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FDA NEWS RELEASE

Coronavirus (COVID-19) Update: FDA Informs Public About Possible Accuracy Concerns with Abbott ID NOW Point-of-Care Test

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For Immediate Release: May 14, 2020

Today, the U.S. Food and Drug Administration is alerting the public to early data that suggest potential inaccurate results from using the Abbott ID NOW point-of-care test to diagnose COVID-19. Specifically, the test may return false negative results.

“We are still evaluating the information about inaccurate results and are in direct communications with Abbott about this important issue. We will continue to study the data available and are working with the company to create additional mechanisms for

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- The FDA has received 15 adverse event reports about the Abbott ID NOW device that suggest some users are receiving inaccurate negative results. The agency is reviewing these reports.

FDA NEWS RELEASE

Coronavirus (COVID-19) Update: Daily Roundup May 15, 2020

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For Immediate Release: May 15, 2020

The U.S. Food and Drug Administration today announced the following actions taken in its ongoing response effort to the COVID-19 pandemic:

- Today, the FDA issued an updated At-A-Glance that provides a quick look at facts, figures and highlights of agency's response efforts.
- The FDA issue a Consumer Update, Coronavirus Testing Basics, to provide information about the different types of tests available and the steps involved in obtaining results.
- The FDA and Federal Trade Commission (FTC) issued warning letters to two companies for selling fraudulent COVID-19 products, as part of the agency's effort to protect consumers. There are currently no FDA-approved products to prevent or treat COVID-19. Consumers concerned about COVID-19 should consult with their health care provider.
    - The first seller warned, Benjamin McEvoy, participates in the Amazon

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Coronavirus (COVID-19) Update: Daily Roundup May 15, 2020

- https://www.fda.gov/media/138094/download

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Coronavirus Testing Basics

You've probably heard a lot about coronavirus testing recently. If you think you have coronavirus disease 2019 (COVID-19) and need a test, contact your health care provider immediately. The FDA has been working around the clock to increase the availability of critical medical products, including tests for the coronavirus, to fight the COVID-19 pandemic. Learn more about the different types of tests and the steps involved.

There are two different types of tests – diagnostic tests and antibody tests.

A **diagnostic test** can show if you have an active coronavirus infection and should take steps to quarantine or isolate yourself from others. Currently there are two types of diagnostic tests – **molecular (RT-PCR) tests** that detect the virus's genetic material, and **antigen tests** that detect specific proteins on the surface of the virus.

An **antibody test** looks for antibodies that are made by the immune system in response to a threat, such as a specific virus. Antibodies can help fight infections. Antibodies can take several days or weeks to develop after you have an infection and may stay in your blood for several weeks after recovery. Because of this, antibody tests should not be used to diagnose an active coronavirus infection. At this time researchers do not know if the presence of antibodies means that you are immune to the coronavirus in the future.

	MOLECULAR TEST	ANTIGEN TEST	ANTIBODY TEST
Also known as...	Diagnostic test, viral test, molecular test, nucleic acid amplification tests (NAAT), RT-PCR tests	Rapid diagnostic test*	Serological test, serology, blood test, serology test
How the sample is taken...	Nasal or throat swab (most tests) Saliva (a few tests)	Nasal or throat swab	Finger stick or blood draw

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Multisystem Inflammatory Syndrome in Children (MIS-C) Associated with Coronavirus Disease 2019 (COVID-19)

Distributed via the CDC Health Alert Network
May 14, 2020, 4:45 PM ET
CDCHAN-00432

Summary

The Centers for Disease Control and Prevention (CDC) is providing 1) background information on several cases of a recently reported multisystem inflammatory syndrome in children (MIS-C) associated with coronavirus disease 2019 (COVID-19); and 2) a case definition for this syndrome. CDC recommends healthcare providers report any patient who meets the case definition to local, state, and territorial health departments to enhance knowledge of risk factors, pathogenesis, clinical course, and treatment of this 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 of the following: 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

Multisystem Inflammatory Syndrome in Children (MIS-C) Associated with Coronavirus Disease 2019 (COVID-19)

Overview

During this COCA call, clinicians will learn about the clinical characteristics of multisystem inflammatory syndrome in children, how cases have been diagnosed and treated, and how clinicians are responding to recently reported cases associated with COVID-19.

