NEUROLOGIC MANIFESTATIONS

Type of Reference	#Refs	Author	Country	Focus
1. Reviews	7	1. Asadi-Pooya AA	Iran, USA	CNS manifestations of COVID-19: a systematic review
		2. Troyer EA	USA	Neuropsychiatric sequelae of COVID-19 – potential immunologic mechanisms
		3. Wu Y	China	CNS involvement after infection with COVID19 and other coronaviruses
		4. Li H	China	Involvement of the Nervous System in SARS-CoV-2
		5. Daou BJ	USA	Neurologic implications of COVID19: lessons learned from prior epidemics
		6. Liu K	China	Nurologic manifestations of SARS-CoV-2
		7. Finsterer J	Austria	Update on the neurology of COVID-19
2. Meta- Analyses	2	1. Tong JY	USA	Prevalence of olfactory & gustatory dysfunction in COVID19: SystRev/Meta-Analysis
		2. Aziz	USA	Taste Changes (Dysgeusia) in COVID-19: Systematic review/Meta-analysis.
3. Pathogenesis / hypothesis	7	1. Baig AM	Pakistan	Tissue Distribution, Host-Virus interaction & proposed neurotropic mechanisms
		2. De Felice FG	Brazil,Canada	SARS-CoV-2 and the CNS
		3. Gandhi S	India	Is collapse of brain respiratory centre responsible for COVID resp breakdown
		4. Li Z	China, UK	Potential routes of SARS-CoV-2 neuroinvasion from periphery to the brain
		5. Paniz-Mondolfi P	USA	CNS involvement by SARS-CoV-2
		6. Steardo L	Italy, UK	Neuroinfection may contribute to pathophysiology/clinical manifestations
		7. Vaira LA	Italy	Potential pathogenesis of ageusia and anosmia
4. Guidelines or Reviews focused on Management	3	1. Lao wP	USA	Anosmia, hyposmia & dysgeusia as indicators for positive SARS-CoV-2 infection
		2. Needham EJ	UK, USA	Neurological implications of COVID-19 infections
		3. Soler ZM	USA	A primer on viral-associated olfactory loss in the era of COVID19
5. Studies	17	1. Kandemirli SG	Turkey	Brain MRI findings in ICU patients with COVID-19
		2. Beltran-Corbellini	Spain	Acute-onset smell&taste disorders: pilot multicenter PCR based case-ctl study
		3. Giacomelli A	Italy	Self-reported olfactory & taste disorders in SARS-CoV-2: cross-sectional study
		4. Hopkins C	UK	Presentation of new anosmia during COVID-19 pandemic
		5. Hopkins C	UK	Early recovery following new onset anosmia: observational cohort study
		6. Jitaroon K	Thailand,	Evaluation of Incidence of other cranial neuropathies in patients with anosmia
		7. Klopfenstein T	USA	Features of anosmia in COVID-19
		8. Luers JC	France	Olfactory & gustatory dysfunction in COVID-19
		9. Mao L	Germany	Neurologic manifestations of hospitalized patients with COVID-19
		10. Moein ST	China	Smell dysfunction: a biomarker for COVID-19
		11. Spinato G	Iran, USA	Alterations in smell or taste in mildly symptomatic outpatients with SARS-CoV-2

		12. Yan CH	Italy, UK	Association of chemosensory dysfunction and COVID19 in patients with ILI
		13. De Maria A	USA	High prevalence of olfactory and taste disorder during ARS-CoV-2 in outpatients
		14. Lee Y	Italy	Prevalence & Duration of acute loss of smell or Taste in COVID-19 patients
		15. Lu L	Korea	New onset acute symptomatic seizure and risk factors in COVID-19
		16. Vaira LA	China	Validation of a self-administered olfactory & gustatory test
		17. Kaye R	Italy USA	Anosmia reporting tool: initial findings
6. Case Reports/Series				
6.1. Encephalitis	4	1. Duong L	USA	Meningoencephalitis without respiratory failure in young female patient
		2. Moriguchi T	Japan	A first case of meningitis / encephalitis associated with SARS-CoV-2
		3. Ye M	China	Encephalitis as a clinical manifestation of COVID-19
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6.2. GBS	13	1. Scheidl E	Germany	GBS during SARS-CoV-2: case report and review of recent literature
		2. Alberti P	Italy	GBS related to COVID-19 infection
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		9. Virani A	USA	GBS associated with SARS-CoV-2 infection
		10. Zhao H	China	GBS associated with SARS-CoV-2 infection: causality or coincidence
		11. Coen M	Switzerland	Fatal GBS after infection with SARS-CoV-2
		12. Ottoviani D	Italy	GBS in COVID-19: a case report
		13. Pfefferkorn	Germany	Acute polyradiculoneuritis with locked-in syndrome in a patient with COVID-19
6.3. CNS bleed	3	1. Sharifi-Razavi A	Iran	COVID-19 and intracerebral haemorrhage: causative or coincidental
		2. Poyiadii N	USA	COVID-19 associated Acute Hemorrhagic Necrotizing Encephalopathy
		3. Muhammad S	Germany	Severe brain haemorrhage and concomitant COVID-19
6.4. Cranial Nerve abnormalities	7	1. Galougahi MK	Iran	Olfactory bulb MRI in SARS-CoV-2 induced anosmia
		2. Gane SB	UK	Isolated sudden onset anosmia in COVID-19 infection. A novel syndrome?
		3. Gilani S	Iran	COVID-19 and anosmia in Tehran, Iran
		4. Ollarves-Carrero	Spain	Anosmia in a healthcare worker with COVID-19
		5. Hielmesaeth J	Norway	Loss of smell or taste as the only symptom of COVID-19

