Clinical Management of Multisystem Inflammatory Syndrome in Children (MIS-C) Associated with Coronavirus Disease (COVID-19)

Clinician Outreach and Communication Activity (COCA) Webinar

Thursday, July 16, 2020

Continuing Education

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For More Clinical Care Information on COVID-19

- **Call** COVID-19 Clinical Call Center at 770-488-7100 (24 hours/day).
- **Refer** patients to state and local health departments for COVID-19 testing and test results.
  - Clinicians should NOT refer patients to CDC to find out where or how to get tested for COVID-19, OR to get test results.
- **Visit** CDC's Coronavirus (COVID-19) website: https://www.cdc.gov/coronavirus
- **Visit** emergency.cdc.gov/coca over the next several days to learn about future COCA Calls.

Today's Presenters

- **Ermias Belay, MD**
  MIS-C Team Lead
  COVID-19 Response
  Centers for Disease Control and Prevention

- **Matthew Oster, MD, MPH**
  CDC COVID-19 Response, MIS-C Team
  Associate Professor of Pediatrics
  Children's Healthcare of Atlanta, Sibley Heart Center
  Emory University School of Medicine

- **Eva Cheung, MD**
  Assistant Professor of Pediatrics – Divisions of Pediatric Cardiology and Critical Care Medicine
  Columbia University Irving Medical Center/NewYork-Presbyterian Morgan Stanley Children's Hospital

- **Adriana Tremoulet, MD**
  Professor of Pediatrics and Associate Director of the Kawasaki Disease Research Center
  University of California, San Diego and
  Rady Children's Hospital San Diego

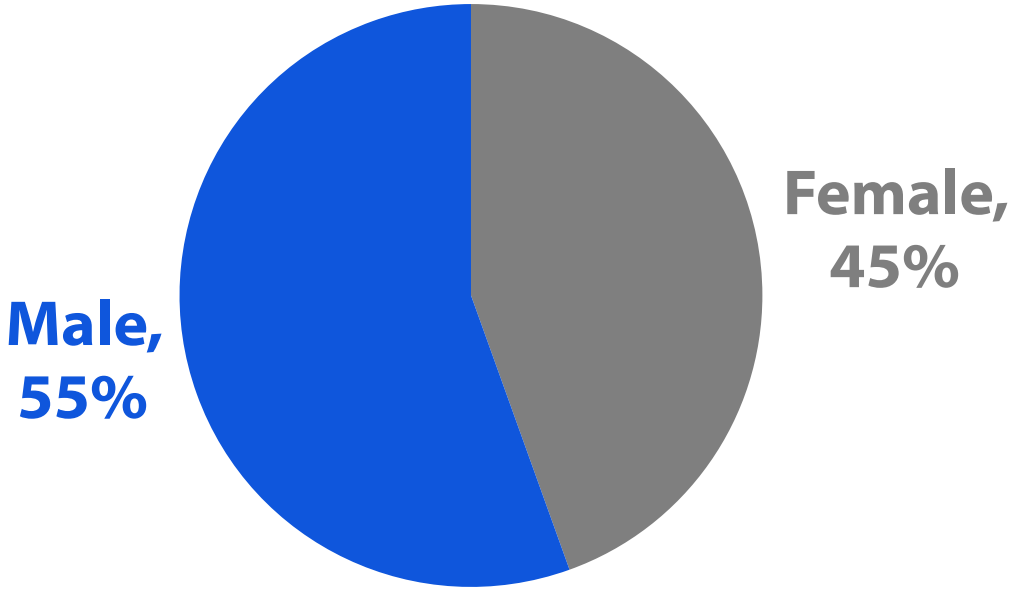
Multisystem Inflammatory Syndrome in Children (MIS-C)

Introduction

- MIS-C first reported in late April in the United Kingdom in association with COVID-19[1,2]
- MIS-C presentations may include persistent fever, gastrointestinal, mucocutaneous, and cardiac signs and symptoms, and elevated inflammatory markers[3]
- Some overlap with Kawasaki disease, toxic shock syndrome, and acute COVID-19[3]
- On May 14, CDC published a Health Advisory along with a case definition and requested reporting of suspected MIS-C cases from jurisdictions[2]

[1]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
[2]https://emergency.cdc.gov/han/2020/han00432.asp
[3]https://www.cdc.gov/mis-c/index.html

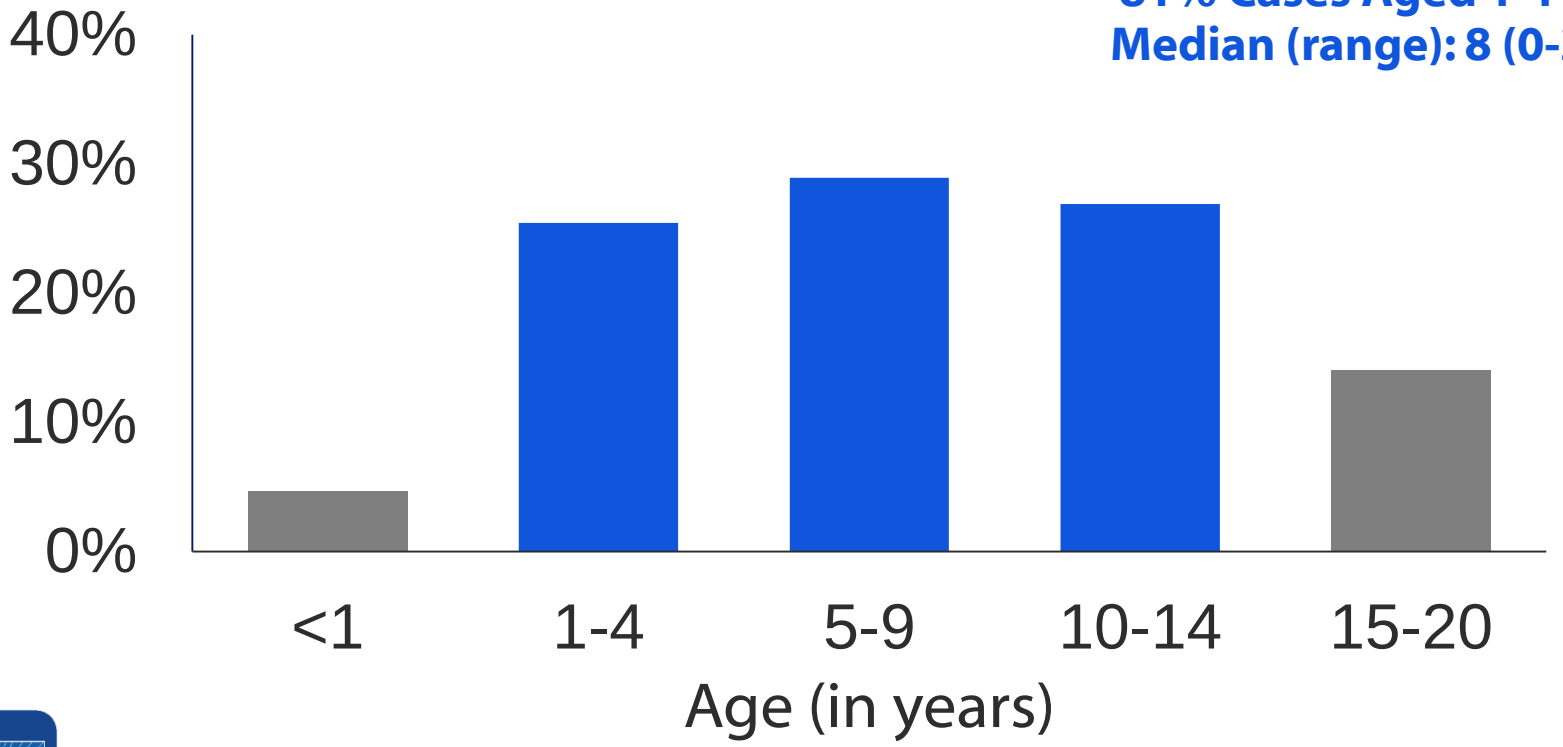
Sex Distribution of MIS-C Cases Reported to CDC (N=342), as of 7/15/20*



*Suspected MIS-C cases with complete MIS-C case report forms submitted to CDC that met all MIS-C case inclusion criteria

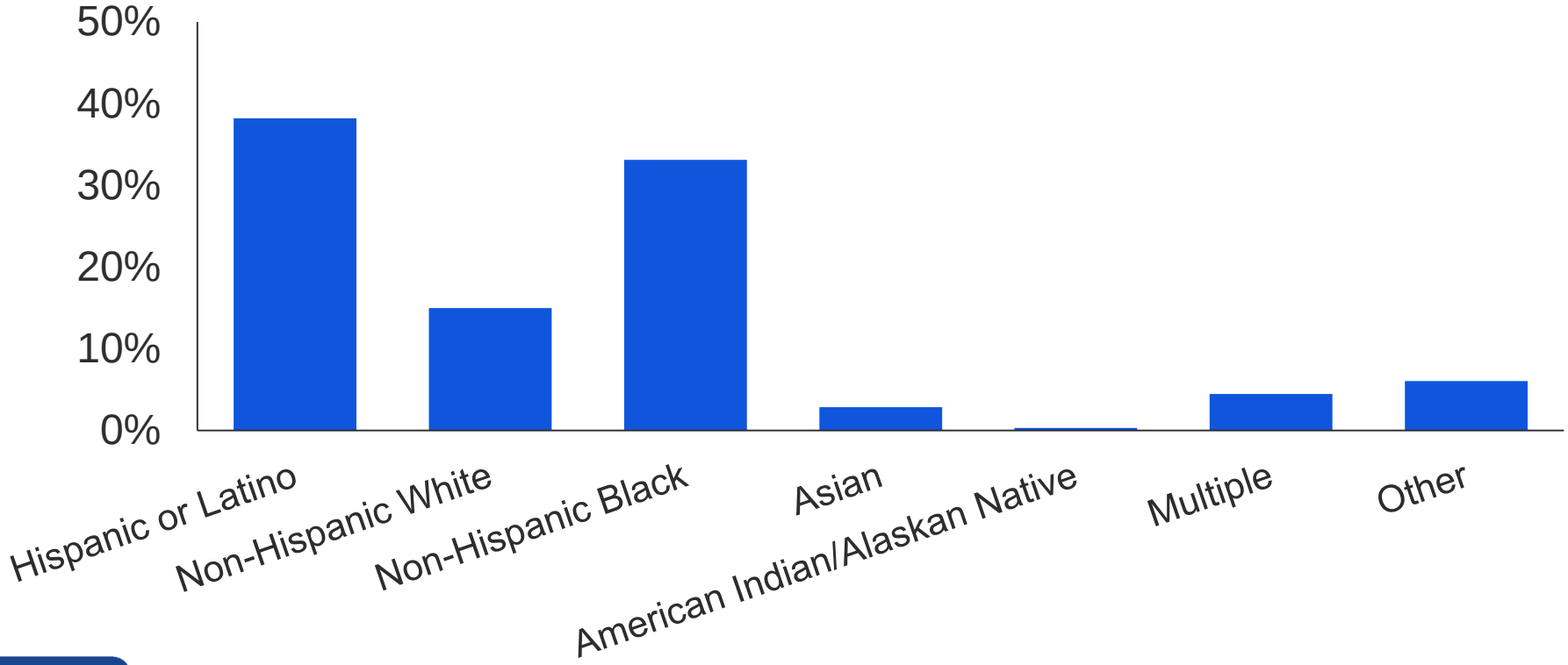
Age Distribution of MIS-C Cases Reported to CDC (N=342), as of 7/15/20*

81% Cases Aged 1-14 y
Median (range): 8 (0-20)