Presenters

Sapna Bamrah Morris, MD, MBA
Clinical Team Lead
COVID-19 Response
Centers for Disease Control and Prevention

Ermias Belay, MD
Special Investigations Team Lead
COVID-19 Response

Call Details

When: Tuesday, May 19, 2020, 2 p.m. to 3:30 p.m. (Eastern Time)

Watch on Facebook: You may also participate in this COCA Call by joining COCA's Facebook Live.

Webinar Link:
https://www.zoomgov.com/j/1602255337

Dial In:
US: +1 669 254 5252
or +1 646 828 7666

COVID-19 among children

US: 2% among persons age <18 years
China: 2.2% among persons age <19 years
Italy: 1.2% among persons age <18 years
Spain: 0.8% among persons age <18 years

Incubation period: 2-10 days in study of children in China

One study reported up to 13% of pediatric cases were asymptomatic

Largest study of children and COVID-19 (>2000 children):

- 5% Severe (dyspnea, central cyanosis, hypoxia)
- 0.6% Critical (acute respiratory distress syndrome [ARDS], respiratory failure, shock, or multi-organ dysfunction)

3 deaths in US (as of 4.2.2020) among children with laboratory-confirmed SARS-CoV-2 infection

https://www.cdc.gov/coronavirus/2019-ncov/hcp/pediatric-hcp.html

An outbreak of severe Kawasaki-like disease at the Italian epicentre of the SARS-CoV-2 epidemic: an observational cohort study

Lucio Verdoni, Angelo Mazza, Annalisa Gervasoni, Laura Martelli, Maurizio Ruggeri, Matteo Ciuffreda, Ezio Bonanomi, Lorenzo D'Antiga

Summary

Background The Bergamo province, which is extensively affected by the severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) epidemic, is a natural observatory of virus manifestations in the general population. In the past month we recorded an outbreak of Kawasaki disease; we aimed to evaluate incidence and features of patients with Kawasaki-like disease diagnosed during the SARS-CoV-2 epidemic.

Methods All patients diagnosed with a Kawasaki-like disease at our centre in the past 5 years were divided according to symptomatic presentation before (group 1) or after (group 2) the beginning of the SARS-CoV-2 epidemic. Kawasaki-like presentations were managed as Kawasaki disease according to the American Heart Association indications. Kawasaki disease shock syndrome (KDSS) was defined by presence of circulatory dysfunction, and macrophage activation syndrome (MAS) by the Paediatric Rheumatology International Trials Organisation criteria. Current or previous infection was sought by reverse-transcriptase quantitative PCR in nasopharyngeal and oropharyngeal swabs, and by serological qualitative test detecting SARS-CoV-2 IgM and IgG, respectively.

Findings Group 1 comprised 19 patients (seven boys, 12 girls; aged 3·0 years [SD 2·5]) diagnosed between Jan 1, 2015, and Feb 17, 2020. Group 2 included ten patients (seven boys, three girls; aged 7·5 years [SD 3·5]) diagnosed between Feb 18 and April 20, 2020; eight of ten were positive for IgG or IgM, or both. The two groups differed in disease incidence (group 1 *vs* group 2, 0·3 *vs* ten per month), mean age (3·0 *vs* 7·5 years), cardiac involvement (two of 19 *vs* six of ten), KDSS (zero of 19 *vs* five of ten), MAS (zero of 19 *vs* five of ten), and need for adjunctive steroid treatment (three of 19 *vs* eight of ten; all $p<0·01$).

Interpretation In the past month we found a 30-fold increased incidence of Kawasaki-like disease. Children diagnosed after the SARS-CoV-2 epidemic began showed evidence of immune response to the virus, were older, had a higher rate of cardiac involvement, and features of MAS. The SARS-CoV-2 epidemic was associated with high incidence of a severe form of Kawasaki disease. A similar outbreak of Kawasaki-like disease is expected in countries involved in the SARS-CoV-2 epidemic.