		6. Dinkin M	USA	COVID-19 infection presenting with ophthalmoparesis from cranial nerve palsy
		7. Kaya Y	Turkey	Transient cortical blindness in COVID-19 pneumonia
6.5. Peripheral neuropathy	1	1. Abdelnour L	UK	COVID-19 infection presenting as a motor peripheral neuropathy
6.6. Other	2	1. Zanin L	Italy	SARS-CoV-2 can induce brain and spine demyelinating lesions
		2. Yousaf Z	Qatar	COVID-19 associated SIADH: a clue in the times of pandemic

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APPENDIX 3. COVID-19 DERMATOLOGIC MANIFESTATIONS

Type of Reference	#Refs	Author	Country	Focus
1. Reviews	5	1. Wollina U	Germany	Cutaneous signs in COVID-19 patients
		2. Sachdeva M	Italy	Cutaneous manifestations of COVID-19: report of 3 cases and review of literature
		3. Tang K	China	Cutaneous manifestations of COVID-19: a brief review
		4. Almutairi N	USA	COVID-19 with Dermatologic Manifestations & implications: an unfolding Conundrum
		5. Young S	USA	Skin manifestations of COVID-19
2. Meta- Analyses	0			
3. Pathogenesis / hypothesis	0			
4. Guidelines or Reviews focused on Management	0			
5. Studies	3	1. Galvan Casas C	Spain	Classification of the cutaneous manifestations of COVID-19
		2. Recalcati S	Italy	Cutaneous manifestations in COVID-19: a first perspective
		3. Bouaziz	France	Vascular skin symptoms in COVID-19: French observational study
6. Case Reports/Series				
6.1. Rash – general or multiple forms	2	1. Najarian DJ	USA	Morbiliform exanthema associated with COVID-19
		2. Gianotti R	Italy	Cutaneous clinic0pathological findings in 3 COVID-19 positive patients
6.2. Chillblain like lesions	8	1. Locatelli AG	Italy	Histologic features of long lasting chilblain-like lesions in a pediatric COVID-19 patient
		2. Andina D	Spain	Chillblains in children in the setting of COVID19 pandemic
		3. Lopez-Robles J	Spain	Chillblain-like lesions: case series of 41 patients during COVID19 pandemic
		4. Suarez-Valle A	Spain	Acro-ischemia in hospitalized COVID-19 patients
		5. Alramthan A	Middle East	COVID19 presenting with chilblain – like disease
		6. Garcia-Lara G	Spain	Chilblain-like lesions in pediatric dermatologic outpatients
		7. Piccolo V	Italy	Chilblain-like lesions during COVID19 epidemic: preliminary stud on 63 patients
		8. Landa N	Spain	Chilblain-like lesions on feet and hands during COVID-19 pandemic
6.3. Petechial rash	1	1. Diaz-Guimaraens	Spain	Petechial skin rash associated with SARS-CoV2

6.4. Vesiculo-bullous varicella-like	4	1.	Marzano AV	Italy	Varicella like exanthema as a specific COVID19 associated skin manifestation: 22 cases
		2.	Carreras-Presas	Spain	Oral vesiculobullous lesions associated with SARS-CoV-2 infection
		3.	Genovese G	Italy	Varicella-like exanthema associated with COVID-19 in an 8 year old girl
		4.	Fernandez-Nieto	Spain	Clinical and histological characterization of vesicular COVID-19 rashes
6.5. Pustulosis / erythema multiforme like	3	1.	Robustelli Test	Italy	Acute generalized exanthematous pustulosis with erythema multiforme-like lesions
		2.	Janah H	Morocco	Atypical erythema multiforme palmar plaques lesions due to SARS-CoV-2
		3.	Jimenez-Cauhe J	Spain	Erythema multiforme-like eruption in patients with COVID-19: clinical/histological
6.6. Urticaria	3	1.	Naziroglu T	Turkey	COVID-19 pneumonia presenting with acute urticarial
		2.	Rodriguez-Jimen	Spain	Acute urticarial with pyrexia as first manifestation of COVID-19 infection
		3.	Gunawan C	Indonesia	Urticarial eruption in COVID-19: a case report
6.7. Vasculitic	1	1.	Castelnovo L	Italy	Symmetric cutaneous vasculitis in COVID-19 pneumonia
6.8. Other	1	2.	Joob B	Thailand	COVID-19 can present with a rash and be mistaken for Dengue

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   1.1. Wollina U, Karadağ AS, Rowland-Payne C et al. Dermatol Ther. 2020 May 10. doi: 10.1111/dth.13549. [Epub ahead of print] Review. PubMed PMID: 32390279. Cutaneous Signs in COVID-19 Patients: A Review.
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   6.1. Rash – general or multiple forms
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6.7. Vasculitic

6.7.1. Castelnovo L, Capelli F, Antonio T et al. JDV doi 10.1111/JDV.16589 Symmetric cutaneous vasculitis in COVID-19 pneumonia.