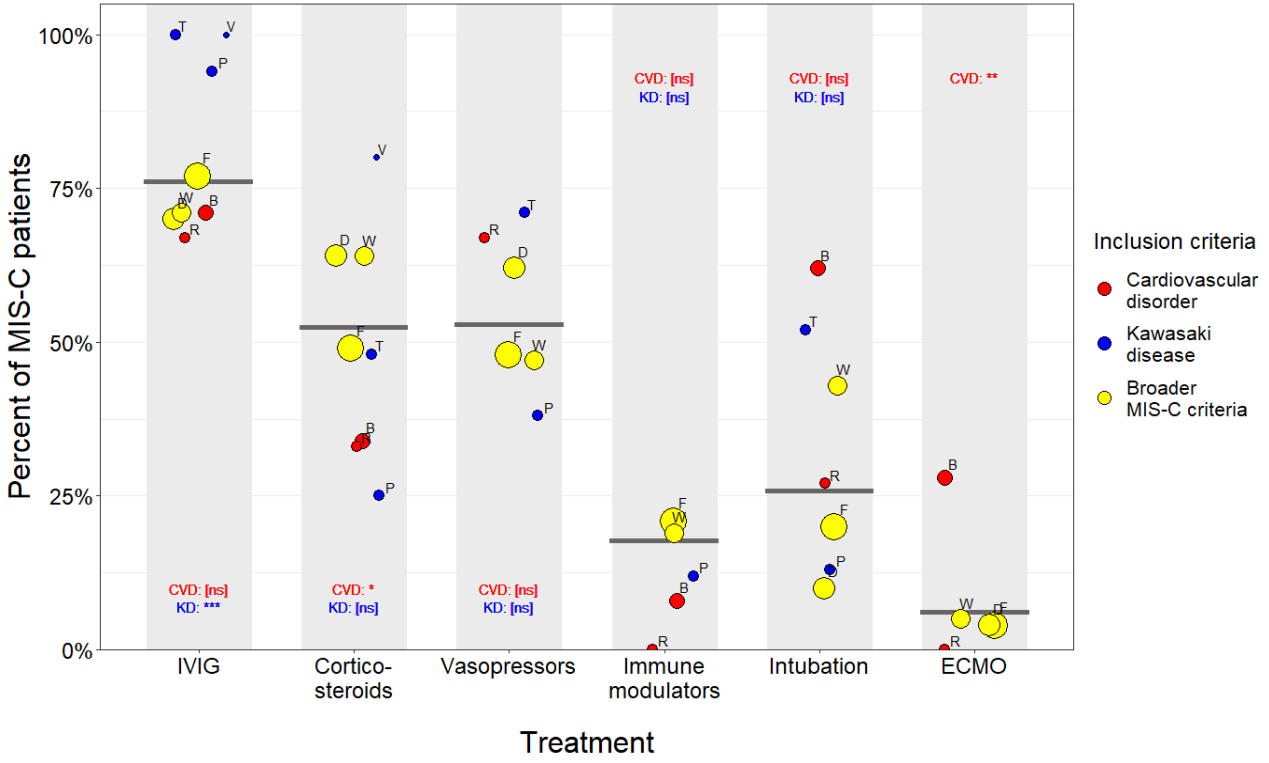
*Suspected MIS-C cases with complete MIS-C case report forms submitted to CDC that met all MIS-C case inclusion criteria

Race and Ethnicity Distribution of MIS-C Cases Reported to CDC (N=342), as of 7/15/20*



*Suspected MIS-C cases with complete MIS-C case report forms submitted to CDC that met all MIS-C case inclusion criteria

Proportion of MIS-C Patients Receiving Different Types of Treatment: Summary of 8 Published Studies



Created by Joseph Abrams, PhD

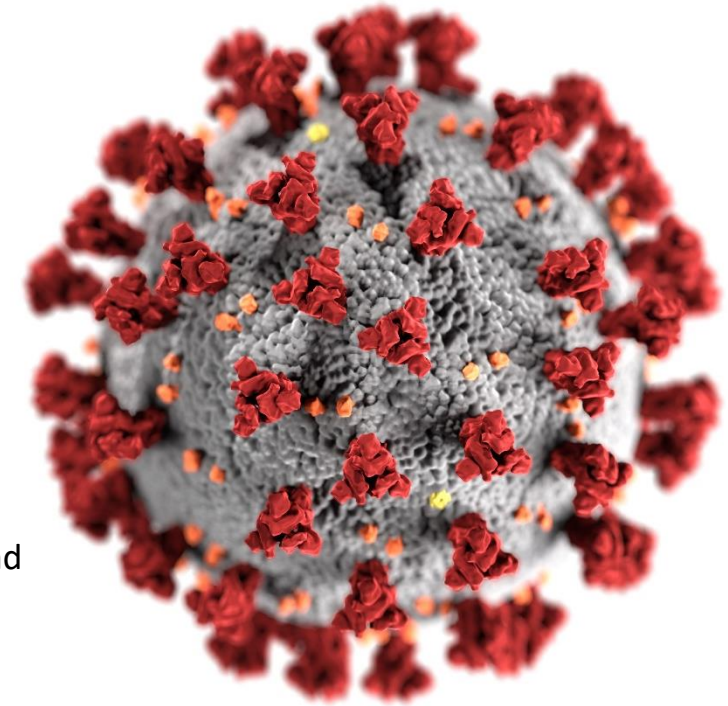
Acknowledgments

- **Local and State Health Departments** for their valuable assistance in investigating suspected MIS-C cases and reporting to CDC

- **CDC MIS-C Team**
  - Ermias Belay (Lead)
  - Shana Godfred Cato (Deputy)
  - Bobbi Bryant
  - Matt Oster
  - Joseph Y. Abrams
  - Emily Koumans
  - Laura Conklin
  - Jessica Leung
  - Emily Prezzato

For More Information

Please visit the CDC webpage on Multisystem Inflammatory Syndrome in Children (MIS-C):
https://www.cdc.gov/mis-c/hcp/



The findings and conclusions of this report are those of the authors and do not necessarily represent the official position of the Centers for Disease Control and Prevention.

cdc.gov/coronavirus

COLUMBIA UNIVERSITY CHILDREN'S MEDICINE

NewYork-Presbyterian KIDS
Morgan Stanley Children's Hospital

Multi-system Inflammatory Syndrome in Children Related to COVID-19:
Clinical Cases and Lessons Learned

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Divisions of Pediatric Cardiology and Critical Care Medicine
Medical Director, Pediatric ECMO
July 16, 2020

The NEW ENGLAND JOURNAL of MEDICINE

ORIGINAL ARTICLE

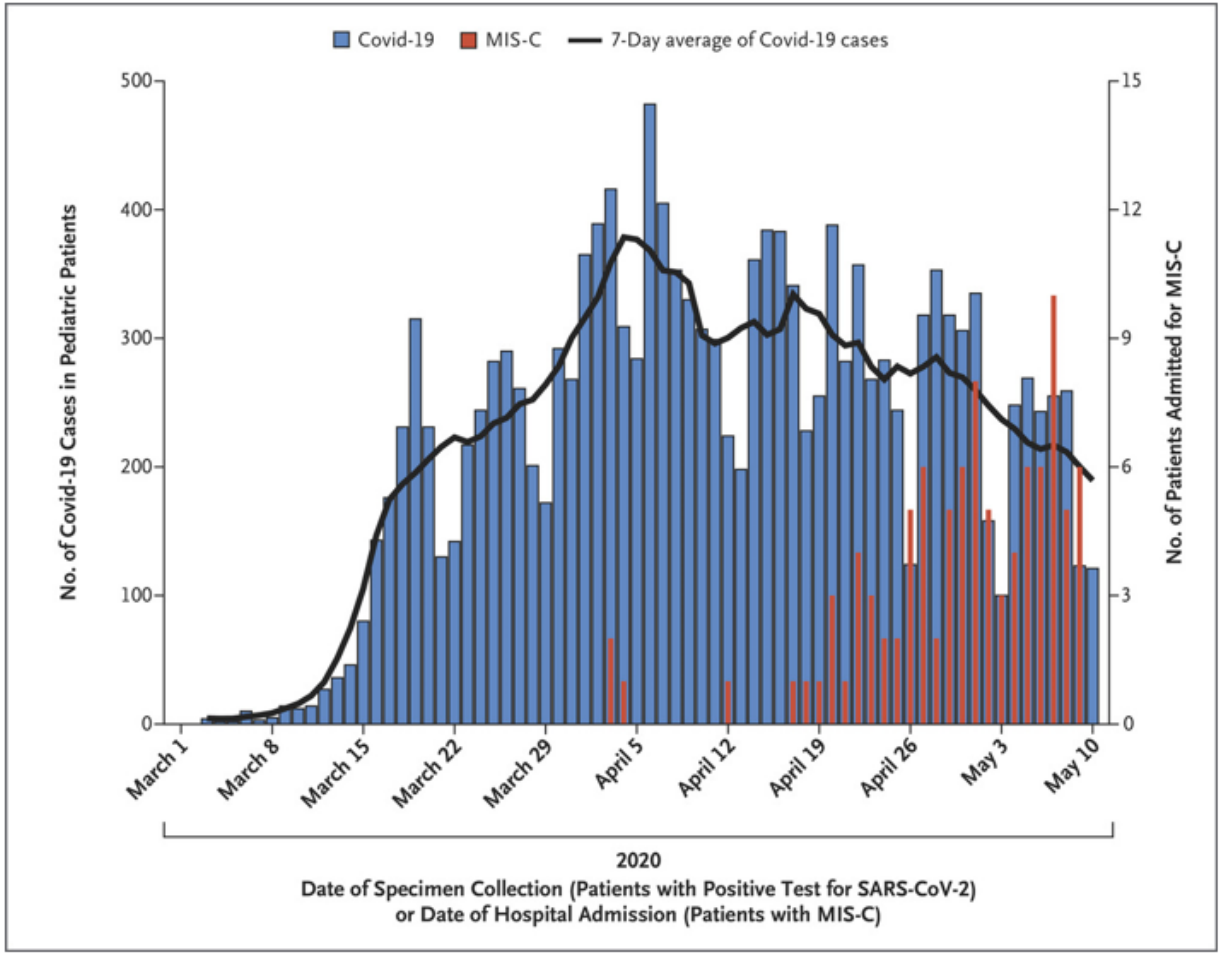
Multisystem Inflammatory Syndrome in Children in New York State

Elizabeth M. Dufort, M.D., Emilia H. Koumans, M.D., M.P.H., Eric J. Chow, M.D., M.P.H., Elizabeth M. Rosenthal, M.P.H., Alison Muse, M.P.H., Jemma Rowlands, M.P.H., Meredith A. Barranco, M.P.H., Angela M. Maxted, D.V.M., Ph.D., Eli S. Rosenberg, Ph.D., Delia Easton, Ph.D., Tomoko Udo, Ph.D., Jessica Kumar, D.O., Wendy Pulver, M.S., Lou Smith, M.D., Brad Hutton, M.P.H., Debra Blog, M.D., M.P.H., and Howard Zucker, M.D., for the New York State and Centers for Disease Control and Prevention Multisystem Inflammatory Syndrome in Children Investigation Team*

Columbia University College of Physicians and Surgeons

EM Dufort et al. N Engl J Med 2020. DOI: 10.1056/NEJMoa2021756

NewYork-Presbyterian Kids Morgan Stanley Children's Hospital


Covid-19
MIS-C
7-Day average of Covid-19 cases
No. of Covid-19 Cases in Pediatric Patients
No. of Patients Admitted for MIS-C
500
400
300
200
100
0
15
12
9
6
3
0
March 1
March 8
March 15
March 22
March 29
April 5
April 12
April 19
April 26
May 3
May 10
2020
Date of Specimen Collection (Patients with Positive Test for SARS-CoV-2)
or Date of Hospital Admission (Patients with MIS-C)