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See Online/Comment
https://doi.org/10.1016/S0140-6736(20)31129-6

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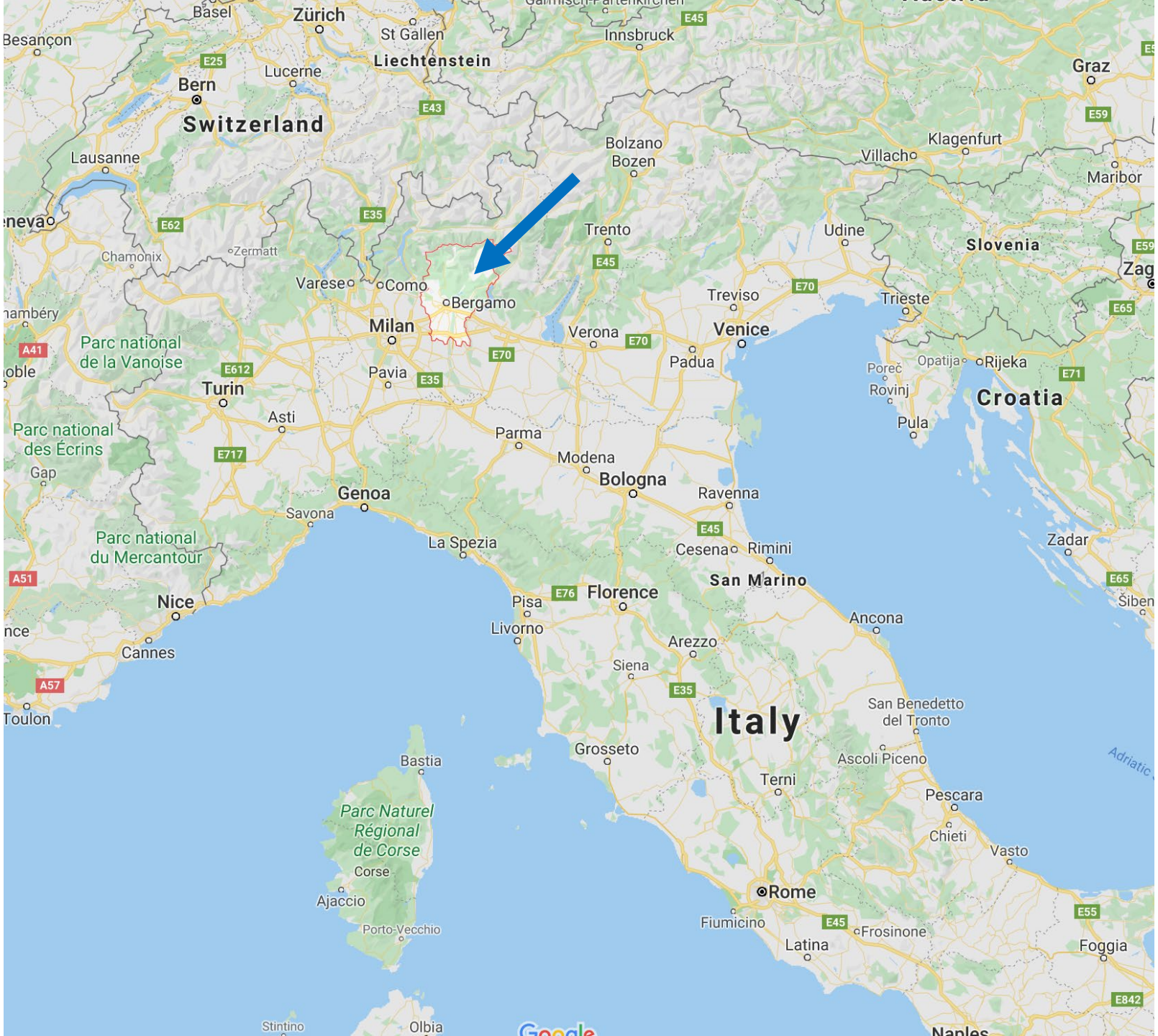
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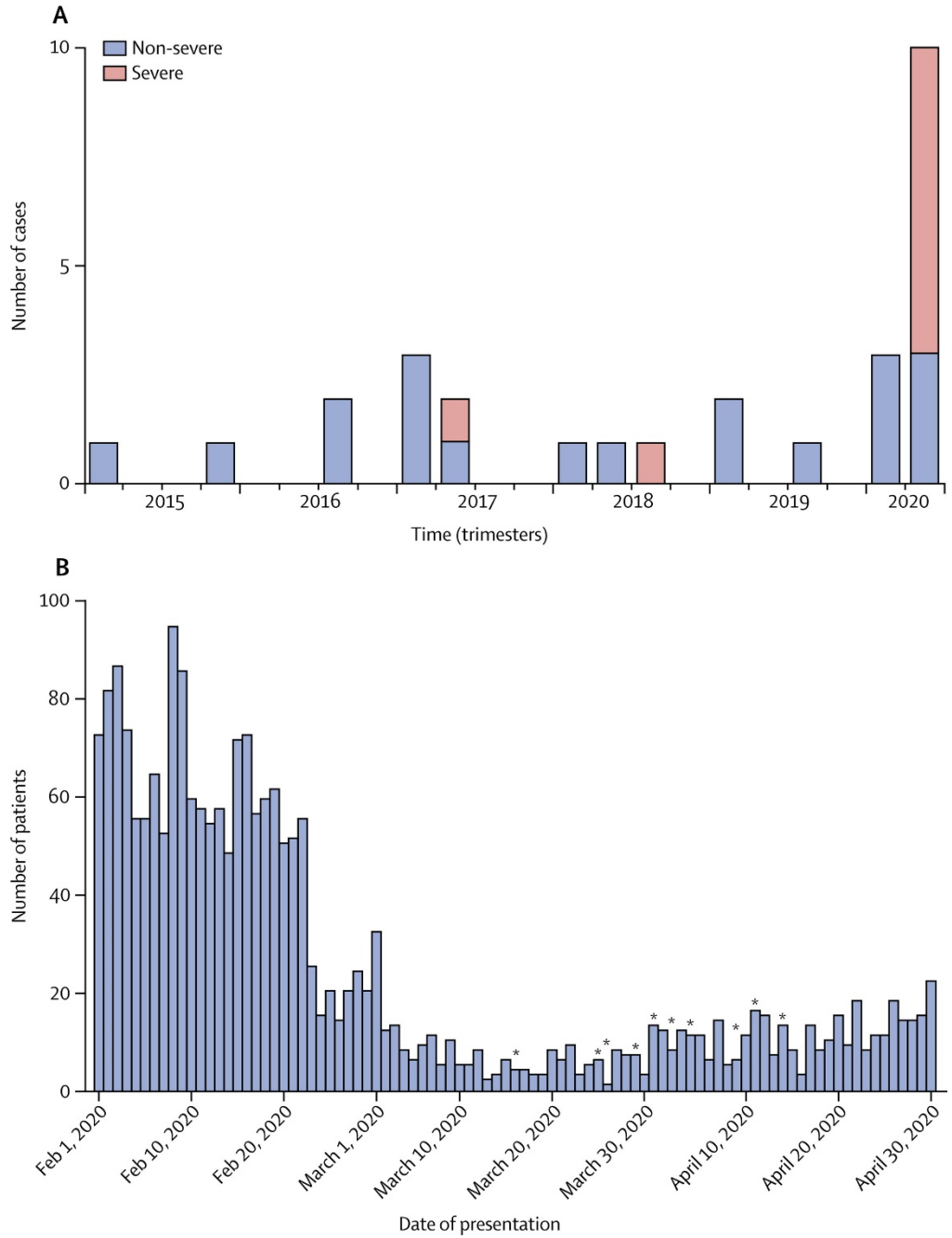
Naples

- Reviewed medical notes of patients 5 years before COVID-19 hit diagnosed with Kawasaki disease (Group 1: Jan. 1, 2015 to Feb. 17, 2020) and after COVID-19 (Group 2: Feb. 18, 2020 to Apr. 20, 2020).
- Group 1: n=19 patients (7 boys, 12 girls; aged 3·0 years [SD 2·5])
- Group 2: n=10 patients (7 boys, 3 girls; aged 7·5 years [SD 3·5])
  - 8 of 10 were positive for IgG or IgM, or both.

	Group 1, n=19 children	Group 2, n=10 children
Kawasaki disease	0.3 per month	10 per month
Mean age	3.0 years	7.5 years
Cardiac involvement	2	6
KDSS	0	5
MAS	0	5
Adjunctive Steroid tx	3	8


A
Non-severe
Severe
Number of cases
10
5
0
2015
2016
2017
2018
2019
2020
Time (trimesters)
B
Number of patients
100
80
60
40
20
0
Feb 1, 2020
Feb 10, 2020
Feb 20, 2020
March 1, 2020
March 10, 2020
March 20, 2020
March 30, 2020
April 10, 2020
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Guide to COVID-19 Guidelines, Information, and Websites as of May 13, 2020

Topics

Thank You