6.8. Other

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APPENDIX 4: COVID-19 GASTROINTESTINAL MANIFESTATIONS

Type of Reference	#Refs	Author	Country	Focus
1. Reviews	8	1. Cheung KS	China	GI manifestations of COVID-19 & fecal virus load; Systematic Review & Meta-Analysis
		2. Li J	China	GI & Liver manifestations in COVID-19
		3. Tian Y	China	Liver injury during highly pathogenic human coronavirus infections
		4. Li Y	China/USA	Liver injury in COVID-19: management and challenges
		5. Lee IC	Taiwan	Gastrointestinal, hepatobiliary and pancreatic manifestations of COVID-19
		6. Xu L	China	Characteristics & Mechanism of Liver injury in COVID-19
		7. Zhang C	China	Review: GI features in COVID-19 & possibility of fecal transmission
		8. Patel KP	USA	Hepatic involvement in COVID-19 patients: pathology, pathogenesis, clinical
2. Meta- Analyses	1	1. Parohan M	Iran	Liver injury associated with severe COVID19: systematic review and meta-analysis
3. Pathogenesis / hypothesis	1	1. Liang W	China	Diarrhoea may be underestimated: a missing link in COVID-19
4. Guidelines or Reviews focused on Management	3	1. Musa S	Egypt	Hepatic and GI involvement in COVID-19: what do we know till now?
		2. Su TH	Taiwan	Clinical manifestations & management of COVID-19 related liver injury
		3. Sun J	China, Italy	COVID-19 and liver disease
5. Studies	8	1. Cardoso FS	Portugal	Liver injury in critically ill patients with COVID-19: case series
		2. Jin X	China	Epidemiologic, clinical, virologic characteristics of 74 cases with GI symptoms
		3. Lin L	China	GI symptoms of 95 cases
		4. Wang F	China	Pancreatic injury patterns in patients with COVID-19 pneumonia
		5. Wei XS	China	Diarrhea is associated with prolonged symptoms and viral carriage
		6. Xie H	China	Clinical characteristics of non-iCU hospitalized patients with COVID-19 liver injury
		7. Zhang Y	China	Liver impairement in COVID-19 patients: 115 cases from single centre in Wuhan
		8. Hajifathalian K	USA	GI and hepatic manifestations of COVID19 in large Ney York cohort
6. Case Reports/Series				
6.1. Acute hepatitis	2	1. Lagana SM	USA	COVID-19 associated hepatitis complicating living donor liver transplantations
		2. Wander P	USA	COVID=19 presenting as acute hepatitis
6.2. Hematochezia	2	1. Guotao L	China	SARS-CoV-2 presenting with hematochezia
		2. Li G	China	SARS-CoV-2 infection presenting with hematochezia
6.3. Pancreatitis	1	1. Hadi A	Denmark	COVID-19 associated with severe acute pancreatitis: case report on 3 family members

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APPENDIX 5. COVID-19 HEMATOLOGIC MANIFESTATIONS

Type of Reference	#Refs	Author	Country	Focus
1. Reviews	1	1. Giannis D	USA + more	Coagulation disorders in coronavirus infected patients (COVID/SARS/MERS)
2. Meta-Analyses	2	1. Lippi G	Italy	Thrombocytopenia
		2. Xiong M	China	Changes in blood coagulation
3. Pathogenesis / hypothesis	2	1. Gavrillaki E	Greece/US	COVID and thrombotic microangiopathy
		2. Xu P	China	Mechanism of thrombocytopenia in COVID19 patients
4. Guidelines or Reviews focused on Management	3	1. Bikdeli B	Multiple	COVID19 thromboembolic disease: implications_prevention_therapy_follow-up
		2. Castelli R	Italy	Abnormal hemostatic parameters/risk of TE
		3. Zhai Z	China	Prevention/treatment of TE: Consensus statement
5. Studies	18	1. Cui S	China	Prevalence of venous Thromboembolism
		2. Fogarty H	Ireland	Coagulopathy in Caucasian patients
		3. Klok FA	Holland	Incidence of thrombotic complications in critically ill ICU patients
		4. Han H	China	Prominent changes in blood coagulation
		5. Helms J	France	Multicentre prospective cohort: High risk of thrombosis
		6. Llitjos JF	France	High incidence of venous thromboembolic events in anticoagulated patients
		7. Lodigiani C	Italy	Venous & arterial thromboembolic complications
		8. MiddledorpS	Holland	Incidence of venous thromboembolism in hospitalized
		9. Panigada M	Italy	Hypercoagulability of COVID19 patients in ICU
		10. Ranucci M	ItalyUSA(2)	Procoagulant pattern of patients with ARDS
		11. Spiezia L	Italy	Severe hypercoagulability in ICU pts with respiratory failure
		12. Tang N	China	Anticoagulant therapy associated with decreased mortality
		13. Yang X	China	Thrombocytopenia association with mortality
		14. Zou Y	China	Analysis of coagulation parameters
		15. Thomas W	UK	Thrombotic complications of patients admitted to ICU with COVID-19
		16. Wichmann D	Germany	Autopsy findings and venous thromboembolism in patients with COVID-19
		17. Yaghi S	USA	SARS-CoV-2 and Stroke in New York healthcare system
		18. Tejada Meza H	Spain	Ischaemic stroke in the time of COVID-19
6. Case Reports/Series				