DISCLAIMER: SINGLE INSTITUTION APPROACH AND EXPERIENCE

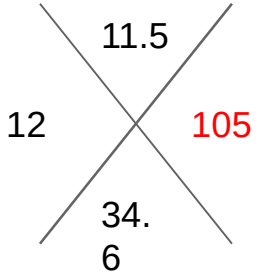
MIS-C at NYP Morgan Stanley Children's Hospital of Columbia Irving Medical Center

- First case in April 2020
- As of July 1, 2020, ~60 cases admitted
  - ~60% admitted to the PICU for shock and vasoactive support
  - Pediatric Intensive Care Unit (PICU) admission before 5/9/20 = 70%, after 5/9/20 = 40%
- Majority with no prior co-morbidities (~90%)
- Male 46%, median age 7 years (range 2 mos. - 20yrs)
- Caucasian 30%, Black 28%, Hispanic 30%, Unknown 12%

4 year-old Male, History of Mild Asthma with 4 days of Fever

- Fatigue and lethargy for 4 days, decreased oral intake
- Vomiting and diarrhea
- No respiratory symptoms, no rash
- Physical Exam: Tachycardic, hypotensive, dry mucous membranes, normal conjunctiva, no rash, soft abdomen, delayed capillary refill
- ED: Placed on high-flow nasal cannula, IVF resuscitation and antibiotics given, started on dopamine for BP 50/40's ➡ Transfer to PICU

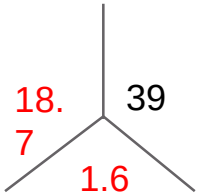
Admission Laboratory Data 1



Bands 24%
ALC 1 x10(3)/uL

Procalcitonin: 126.9
(< 0.08 ng/mL)

C-Reactive Protein:
>300
(< 10 mg/L)

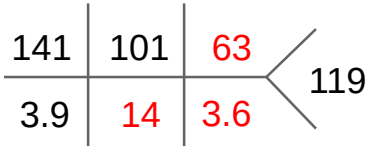


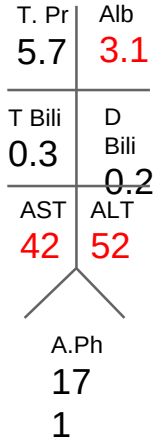
D-dimer: 1.39
(<=0.80 ug/mL)

Ferritin: 1195
(< 400.0 ng/mL)

NT-ProBNP 44677
(<327 pg/mL)

HS-Troponin-T: 85
(<=22 ng/L)

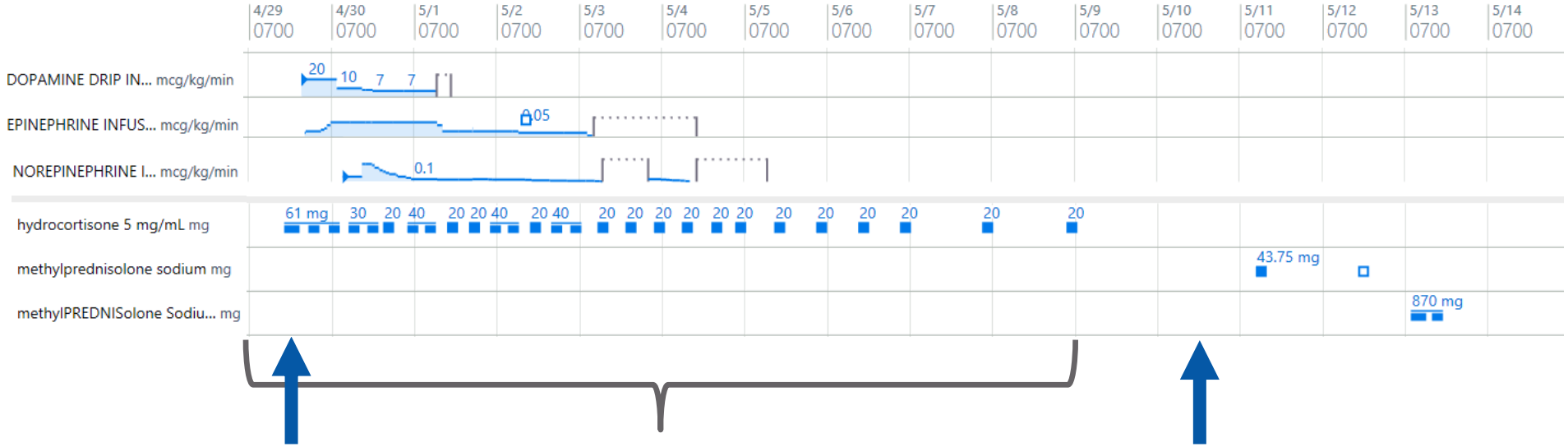




Blood culture:
pending

SARS-CoV-2 PCR
Not Detected

COVID-19 Serology
Positive



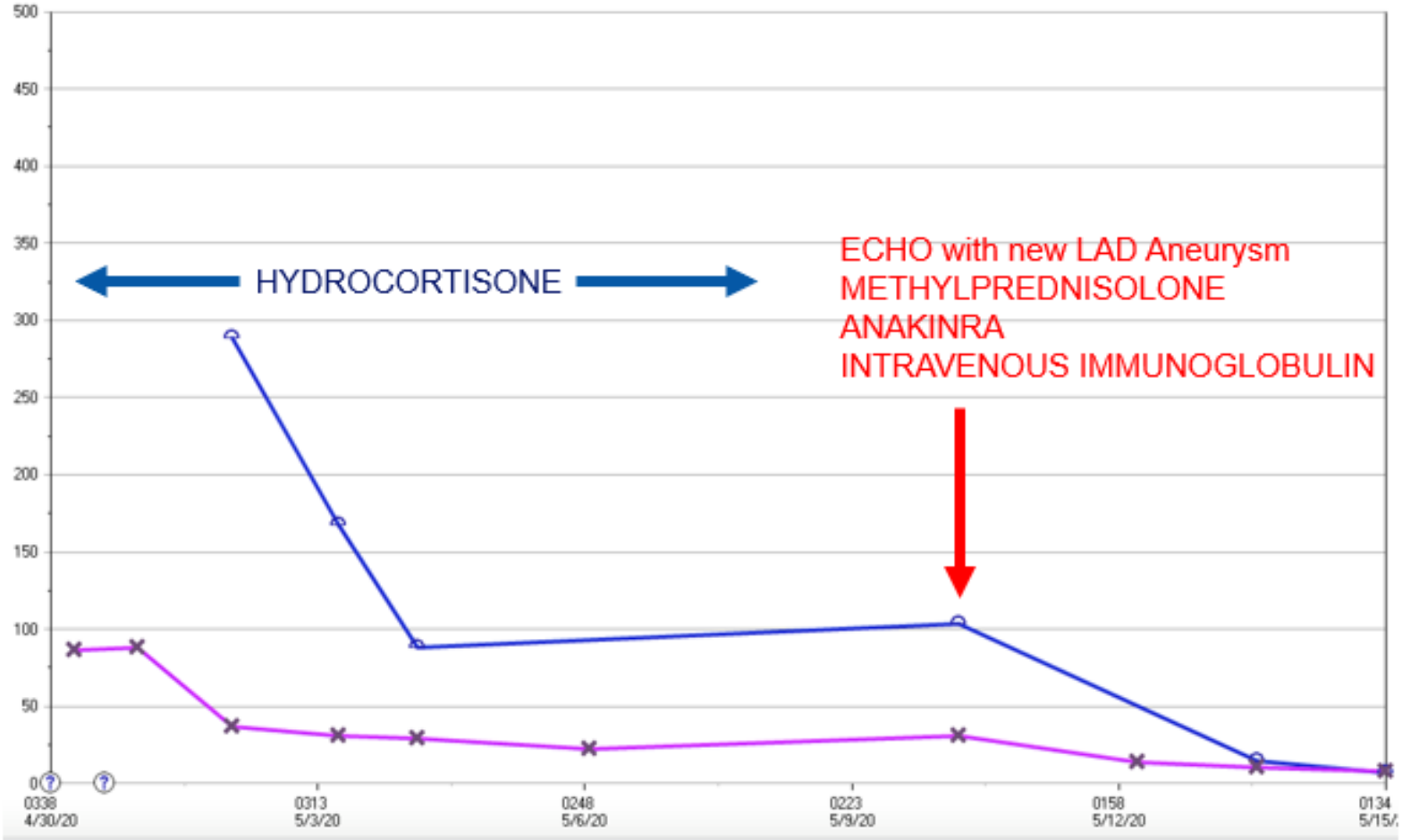
<u>Admission Echo:</u>

- Normal LV function
- Trivial pericardial effusion
- Normal coronary arteries

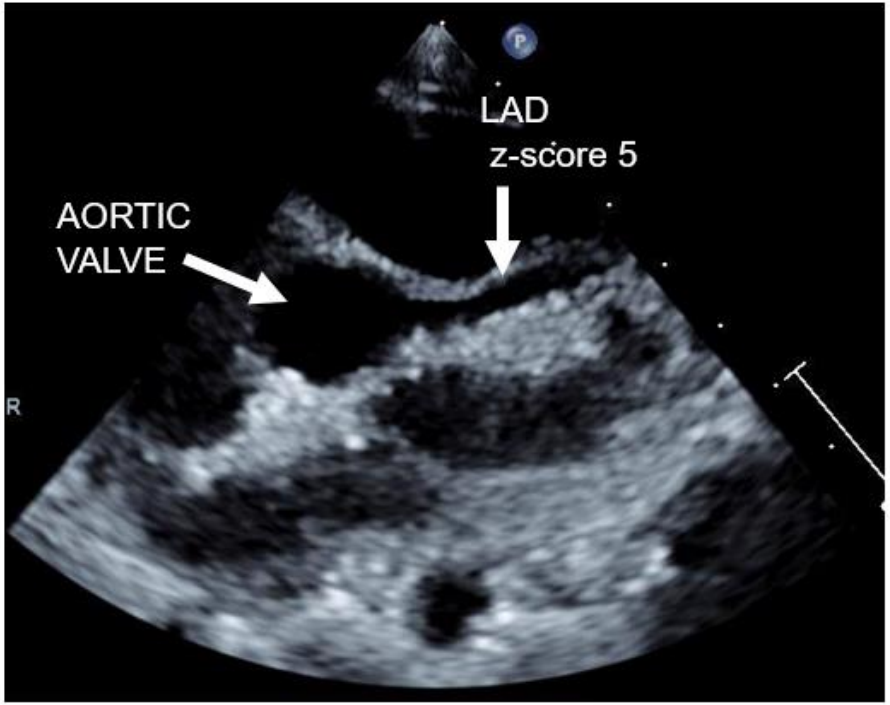
<u>PICU Course:</u>

- High-dose vasopressors for 6 days
- Ceftriaxone x 10 days (BCx neg)
- Improved creatinine with IVF hydration
- Enoxaparin prophylaxis
- HFNC/NIPPV respiratory support

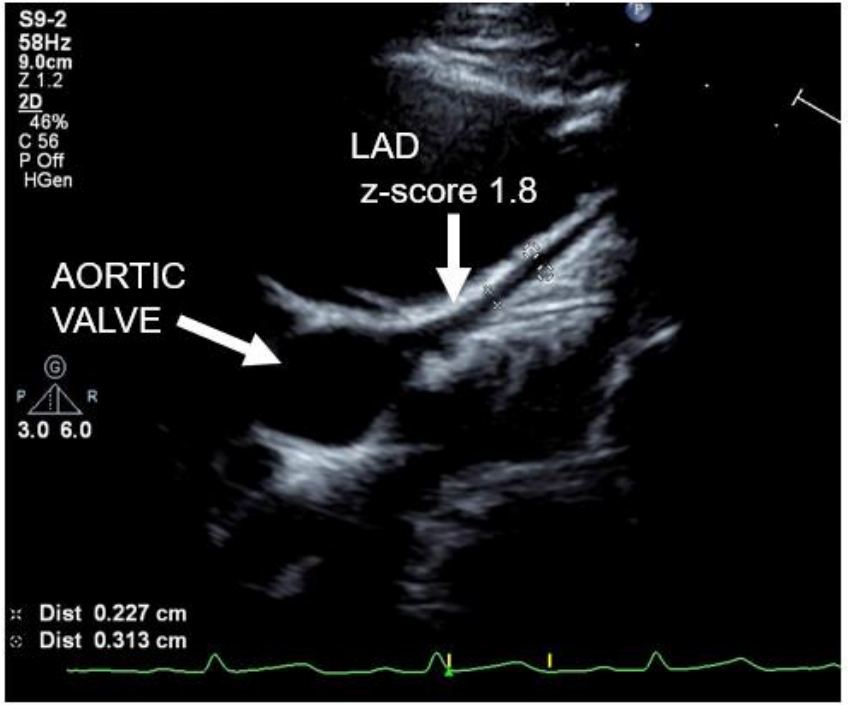
- Inflammatory and cardiac biomarkers trended up
- Echo with new LAD aneurysm (z-score 5).
- IVIG 2g/kg
- Anakinra 100mg subQ daily x 5 days
- Methylprednisolone 20mg/kg once – prednisone taper


500
450
400
350
300
250
200
150
100
50
0
HYDROCORTISONE
ECHO with new LAD Aneurysm
METHYLPREDNISOLONE
ANAKINRA
INTRAVENOUS IMMUNOGLOBULIN
0338
4/30/20
0313
5/3/20
0248
5/6/20
0223
5/9/20
0158
5/12/20
0134
5/15/
C-reactive protein (< 10 mg/L)
Troponin-T (<=22 ng/L)

May 12, 2020



June 2, 2020



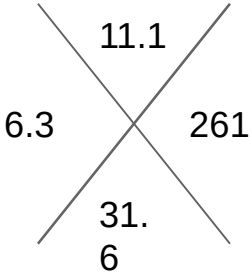
Lessons Learned from Experience with MIS-C in NYC

- Cases with clinical shock (+/- cardiac dysfunction) improved with early institution of methylprednisolone
  - Epidemiologic context of COVID-19 and likelihood of MIS-C needs to be balanced with the likelihood of other causes of shock (e.g., bacterial sepsis, HLH)
- Standardized echo protocols to thoroughly and efficiently evaluate myocardial function and coronary arteries are needed for suspected MIS-C cases
  - Cardiac evaluation is suggested early upon admission, serially throughout hospitalization and after discharge (2 weeks, 6 weeks, 6 months and 1-year post-discharge)
- Inflammatory (e.g, C-reactive protein) and cardiac (troponin and NT-ProBNP) biomarkers should be trended, even in the recovery phase

3 year-old Male with 4 days of Fever and New Onset Rash

- Fever and abdominal pain for 4 days
- SARS-CoV-2 PCR+ at local urgent care center with known exposure to symptomatic COVID-19 positive family members one month ago
- No respiratory symptoms
- Physical Exam: Tachycardia, non-toxic appearing, normal conjunctiva, +cervical lymphadenopathy, macular rash on chest, hands and feet, soft abdomen, normal perfusion
- Admitted to general floor

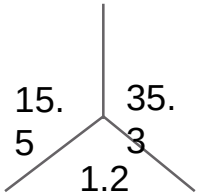
Admission Laboratory Data 2



Neut 75%
Lymph 18%

Procalcitonin: 1.27
(< 0.08 ng/mL)

C-Reactive Protein:
75.4
(< 10 mg/L)

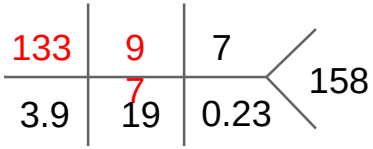


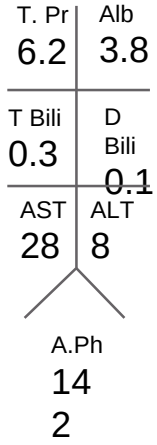
D-dimer: 4.1
(<=0.80 ug/mL)

Ferritin: 178
(< 400.0 ng/mL)

NT-ProBNP 773
(< 327 pg/mL)

HS-Troponin-T: <6
(<=22 ng/L)





Blood culture:
pending

SARS-CoV-2 PCR
Detected

COVID-19 Serology
Positive

3 year-old Male with 4 days of Fever and New Onset Rash

- Continued fever and rash the next day
- Echo: LV EF 55%, trivial pericardial effusion, normal coronary arteries
- Trended laboratory data …
  - C-reactive protein 75.4 → 140.4
  - Troponin-T < 6 → 39
  - NT-ProBNP 773 → 12463
- Methylprednisolone 2 mg/kg/day and IVIG 2 g/kg
- Afebrile, resolved rash and abdominal pain
- Discharged home 2 days later on ASA 81mg and prednisone taper

CLASSIFICATION OF CLINICAL SEVERITY

- **Mild:** No vasoactive requirement, minimal/no respiratory support, minimal organ injury
- **Moderate:** Vasoactive-inotropic score** (VIS) ≤ 10, significant supplemental oxygen requirement, mild or isolated organ injury
- **Severe:** Vasoactive-inotropic score > 10, non-invasive or invasive ventilatory support, moderate or severe organ injury including moderate to severe ventricular dysfunction

**See supplement for instructions on VIS calculation

MANAGEMENT BY CLINICAL SEVERITY

Therapeutic Category	Mild	Moderate	Severe
Steroid Initial Dosing For 2mg/kg/day dosing: max 60mg/day For pulse dosing: max 1g/day	Methylprednisolone 2mg/kg/day	Methylprednisolone 10mg/kg x1, then 2mg/kg/day	Methylprednisolone 20-30mg/kg/day for 1-3 days, then 2mg/kg/day
Other Immunomodulation (see "Other Management Considerations" below for specific guidance) For Anakinra dosing: 2-10mg/kg/dose (max 100mg/dose) up to q6h frequency	Consider pulse Methylprednisolone or Anakinra if refractory illness course	Consider 1-3 days pulse Methylprednisolone, consider Anakinra if refractory to steroids	Consider Anakinra if refractory to steroids, consider other biologics if refractory to Anakinra
Anticoagulation - monitor for bleeding, thrombocytopenia, coagulopathy LMWH = low molecular-weight heparin ASA = aspirin	LMWH prophylaxis **or** low-dose ASA	LMWH prophylaxis **or** low-dose ASA	LMWH prophylaxis **or** low-dose ASA
GI prophylaxis with proton pump inhibitor	Yes	Yes	Yes
Broad-spectrum antibiotics (see "Other Management Considerations" below for specific guidance)	Yes	Yes	Yes
Steroid Taper	2-3 weeks	6-8 weeks	Steroid taper with subspecialty consultation

[ǂ] Treatment may be deferred (if cardiac evaluation is normal) with close clinical observation and serial trending of inflammatory and cardiac biomarkers.

Jonat B, et al. (in review)

Lessons Learned from Experience with MIS-C in NYC

- General pediatricians and emergency rooms faced challenges in evaluating and triaging patients with “mild” MIS-C symptoms:
  - No symptoms of shock and normal EKG/Echo
  - Close clinical observation and trending of laboratory data indicated
  - Consider full MIS-C work up and treatment if meets American College of Rheumatology Clinical Guidance Criteria*.
- “A few days of abdominal pain and low-grade fever but is better and asymptomatic now” – What do you do? Is this MIS-C?
  - Do you refer into the ER? (only if currently symptomatic or ill-appearing)
  - Do you refer for laboratory evaluation? (probably yes)
  - Do you refer for cardiology evaluation? (it depends)

*https://www.rheumatology.org/Portals/0/Files/ACR-COVID-19-Clinical-Guidance-Summary-MIS-C-Hyperinflammation.pdf

MIS-C Treatment and Outcomes at NYP Morgan Stanley Children's Hospital of Columbia Irving Medical Center

TREATMENT	ALL PATIENTS	ADMITTED to PICU
Methylprednisolone AND IVIG	67%	81%
Methylprednisolone only	9%	13%
IVIG only	17%	3%
Supportive Treatment only	7%	3%

- No mechanical ventilation, no mechanical circulatory support, no mortality
- Median Hospital Length of Stay = 4 days (1-19 days)
- Post-discharge follow-up in 76% of patients (avg 22 days, range 11-62 days):
  - 95% Echo with normal function (1 with mild and 1 with moderate dysfunction)
  - All with normal coronary arteries

Summary of Lessons Learned

- Single institutional evaluation/treatment protocol and experience – more research is needed to understand treatment variations of MIS-C and how it may impact outcomes.
- Strongly encourage a multi-disciplinary team and protocol to uniformly screen, diagnose and treat MIS-C catered to institutional resources and expertise.
- Access to cardiology and intensive care (if shock or cardiac dysfunction present) is an important part of evaluation and management of MIS-C.
- Multi-disciplinary follow-up at discharge is essential to both understand and monitor disease progression.

Clinical Management of Multisystem Inflammatory Syndrome in Children (MIS-C)

Matt Oster, MD, MPH

EMORY
UNIVERSITY

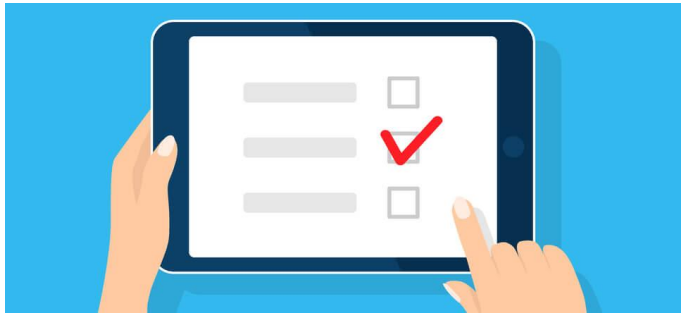
Disclosure

- This presentation represents work performed as part of my non-CDC duties

- The findings and conclusions in this presentation are those of the presenter and do not necessarily represent the official position of the Centers for Disease Control and Prevention

Survey

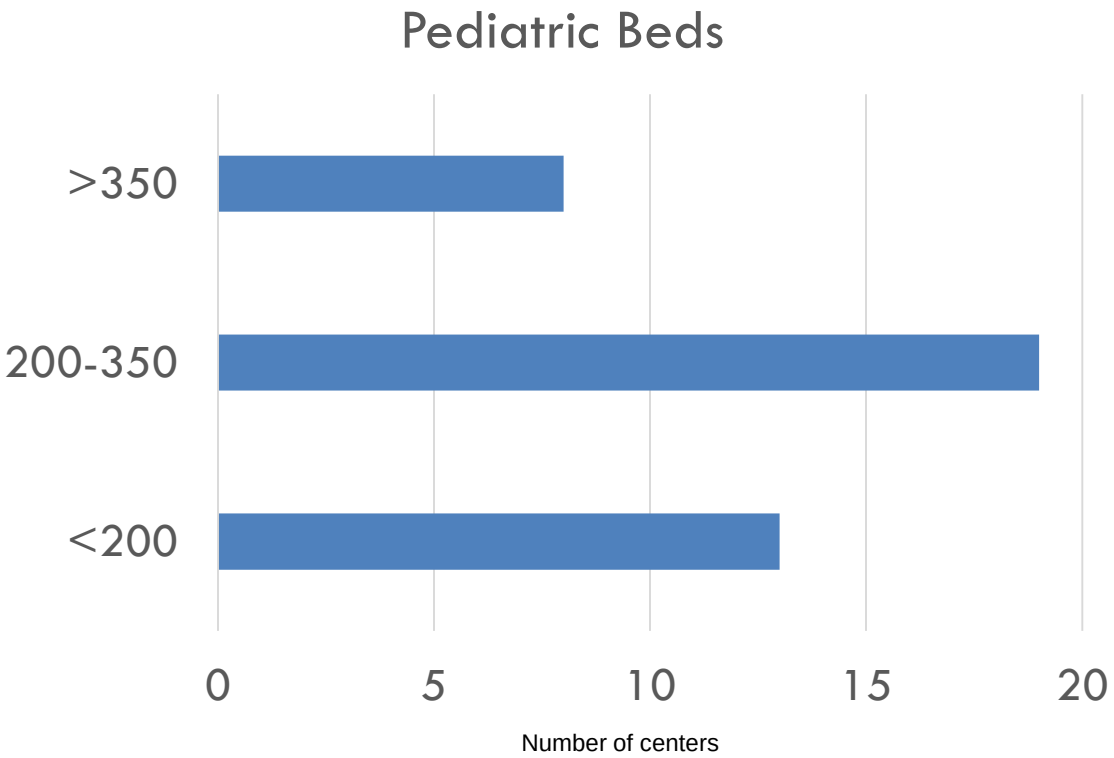
- Protocols for managing MIS-C at US institutions
- June 16 – July 6, 2020
- Elements:
  - Hospital Characteristics
  - Definition
  - Evaluation
  - Treatment
  - Follow-up