6.1. Coagulopathy /Microvascular Injury	2	1. Zhang Y	China	Coagulopathy and antiphospholipid antibodies
		2. Magro C	USA	Complement associated microvascular injury and thrombosis
6.2. Stroke	12	1. Avula A	USA	COVID-19 presenting as stroke (4 cases)
		2. Beyrouti R	UK	Characteristics of ischemic stroke (6 cases)
		3. Oxley TJ	USA	Large-vessel stroke as presenting feature in the young
		4. Viguier A	France	Acute ischemic stroke complicating common carotid artery thrombosis
		5. Valderrama EV	USA	SARS-CoV-2 Infection and Ischemic stroke
		6. Bruggemann R	Netherlands	Arterial and venous thromboembolic disease in a patient with COVID-19
		7. Hughes C	UK	Cerebral venous sinus thrombosis as a presentation of COVID-19
		8. Zhou B	China	Acute Cerebral Infarction and deep vein thrombosis concomitant with COVID-19
		9. Tunc A	Turkey	Coexistence of COVID-19 & acute ischemic stroke – 4 cases
		10. Zayet S	France	Acute cerebral stroke with multiple infarctions & COVID-19
		11. Gunasekaran K	USA	Stroke in a young COVID-19 patient
		12. Morassi M	Italy	Stroke in patients with SARS-CoV-2 infection: case series (6)
6.3. Pulmonary Embolus (PE)	3	1. Fabre O	France	Severe acute proximal PE
		2. Poissy J	France	Increased prevalence of PE in COVID19 patients
		3. Polat V	Turkey	Sudden death due to acute PE in a young woman with COVID-19
6.4. Other Thrombotic Disease	6	1. Griffin DO	USA	Arterial thromboembolic complications in prophylaxed low risk patients
		2. Beccara A	Italy	Arterial Mesenteric Thrombosis as a complication of SARS-CoV-2
		3. Besutti G	Italy	Abdominal Visceral Infarction in 3 patients with COVID-19
		4. Poggiali E	Italy	Deep Vein Thrombosis and Pulmonary Embolism: 2 complications of COVID-19
		5. Schultz K	USA	Digital Ischemia in COVID-19 patients
		6. Bellosta R	Italy	Acute limb ischemia in patients with COVID-19 pneumonia (20 cases)
6.5. Thrombo-cytopenia / ITP	2	1. Ahmed MZ	UK	Thrombocytopenia as an initial manifestation (3 cases)
		2. Zulfiqar AA	France	Idiopathic thrombocytopenic purpura (ITP)
6.6. Autoimmune hemolytic anemia	2	1. Lopez C	USA	Simultaneous onset of COVID 19 and AHA
		2. Lazarian G	France	AHA associated with COVID19
6.7. Other	1	1. Mitra A	USA	Leukoerythroblastic reaction in patient with COVID19

Full Citations for Table Listings

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APPENDIX 6. COVID-19 KIDNEY MANIFESTATIONS

Type of Reference	#Refs	Author	Country	Focus
1. Reviews				
2. Meta- Analyses	2	1. Ali H	Egypt	Survival rate in acute kidney injury in COVID-19 patients: systematic review & meta-analysis
		2. Ng JJ	Singapore	Survival rate in acute kidney injury in COVID-19: systematic review & meta-analysis
3. Pathogenesis / hypothesis	2	1. Fanelli V	Italy	Acute kidney injury in SARS-CoV-2 infected patients
		2. Soleimani M	USA	Acute Kidney injury in SARS-CoV2: Direct effect of virus on kidney proximal tubule cells
4. Guidelines or Reviews focused on Management				
5. Studies	3	1. Wang L	China	COVID-19 doesn't result in acute kidney injury: 116 hospitalized patients-Wuhan
		2. Su H	China	Renal histopathological analysis of 26 postmortem findings
		3. Cheng Y	China	Kidney disease is associated with in-hospital death of patients with COVID-19
6. Case Reports/Series				
6.1. Acute kidney injury	1	1. Gopalakrishnan	USA	Fulminant acute kidney injury in a young patient with COVID-19
6.2. Hematuria	1	1. Almeida	Brazil	Hematuria associated with SARS-CoV-2 infection in a child

Full Citations for Table Listings

1. Reviews
2. Meta-Analyses
   - 2.1. Ali H, Daoud A, Mohamed MM et al. Renal Failure 2020 42(1): 393-7. https://doi.org/10.1080/0886022X.2020.1756322. Survival rate in acute kidney injury superimposed COVID-19 patients: a systematic review and meta-analysis.
   - 2.2. Ng JJ, Luo Y, Phua K, Choong AMTL. J Infect. 2020 May 7. pii: S0163-4453(20)30280-2. doi: 10.1016/j.jinf.2020.05.009. [Epub ahead of print] PubMed PMID: 32389782. Acute kidney injury in hospitalized patients with coronavirus disease 2019 (COVID-19): a meta-analysis.
3. Pathogenesis and/or Hypothesis
   - 3.1. Fanelli V, Fiorentino M, Cantaluppi V et al. Crit Care 2020 Apr 16; 24(1): 155; doi: 10.1186/s13054-020-02872-z. Acute kidney injury in SARS-CoV2 infected patients.
   - 3.2. Soleimani M. Int J Mol Sci. 2020 May 5;21(9). pii: E3275. doi: 10.3390/ijms21093275. PubMed PMID: 32380787. Acute Kidney Injury in SARS-CoV-2 Infection: Direct Effect of Virus on Kidney Proximal Tubule Cells.
4. Guidelines or Reviews Focused on Management
5. Studies
   - 5.1. Wang L, Am J Nephrol doi: 10.1159/000507471. COVID19 does not result in acute kidney injury: analysis of 116 hospitalized patients from Wuhan, China
   - 5.2. Su H Yang M, Wan C et al. Kidney Intl 2020; https://doi.org/10.1016/j.kint.2020.04.003. Renal histopathological analysis of 26 postmortem findings of patients with COVID19 in China.
   - 5.3. Cheng Y, Luo R, Wang K et al. Kidney Int'l; doi.org/10.1016/j.kint.2020.03.005. Kidney disease is associated with in-hospital death of patients with COVID19.
6. Case Reports / Series
   - 6.1. Acute kidney injury
     - 6.1.1. Gopalakrishnan A, Mossaid A, Lo KB et al. Cardiorenal Med. 2020 May 6:1-6. doi: 10.1159/000508179. [Epub ahead of print] PubMed PMID: 32375150. Fulminant Acute Kidney Injury in a Young Patient with Novel Coronavirus 2019.
   - 6.2. Hematuria
     - 6.2.1. Almeida FJ, Olmos RD, Oliveira DBL et al. Pediatr Infect Dis J. 2020 May 6. doi: 10.1097/INF.0000000000002737. [Epub ahead of print] PubMed PMID: 32384396. Hematuria Associated With SARS-CoV-2 Infection in a Child.
7. Commentaries/Op-Eds/Letters to editor
   - 7.1. Nasr SH, Kopp JB Kidney Int Rep 2020 may 4. Doi:10.1016/j.3kir.2020.04.030 COVID19 associated collapsing glomerulopathy: an emerging entity.
   - 7.2. Durvasula R, wellington T, McNamara E, Watnick S. AJ Kid Diseases; https://doi.org/10.1053/j.ajkd.2020.04.001 COVID19 and Kidney Failure in the actue care setting: our experience from Seattle.