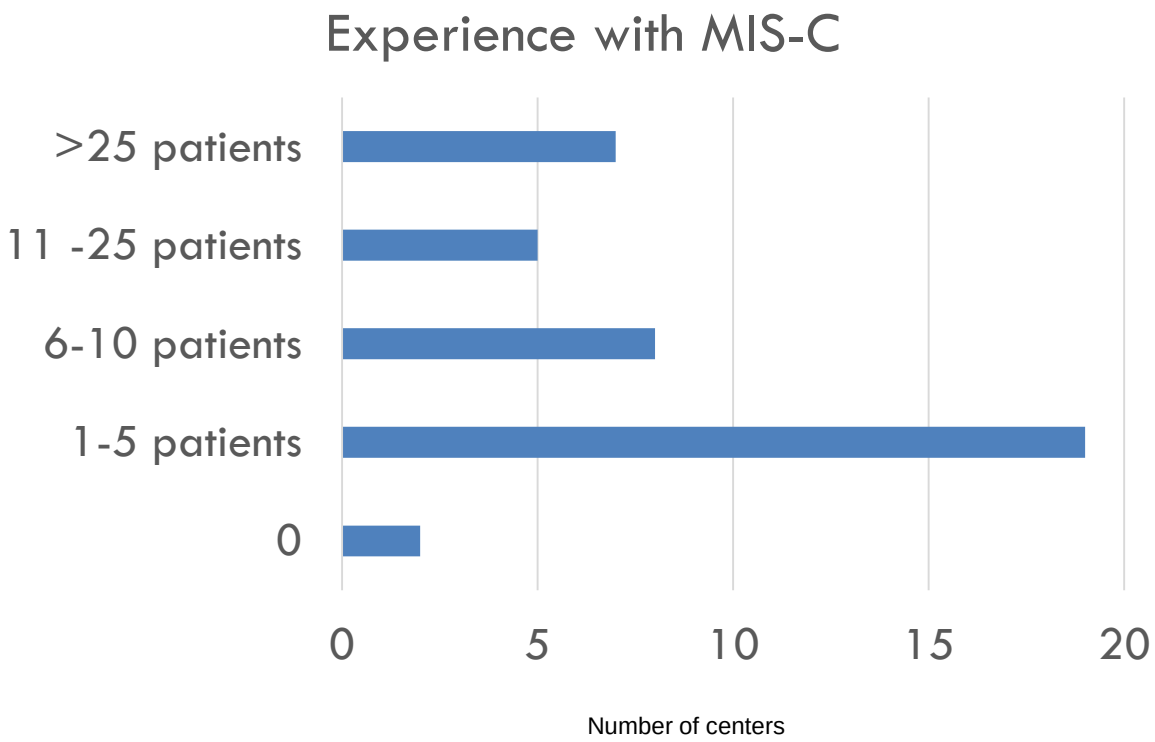
Participants

- 41 centers across the United States
- 35 with established protocols

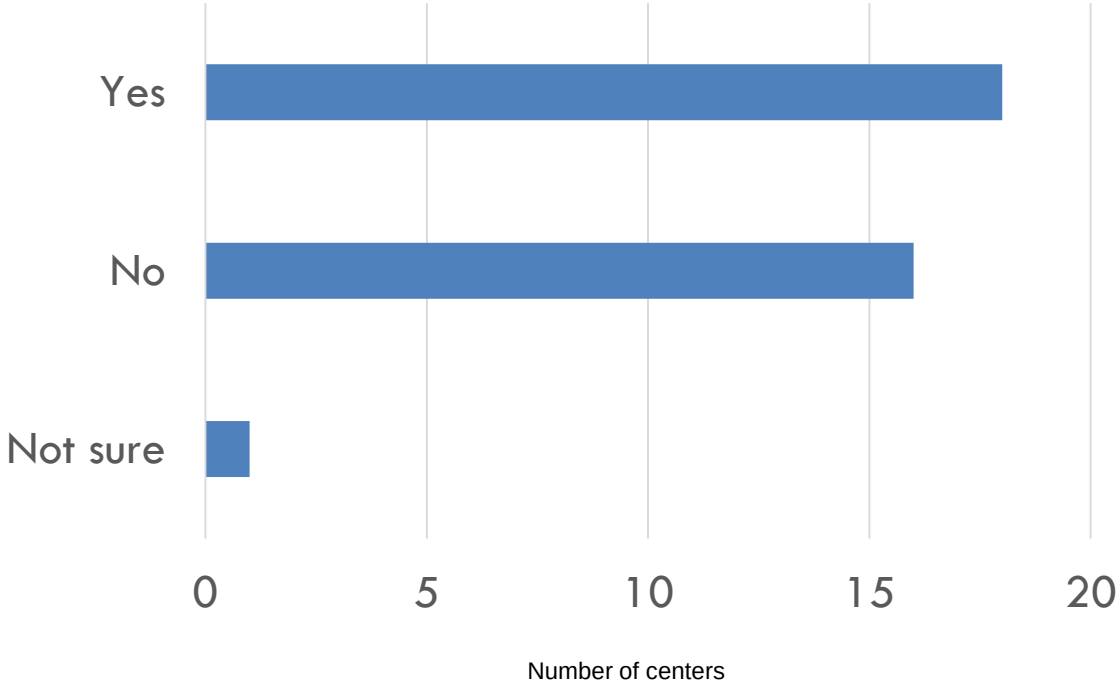
Participants: Pediatric Beds



Participants: Experience with MIS-C



Participants: Has Protocol Changed?



CDC: Multisystem Inflammatory Syndrome

Case Definition for Multisystem Inflammatory Syndrome in Children (MIS-C)

- An individual aged <21 years presenting with fever[i], laboratory evidence of inflammation[ii], and evidence of clinically severe illness requiring hospitalization, with multisystem (≥2) organ involvement (cardiac, renal, respiratory, hematologic, gastrointestinal, dermatologic or neurological); **AND**

- No alternative plausible diagnoses; **AND**

- Positive for current or recent SARS-CoV-2 infection by RT-PCR, serology, or antigen test; or COVID-19 exposure within the 4 weeks prior to the onset of symptoms

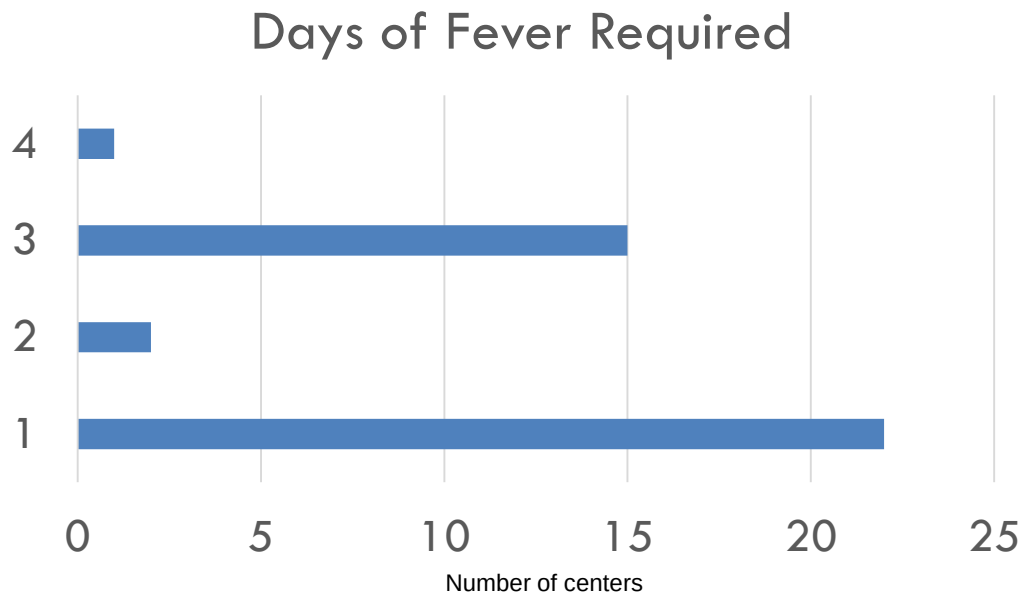
[i]Fever ≥38.0°C for ≥24 hours, or report of subjective fever lasting ≥24 hours

[ii]Including, but not limited to one or more; an elevated C-reactive protein (CRP), erythrocyte sedimentation rate (ESR), fibrinogen, procalcitonin, d-dimer, ferritin, lactic acid dehydrogenase (LDH), or interleukin 6 (IL-6), elevated neutrophils, reduced lymphocytes and low albumin

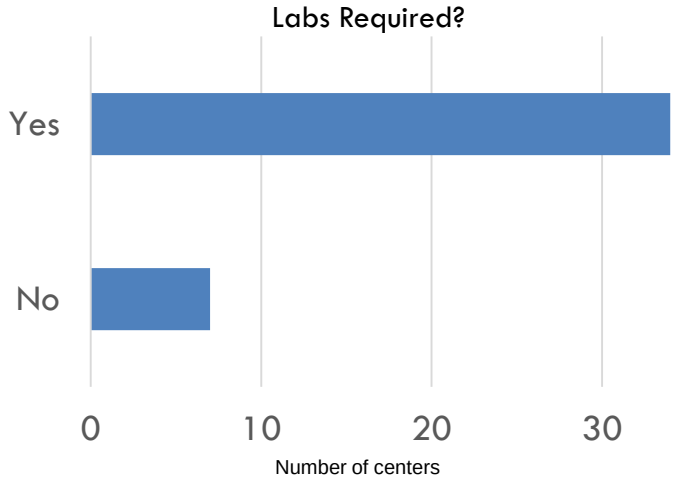
Additional comments

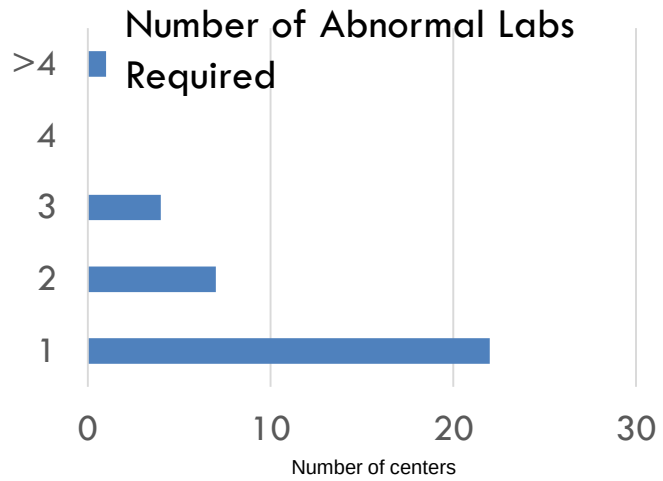
- Some individuals may fulfill full or partial criteria for Kawasaki disease but should be reported if they meet the case definition for MIS-C
- Consider MIS-C in any pediatric death with evidence of SARS-CoV-2 infection

Case Definition: Days of Fever

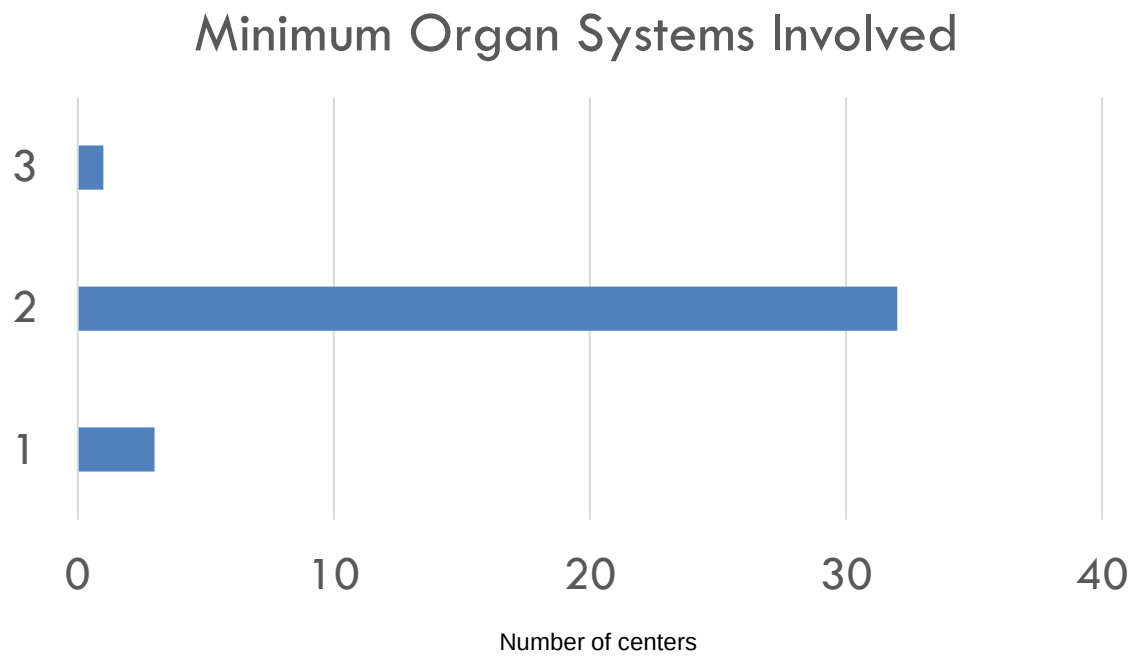


Case Definition: Labs



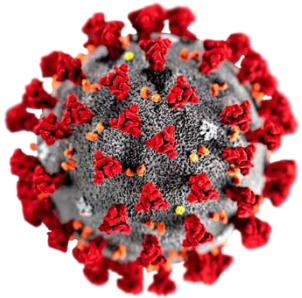


Case Definition: Minimum Organ Systems



Case Definition: COVID Link

- Most require either:
  - SARS-CoV-2 PCR *or*
  - SARS-CoV-2 Antibody *or*
  - Known exposure to someone with COVID



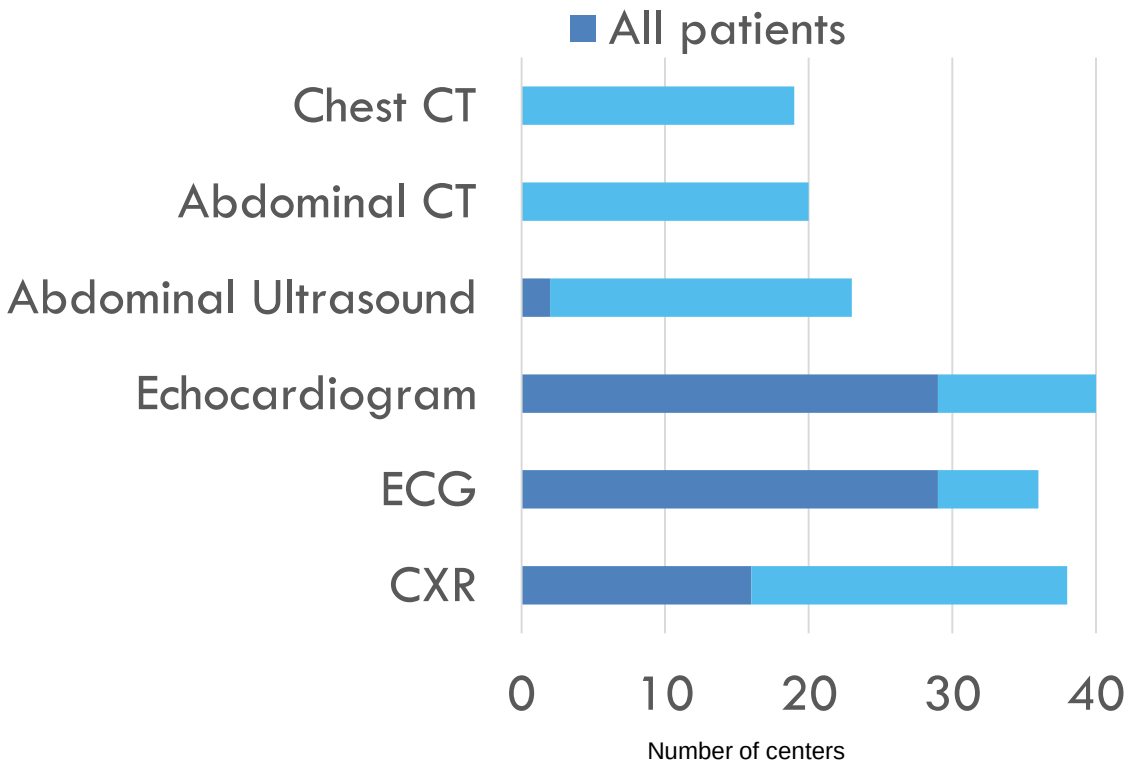
BUT: In hotspot areas, some centers work under the assumption that all are exposed, so this requirement is not necessary

Evaluation: Bloodwork

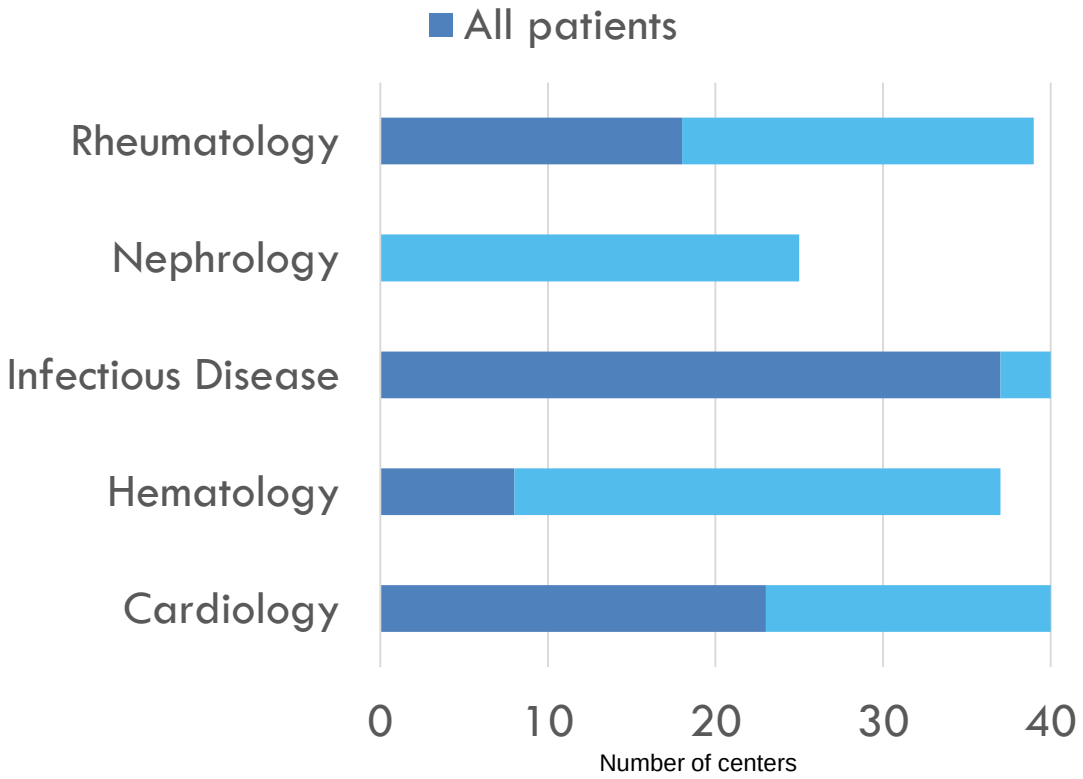
Common bloodwork

- CRP, ESR
- Ferritin, D-dimer
- CMP
- CBC
- Troponin, BNP/pro-BNP
- Coagulation tests
- Blood culture
- Respiratory viral panel

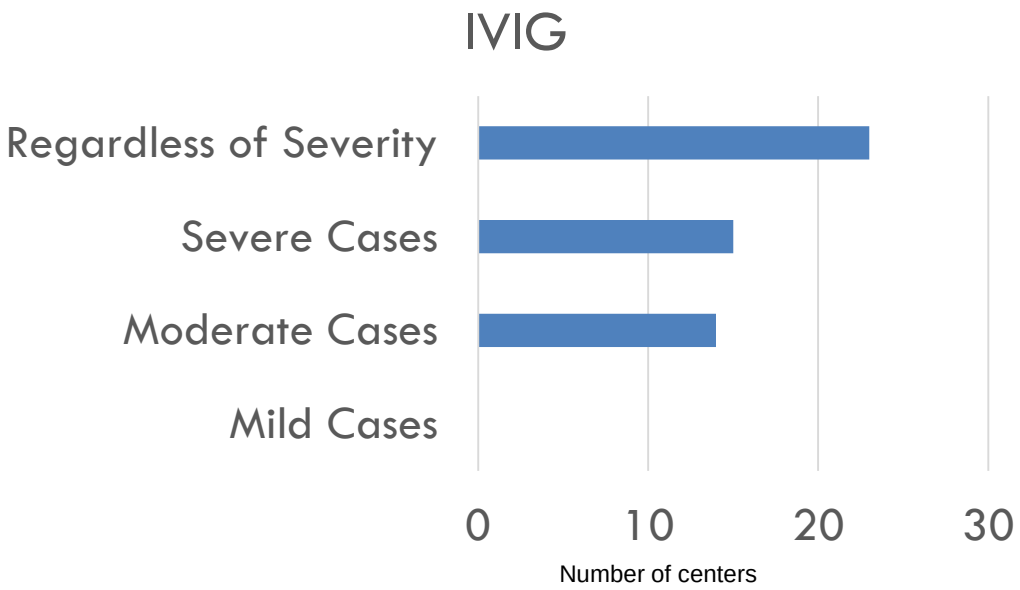
Evaluation: Other Tests



Evaluation: Consultants

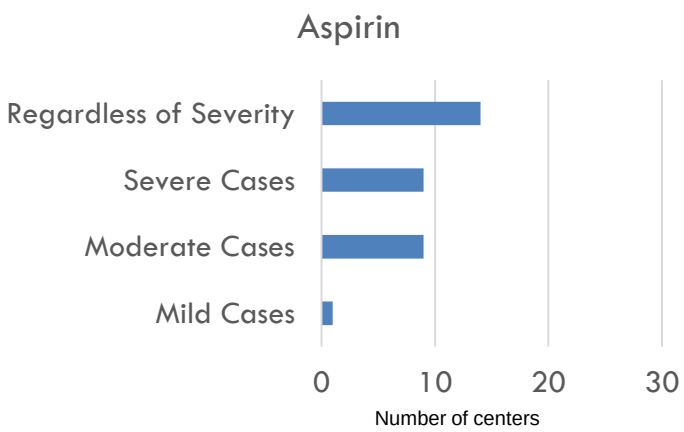


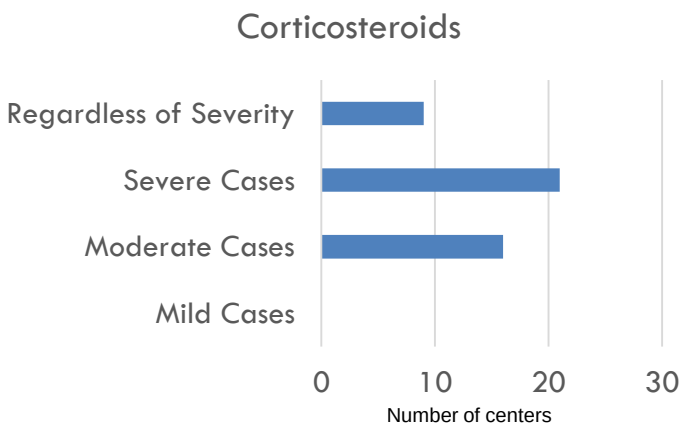
Treatment (information provided by 39 centers)