APPENDIX 7. COVID-19 MULTISYSTEM INFLAMMATORY SYNDROMES

Type of Reference	#Refs	Author	Country	Focus
1. Reviews	1	1. Zhang Y	China	New understanding of the damage of SARS-CoV-2 infections outside the respiratory system.
2. Meta- Analyses	0			
3. Pathogenesis / hypothesis	8	1. Colafrancesco S	X	COVID19 gone bad: New character in the spectrum of hyperferritinemic syndrome?
		2. Calabrese LH	USA	Cytokine storm and prospects for immunotherapy with COVID-19.
		3. McGonagle D		COVID-19 induced pneumonia and macrophage activation syndrome-like disease.
		4. Ruscitti P	Italy	Cytokine storm syndrome in severe COVID-19.
		5. Amiral J	France	COVID-19 induced activation of hemostasis & immune reactions: Auto-immune reaction?
		6. Alunno A	Italy	Storm, typhoon, cyclone or hurricane in COVID-19? Beware_same storm_different origin.
		7. Li H	China	SARS-CoV-2 and viral sepsis: observations and hypotheses.
		8. Jamilloux Y	France	Should we stimnulate or suppress immune responses in COVID-19? Cytokine_anti-cytokines
4. Guidelines or Reviews focused on Management	4	1. ECDC	Europe	Pediatric inflammatory multisystem syndrome & SARS-CoV-2: rapid risk assessment
		2. RCPCH	UK	Pediatric multisystem inflammatory syndrome temporally associated with COVID-19
		3. WHO	Global	Multisystem inflammatory syndrome in children and adolescents with COVID-19
		4. CDCP	USA	Multisystem Inflammatory Syndrome in Children (MIS-C) Associated with COVID-19
5. Studies	2	4. Verdoni L	Italy	Outbreak of severe Kawasaki-like disease at Italian COVID epicenter: observational cohort
		5. Belhadjer Z	France	Acute heart failure in multisystem inflammatory syndrome in children
6. Case Reports/Series				
6.1. Kawasaki Disease and Kawasaki-like syndromes	4	1. Jones VG	USA	COVID-19 and Kawasaki Disease: novel virus and novel case
		2. Rivera-Figueroa EI	USA	Incomplete Kawasaki Disease in a child with COVID-19.
		3. Licciardi F	Italy	SARS-CoV-2 induced Kawasaki-like hyperinflammatory Syndrome: novel child phenotype
		4. Acharyya	India	Novel Coronavirus mimicking KD in an infant.
6.2. Hyper-inflammatory syndrome	2	1. Riphagen	UK	Hyperinflammatory shock in children during COVID-19 pandemic.
		2. Chiotos K	USA	Multisystem Inflammatory Syndrome in Children: a case series (6 cases)
6.3. Other	1	1. Patel PA	USA	Severe Pediatric COVID19 with respiratory failure and severe thrombocytopenia.