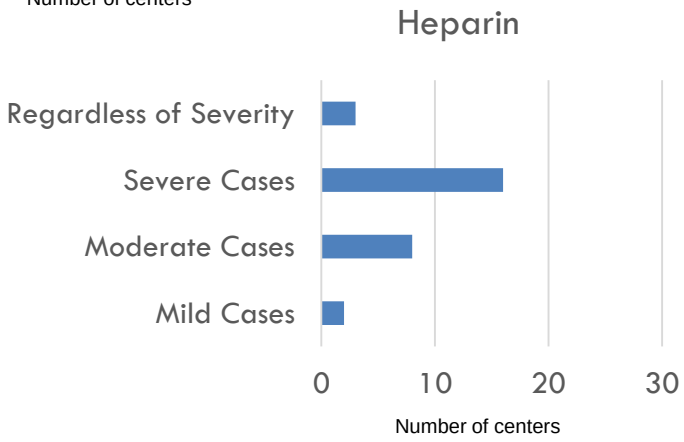


- Of the 38 centers using IVIG, 22 recommend a 2nd dose if refractory to 1st dose
- Definition of severity varied widely

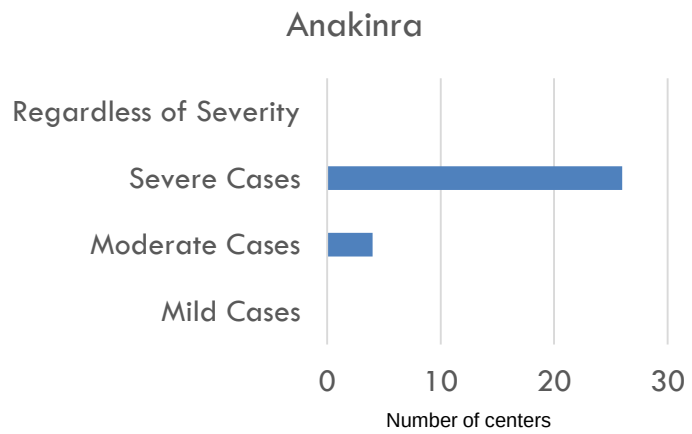
Treatment: Common Drugs

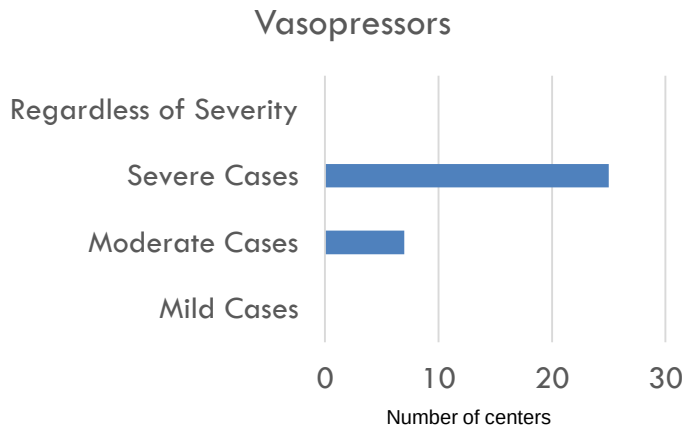






Treatment: For Severe Cases



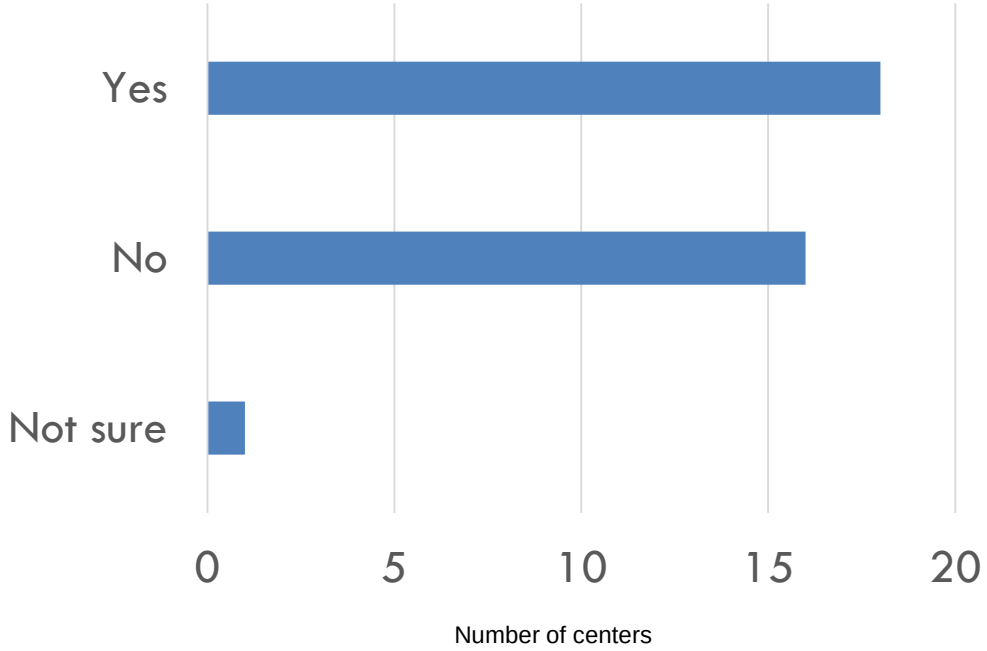


Treatment: Rarely Used

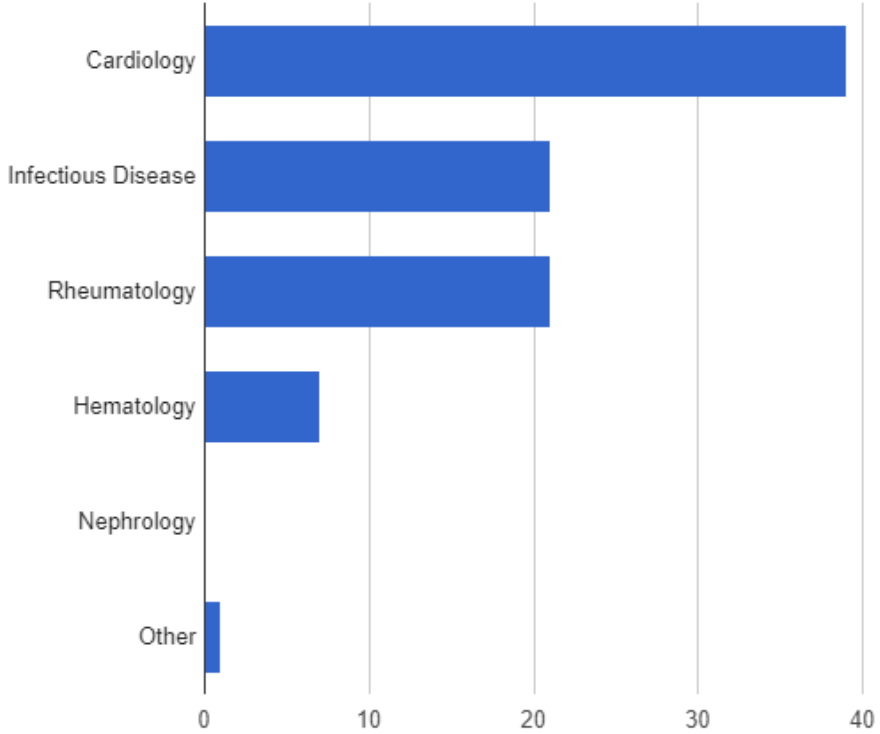
Reported by <20 centers

- Tocilizumab (11)
- Remdesivir (11)
- Warfarin (6)
- Clopidogrel (5)
- Hydroxychloroquine (1)

Follow-Up: Per AHA Kawasaki Guidelines?



Follow-Up: Clinic Visits



Conclusions

- Much variability in the evaluation and management of patients

- Common themes:
  - It takes a team approach
  - IVIG and aspirin are common regardless of severity Steroids are common in severe cases
  - Follow-up currently similar to Kawasaki guidelines

- Protocols change often, and care is often individualized

Acknowledgments

- Children's Healthcare of Atlanta/Emory
  - Matthew Dove, MD
  - Preeti Jaggi, MD
  - Mike Kelleman, MS

- Participants at collaborating centers

American College of Rheumatology:
Clinical Guidance for Pediatric Patients with MIS-C Associated with SARS-CoV-2 and Hyperinflammation in COVID-19

Adriana Tremoulet, MD, MAS
Associate Director, Kawasaki Disease Research Center
Professor, Dept. of Pediatrics, UCSD