Full Citations for Table Listings

1. Reviews
   1.1. Zhang Y, Geng X, Tan Y et al. Biomed & Pharmacotherapy 2020, 1127. https://doi.org/10.1016/j.biopha.2020.110195. New understanding of the damage of SARS-CoV-2 infection outside the respiratory system.
2. Meta-Analyses
3. Pathogenesis and/or Hypothesis
   3.1. Colafrancesco S, Alessandri C, Conti F, Priori R. Autoimmun Rev. 2020 May 5:102573. doi: 10.1016/j.autrev.2020.102573. [Epub ahead of print] Review. PubMed PMID: 32387470.COVID-19 gone bad: A new character in the spectrum of the hyperferritinemic syndrome?
   3.2. Calabrese LH. Cleve Clin J Med. 2020 May 11. pii: ccc008. doi: 10.3949/ccjm.87a.ccc008. [Epub ahead of print] PubMed PMID: 32393592. Cytokine storm and the prospects for immunotherapy withCOVID-19.
   3.3. McGonagle D, Sharif K, O'Regan A, Briodgewood C. Autoimmunity Reviews Role of cytokines including IL6 in COVID19 induced pneumonia and macrophage activation syndrome like disease.
   3.4. Ruscitti P, Berardicurti O, Iagnocco A, Giacomelli R. Autoimmun Rev. 2020 May 3:102562. doi: 10.1016/j.autrev.2020.102562. [Epub ahead of print] PubMed PMID: 32376400. Cytokine storm syndrome in severe COVID-19.
   3.5. Amiral J, Vissac AM, Seghatchian J. Transfus Apher Sci. 2020 May 3:102804. doi: 10.1016/j.transci.2020.102804. [Epub ahead of print] PubMed PMID: 32387238. Covid-19, induced activation of hemostasis, and immune reactions: Can an auto-immune reaction contribute to the delayed severe complications observed in some patients?
   3.6. Alunno A, Carubbi F, Rodriguez-Carrio J. Rheumatic & Musculoskeletal Diseases; RMD Open 2020; 6:3001295. Doi:10.1136/rmdopen-2020-001295. Storm, typhoon, cyclone or hurricane in patients with COVID-19? Beware of the same storm that has a different origin.
   3.7. Li H, Liu L, Zhang D et al. Lancet 2020, Apr 17. https://doi.org/10.1016/S0140-6736(20)20920-X. SARS-CoV-2 and viral sepsis: observations and hypotheses.
   3.8. Jamilloux Y, Henry T, Belot A et al. Autoimmunity Reviews 2020; https://doi.org/1.1016/j.17trev.2020.102567. Should we stimulate or suppress immune responses in COVID-19? Cytokine and anti-cytokine interventions.
4. Guidelines or Reviews Focused on Management
   1.1. European Centre for Disease Prevention and Control. Paediatric inflammatory multisystem syndrome and SARS-CoV-2 infection in Children. May 14, 2020. Rapid risk assessment. https://www.ecdc.europa.eu/sites/default/files/documents/covid-19-risk-assessment-paediatric-inflammatory-multisystem-syndrome-15-May-2020.pdf
   1.2. Royal College of Paediatrics and Child Health Guidance: Paediatric multisystem inflammatory syndrome temporally associated with COVID-19. https://www.rcpch.ac.uk/sites/default/files/2020-05/COVID-19-Paediatric-multisystem-%20inflammatory%20syndrome-20200501.pdf
   1.3. WHO Scientific brief May 15, 2020. Multisystem inflammatory syndrome in children and adolescents with COVID-19. https://www.who.int/publications-detail/multisystem-inflammatory-syndrome-in-children-and-adolescents-with-covid-19 (link leads to article, which has a link to the WHO case report form)
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5. Studies
   5.1. Verdoni L, Mazza A, Gervasoni A et al. Lancet 2020, May 13; https://doi.org/10.1016/S0140-6736(31103-X An outbreak of severe Kawasaki-like disease at the Italian epicenter of the SARS0CoV-2 epidemic: an observational cohort study.

5.2. Belhadjer Z, Meot M, Bajolle F et al. Circulation DOI: 10.1161/CIRCULATIONAHA.120.048360. Acute heart failure in multisystem inflammatory syndrome in children (MIS-C) in the context of global SARS-CoV0-2 pandemic.

6. Case Reports / Series

6.1. Kawasaki disease and Kawasaki-like syndrome

6.1.1. Jones VG, Mills M, Suarez D et al. Hosp Peds COVID19 and Kawasaki Disease: novel virus and novel case

6.1.2. Rivera-Figueroa EI, Santos R, Simpson S, Garg P. Incomplete Kawasaki Disease in a Child with Covid-19. Indian Pediatr. 2020 May 9. pii: S097475591600179 [Epub ahead of print] PubMed PMID: 32393680.

6.1.3. Licciardi F, Pruccoli G, Denina M et al. Pediatrics 2020; doi: 10.1542/peds.2020-1711. SARS-CoV-2 induced Kawasaki-like hyperinflammatory syndrome: a novel COVID phenotype in children.

6.1.4. Acharyya BC, Acharyya S, Das D. Indian Pediatrics 2020, May 20; pii: S097475591600184 Novel Coronavirus mimicking Kawasaki Disease in an infant.

6.2. Shock-like syndrome with hyperinflammation

6.2.1. Riphagen S, Gomez X, Gonzalez-Martinez C, Wilkinson N, Theocharis P. Hyperinflammatory shock in children during COVID-19 pandemic. Lancet. 2020 May 7. pii: S0140-6736(20)31094-1. doi: 10.1016/S0140-6736(20)31094-1. [Epub ahead of print] PubMed PMID: 32386565.

6.2.2. Chiotos K, Bassiri H, Behrens EM et al. https://academic.oup.com/jpids/advance-article abstract/doi/10.1093/jpids/piaa069/5848127 . Mulitsystem inflammatory syndrome in children during the COVID-10 pandemic: a case series.

6.3. Other (severe multisystem disease in children)

6.3.1. Patel PA, Chandrakasan S, Mickells GE et al. Pediatrics 2020 May 4; doi; 10.1542/peds.2020.1437 Severe pediatric COVID19 presenting with respiratory failure and severe thrombocytopenia

7. Background Pre-COVID

7.1. Rosario C, Zandman-Goddard G, Meyron-Holtz EG, et al. BMC Medicine 2013; 11:185 http://www.biomedcentral.com/1741-7015/11/185. The hyperferritinemic syndrome: macrophage activation syndrome, Still's disease, septic shock and catastrophic antiphopholipid syndrome.

7.2. Esper F, Shapiro ED, Weibel C et al. JID 2005; 191:499-502. Association between a novel human coronavirus and Kawasaki Disease.

8. Commentaries/Op-Eds/Letters to editor

8.1. Mahase E BMJ 2020; 369:m1710; doi: 10.1136/bmj.m1710 COVID19: concerns grow over inflammatory syndrome emerging in children.

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8.3. Pediatric Intensive Care-COVID-19 International Collaborative Conference Call, May 2nd. Statement to the Media.

8.4. Medscape announcement

8.5. Reuters report on European cases

8.6. Kuppalli K, Rasmussen AL. EBioMedicine. 2020; http://dx.doi.org/10.1016/j.3biom.2020.102763. A glimpse into the eye of the COVID-19 cytokine storm.(relates to Verdoni article)

8.7. Schroeder AR, Wilson KM, Ralston SL. Hospital Pediatrics 2020; doi: 10.1542/hpeds.2020-000356. COVID-19 and Kawasaki Disease: Finding the signal in the Noise. (relates to Jones case report and growing number of cases in US)

8.8. Loomba RS, Villarreal E, Flores S. Cardiologoy in the young: Cambridge Coronavirus Collection; DOI: S104795110001432. COVID-19 and Kawasaki syndrome: should we really be surprised?

8.9. Caso F, Costa L, Ruscitti P et al. Autoimmunity Reviews 2020; https://doi.org/10.1016/j.autrev.2020.102524 Could SARS-CoV-2 trigger autoimmune and/or autoinflammatory mechanisms in genetically predisposed subjects?
8.10. Shulman ST. DOI/10.1093/jpids/piaa062/5842094 Pediatric COVID-associated Multi-system Inflammatory Syndrome. (Makes case for this not being KD or KD like)
8.11. Fornell Editor Diagnostic and Interventional Cardiology 2020, May 20. Kawasaki-like Inflammatory Disease Affects Children with COVID-19. https://www.dicardiology.com/article/kawasaki-inflammatory-disease-affects-children-covid-19%C2%A0

APPENDIX 8. COVID-19 MUSCULOSKELETAL COMPLICATIONS

Type of Reference	#Refs	Author	Country	Focus
1. Reviews				
2. Meta- Analyses				
3. Pathogenesis / hypothesis				
4. Guidelines or Reviews focused on Management				
5. Studies				
6. Case Reports/Series				
6.1. Myositis	1	1. Beydon M	France	Myositis as a manifestation of SARS-CoV-2
6.2. Rhabdo-myolysis	2	1. Jin M 2. Suwanwongse K	China USA	Rhabdomyolysis as potential late complications associated with COVID-19 Rhabdomyolysis as a presentation of COVID-19
6.3. Arthralgia	1	1. Joob B	Thailand	Arthralgia as an initial presentation of COVID-19

Citations:

6. Case Reports / Series – all that has been found to date
   6.1. Myositis
      6.1.1. Beydon M, Chevalier K Al Tabaa O et al Ann Rheum Dis doi:10.1136/annrheumdis-2020-217573. Myositis as a manifestation of SARS-CoV-2
   6.2. Rhabdomyolysis
      6.2.1. Jin M, Tong Q . Emerging Infect Diseases 26(7), early release Mar 20; Research letter, Rhabdomyolysis as potential late complication associated with COVID-19.
      6.2.2. Suwanwongse K, Shabarek N. Rhabdomyolysis as a Presentation of 2019 Novel Coronavirus Disease. Cureus. 2020 Apr 6;12(4):e7561. doi: 10.7759/cureus.7561. PubMed PMID: 32382463; PubMed Central PMCID: PMC7202588. USA
   6.3. Arthralgia
      6.3.1. Joob B, Wiwanitkit V.Rheumatol Int. 2020 Mar 28. doi: 10.1007/s00296-020-04561-0. [Epub ahead of print]. Arthralgia as an initial presentation of COVID-19: observation.

APPENDIX 9. COVID-19 OCULAR MANIFESTATIONS

Type of Reference	#Refs	Author	Country	Focus
1. Reviews	2	1. Hu K 2. Seah I	USA Singapore	Ophthalmic manifestations of COVID-19 Can COVID-19 affect the eyes
2. Meta- Analyses	1	1. Ulhaq ZS	Indonesia	The prevalence of ophthalmic manifestations in COVID-19; diagnostic value of ocular fluid
3. Pathogenesis / hypothesis				
4. Guidelines or Reviews focused on Management	1	1. Siedlecki J	Germany	Ophthalmological aspects of the SARS-CoV-2 global pandemic
5. Studies	2	1. Wu P 2. Hong N	China China	Characteristics of ocular findings of patients with COVID-19 Evaluation of ocular symptoms and tropism of SARS-CoV-2
6. Case Reports/Series				
6.1. Folicular conjunctivitis	1	1. Chen L	China	Ocular manifestations of a hospitalized patient with confirmed COVID-19
6.2. Kerato-conjunctivitis	1	1. Cheema M	Canada	Keratoconjunctivitis as the initial medical presentation of COVID-19