Rady Children's Hospital San Diego

Kawasaki Disease Research Center
Rady Children's Hospital/UC San Diego

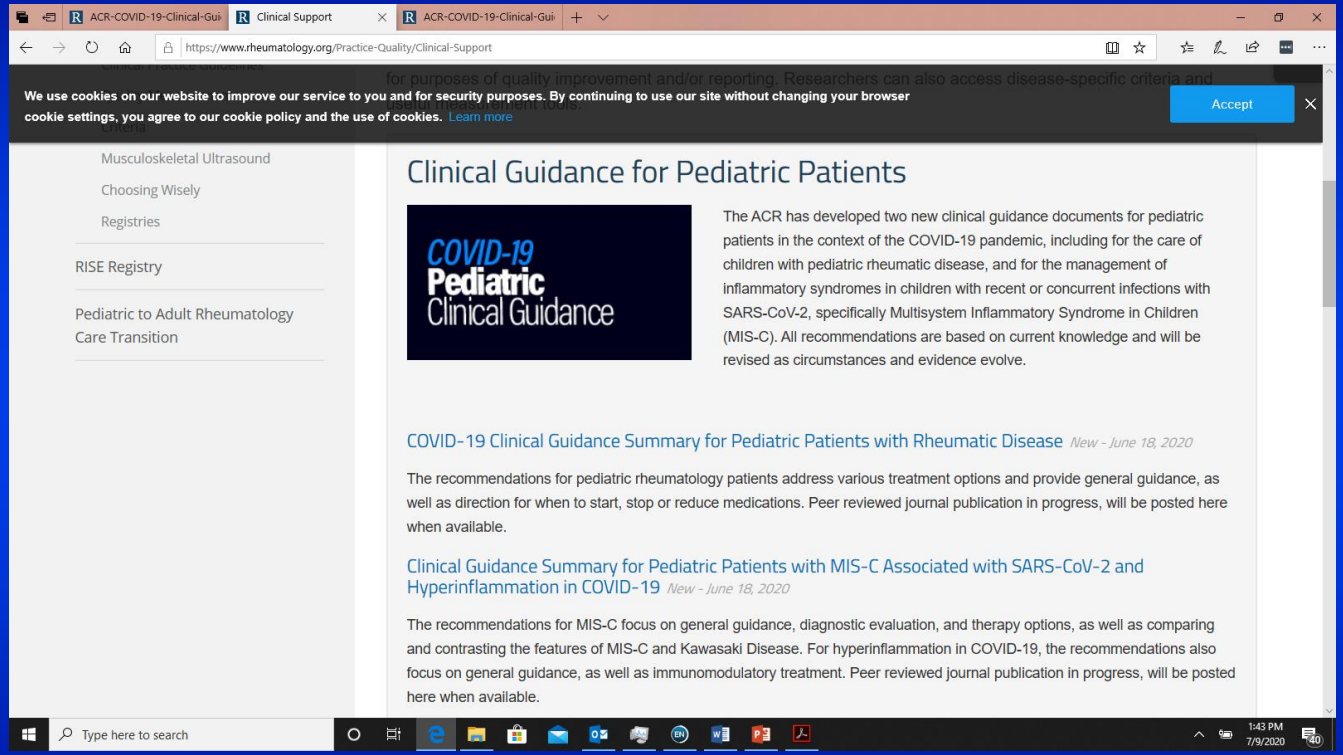
University of California San Diego

Disclosure

- ACR provided stipend to task force members for participation

Where is this document?

www.rheumatology.org



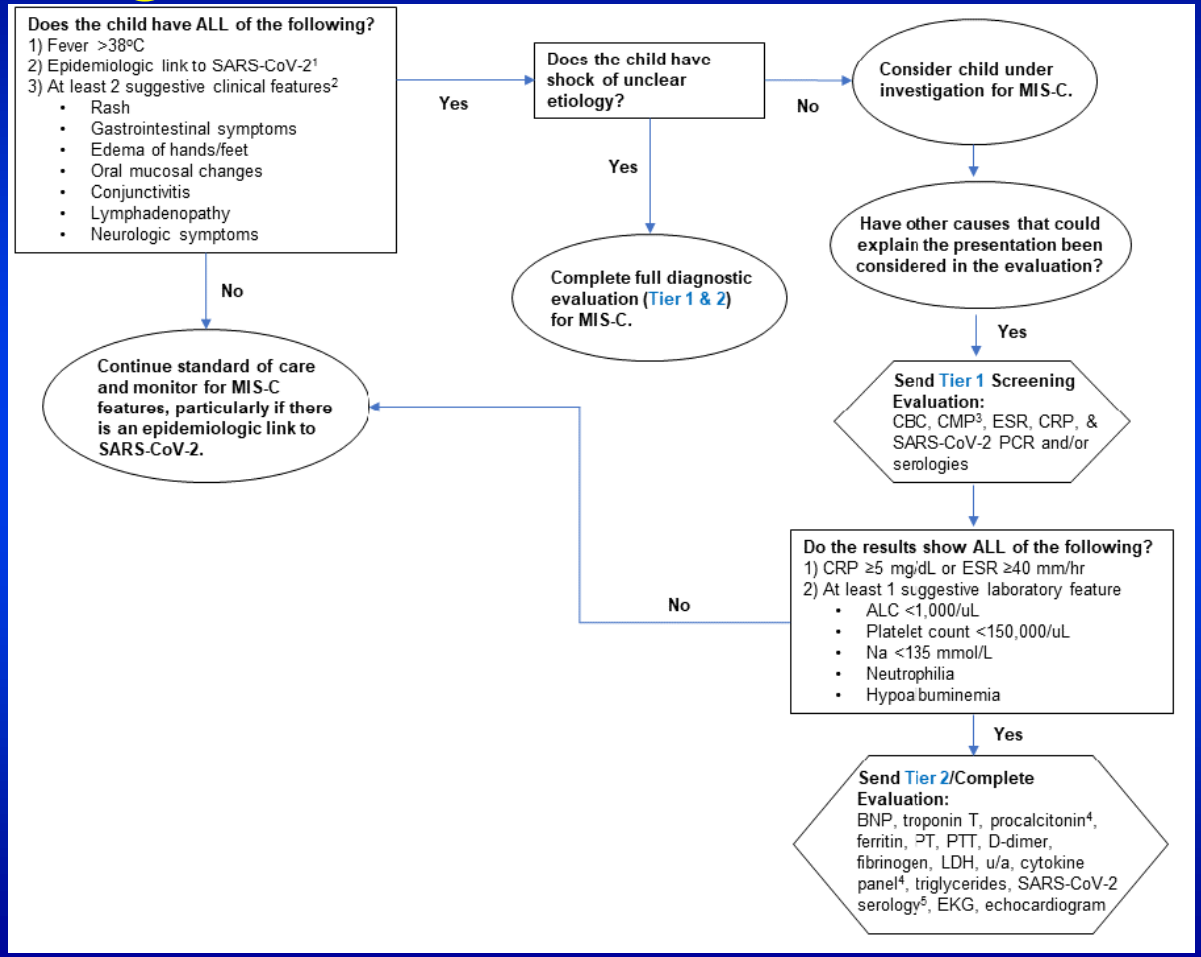
Purpose & Methods

- Goals: Identify the most appropriate
  - (1) diagnostic and therapeutic steps for MIS-C
  - (2) Recommendations for children with hyperinflammation due to COVID-19 respiratory illness
- ACR Task Force
  - » 9 pediatric rheumatologists
  - » 2 adult rheumatologists
  - » 2 pediatric cardiologists
  - » 2 pediatric infectious disease specialists
  - » 1 pediatric critical care physician

Purpose & Methods (continued)

- Consensus built on 2 rounds of anonymous voting
- Used existing case definitions of MIS-C
- Guidance reflects available evidence through late May 2020

Diagnostic Evaluation of MIS-C



Diagnostic Evaluation of MIS-C (continued)

- Outpatient eval may be appropriate if stable vitals, reassuring exam and close f/u
- Considerations for admission:
  - » Abnormal vitals (tachycardia)
  - » Neurological deficits, AMS; renal/hepatic injury
  - » Markedly elevated inflammatory markers
  - » Abnormal EKG, BNP or troponin
- Management of MIS-C requires a multi-disciplinary approach

Comparing and Contrasting Features of MIS-C and KD

- Patients with Kawasaki disease (KD) unrelated to SARS-CoV-2 illness continue to require eval and treatment
- Differences between KD and MIS-C
  - Ethnic/racial differences
  - MIS-C patients are older, have more prominent GI/neuro sxs, more cardiac dysfunction
  - Patients with MIS-C have lower platelet counts, lower absolute lymphocyte count and higher CRP

Cardiac Management of MIS-C

- Abnl BNP/troponin on admission should be trended until normal
- EKG every 48h while hospitalized; f/u at outpatient visits (2 and 6 weeks); if abnl then telemetry in hospital and Holter at f/u
- Echo at admission that includes ventricular function and coronary artery Z scores
- Echo at 2 and 6 week f/u
- Cardiac MRI at 2-6 months if LVEF<50%

Immunomodulatory Treatment in MIS-C

- Stepwise progression of therapies- first tier include low-dose steroids and/or IVIG
  - » Consider cardiac function and fluid status with IVIG
  - » Steroid taper should be over 3 weeks
- Other immunomodulatories include anakinra and higher dose steroids

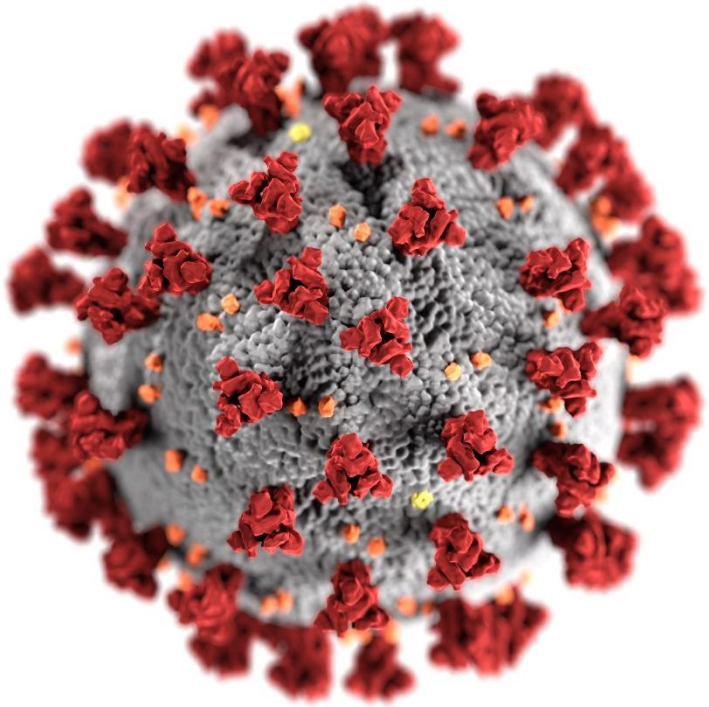
[Infliximab- not mentioned but has been used]

Antiplatelet & anticoagulation therapy in MIS-C

- Low dose aspirin (3-5 mg/kg/day; max 81mg)
  - » Continue until normal platelets/coronaries (~4 wks)
  - » Avoid if platelet count <80,000
- If coronary artery Z-score >10, add anticoagulation therapy
- If EF<35%, consider enoxaparin until 2 wks after discharge

Immunomodulatory Treatment in Children with COVID-19 Illness

- Consider immunomodulatory therapy in children with ARDS, shock, or significant inflammation
  - » Steroids and anakinra
  - » Tocilizumab (though may increase risk of bacterial and fungal infections



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  - Type your question in the **Q&A** box.
  - Submit your question.
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- **For more Clinical Care information on COVID-19**
  - **Call** COVID-19 Clinical Call Center at 770-488-7100 (24 hours/day).
  - **Refer** patients to state and local health departments for COVID-19 testing and test results.
    - Clinicians should NOT refer patients to CDC to find out where or how to get tested for COVID-19 OR to get test results.
  - **Visit** CDC's Coronavirus (COVID-19) website: https://www.cdc.gov/coronavirus.

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Date: Tuesday, July 28, 2020
Time: 2:00-3:00 PM ET

Topic: CDC COVID-19 Telehealth Guidance and Experiences from the Field

Date: Tuesday, August 4, 2020

Time: 2:00-3:00 PM ET

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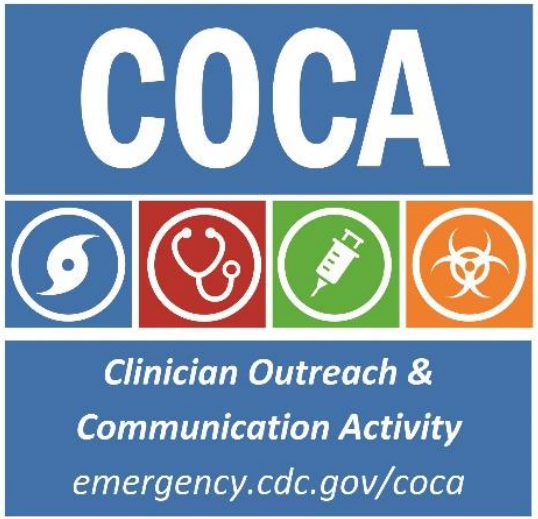

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