Full Citations for Table Listings

1. Reviews
   1.1. Hu K, Patel J, Patel BC StatPearls NCBI Bookshelf Ophthalmic manifestations of COVID19
   1.2. Seah I(1), Agrawal R(2)(3)(4).Ocul Immunol Inflamm. 2020 Mar 16:1-5. doi: 10.1080/09273948.2020.1738501. [Epub ahead of print] Can the Coronavirus Disease 2019 (COVID-19) Affect the Eyes? A Review of Coronaviruses and Ocular Implications in Humans and Animals.
2. Meta-Analyses
   2.1. Ulhaq ZS, Soraya GV. Graefe's Archive for Clinical and Experimental Ophthalmology https://doi.org/10.1007/s00417-020-04695-8 The prevalence of ophthalmic manifestations in COVID19 and the diagnostic value of ocular tissue /fluid Indonesia
3. Pathogenesis and/or Hypothesis
4. Guidelines or Reviews Focused on Management
   4.1. Siedlecki J, Brantl V, Schworm B et al. Klin Monbl Augenheilkd. 2020 May 6. doi: 10.1055/a-1164-9381. [Epub ahead of print] English, German. PubMed PMID: 32375197. COVID-19: Ophthalmological Aspects of the SARS-CoV 2 Global Pandemic. No PDF saved
5. Studies
   5.1. Wu P, Duan F, Luo C et al. JAMA Ophthalmol. 2020 Mar 31. doi: 10.1001/jamaophthalmol.2020.1291. [Epub ahead of print]. Characteristics of Ocular Findings of Patients With Coronavirus Disease 2019 (COVID-19) in Hubei Province, China.
   5.2. Hong N, Yu W, Xia J et al. Acta Ophthalmologica 2020 Apr 26. Doi: 10.1111/aos.14445. Evaluation of ocular symptoms and tropism of SARS-CoV2 in patients confirmed with COVID19.
6. Case Reports / Series
   6.1. Follicular conjunctivitis
      6.1.1. Chen L, Liu M, Zhang Z et al. Br J Ophthalmol 2020; 0:1-4. Ocular manifestations of a hospitalized patient with confirmed COVID19.
   6.2. Keratoconjunctivitis
      6.2.1. Cheema M, Aghazadeh H, Nazaali S et al. Can J Ophthalmol 2020 Apr 2; 10.1016/j.jcjo.2020.03.003. Keratoconjunctivitis as the initial medical presentation of COVID19
7. Commentaries/Op-Eds/Letters to editor

APPENDIX 10. COVID-19 RESPIRATORY MANIFESTATIONS

Type of Reference	#Refs	Author	Country	Focus
1. Reviews				
2. Meta- Analyses				
3. Pathogenesis / hypothesis	2	1. Gattinoni L 2. Gattinoni L	Italy Italy/Germany	COVID-19 Does not lead to a “typical” ARDS COVID19 pneumonia: ARDS or not?
4. Guidelines or Reviews focused on Management				
5. Studies	1	1. Mo P	China	Clinical characteristics of refractory COVID-19 pneumonia in Wuhan
Case Reports/Series				
6.1. Hemoptysis	1	1. Shi F	China	COVID 19 pneumonia with hemoptysis as the initial symptom
6.2. Spontaneous pneumothorax	1	1. Rohailla S	Canada	SARS-CoV-2 infection associated with spontaneous pneumothorax
6.3. Other	2	1. Beerkens F 2. Sivakorn C	USA Thailand	COVID -19 pneumonia as a cause of acute chest syndrome in adult sickle cell patient Walking pneumonia in COVID-19: mild symptoms with marked CT abnormalities

Citations:

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2. Meta-Analyses
3. Focus on Pathogenesis and Hypothesis
   - 3.1. Gattinoni L, Coppola S, Cressoni M, et al Am J Respir Crit Care Med. 2020 Mar 30. doi: 10.1164/rccm.202003-0817LE. [Epub ahead of print] Covid-19 Does Not Lead to a "Typical" Acute Respiratory Distress Syndrome.
   - 3.2. Gattinoni L, Chiumello D, Rossi S. Critical Care 2020; 24:154. https://doi.org/10.1186/s13054-020-02880-z COVID19 pneumonia: ARDS or not?
4. Guidelines or Reviews Focused on Management
5. Studies
   - 5.1. Mo P, Xing Y, Xiao Y Clin Infect Dis. 2020 Mar 16. pii: ciaa270. doi: 10.1093/cid/ciaa270. [Epub ahead of print] Clinical characteristics of refractory COVID-19 pneumonia in Wuhan, China.
6. Case Reports and Series
   - 6.1. Hemoptysis
     - 6.1.1. Shi F(1), Yu Q(2), Huang W(3), Tan C(4).Korean J Radiol. 2020 Mar 13. doi: 10.3348/kjr.2020.0181. [Epub ahead of print] 2019 Novel Coronavirus (COVID-19) Pneumonia with Hemoptysis as the Initial Symptom: CT and Clinical Features
   - 6.2. Spontaneous pneumothorax
     - 6.2.1. Rohailla S, Ahmed N, Gough K. CMAJ 2020 Apr21; doi: 10.1503/cmaj.200609; SARS-CoV2 infection associated with spontaneous pneumothorax
   - 6.3. Other
     - 6.3.1. Beerkens F, John M, Puliafito B et al. ? Journal COVID19 pneumonia as a cause of Acute chest syndrome in an adult sickle cell patient
     - 6.3.2. Sivakorn C, Luvira V, Muangnoicharoen S et al Am J Trop Med Hyg doi:10.4269/ajtmh.20-0203 Case Report: Walking pneumonia in COVID-19: Mild symptoms with Marked abnormalities on Chest Imaging.
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   - 7.1. Boraschi P. Acad Radiol 2020 apr 15 doi: 10.1016/j.acra.2020.04.010 COVIOD19 pulmonary involvement: is really an interstitial pneumonia?
   - 7.2. Bermejo-Martin JF, Almansa R, Menendez R et al. J Infect 2020; https://doi.org/10.1016/j.jinf.2020.02.029 Lymphopenic community acquired pneumonia as signature of severe COVID-19 infection