



COVID-19: KEEPING UP WITH A MOVING TARGET

Sep 2, 2020 UPDATE



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Name of Faculty or Presenter	Reported Financial Relationship
Paul G. Auwaerter, MD, MBA, FIDSA	Scientific Advisor: DiaSorin, Shionogi Inc. JNJ: Ownership equity

Dr. Auwaerter has indicated that he will be referencing the unlabeled or unapproved use of agents currently being investigated in on-going studies and trials. These include COVID-19 convalescent plasma.

All activity, content, and materials have been developed solely by the activity directors, planning committee members, and faculty presenters, and are free of influence from a commercial entity.





CME Information

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Learning Objectives

- Discuss the current data pertaining to COVID-19 infection in children
- Describe the expanded Emergency Use Authorization for remdesivir
- Discuss the challenges associated with the Emergency Use Authorization for convalescent plasma





Thank You

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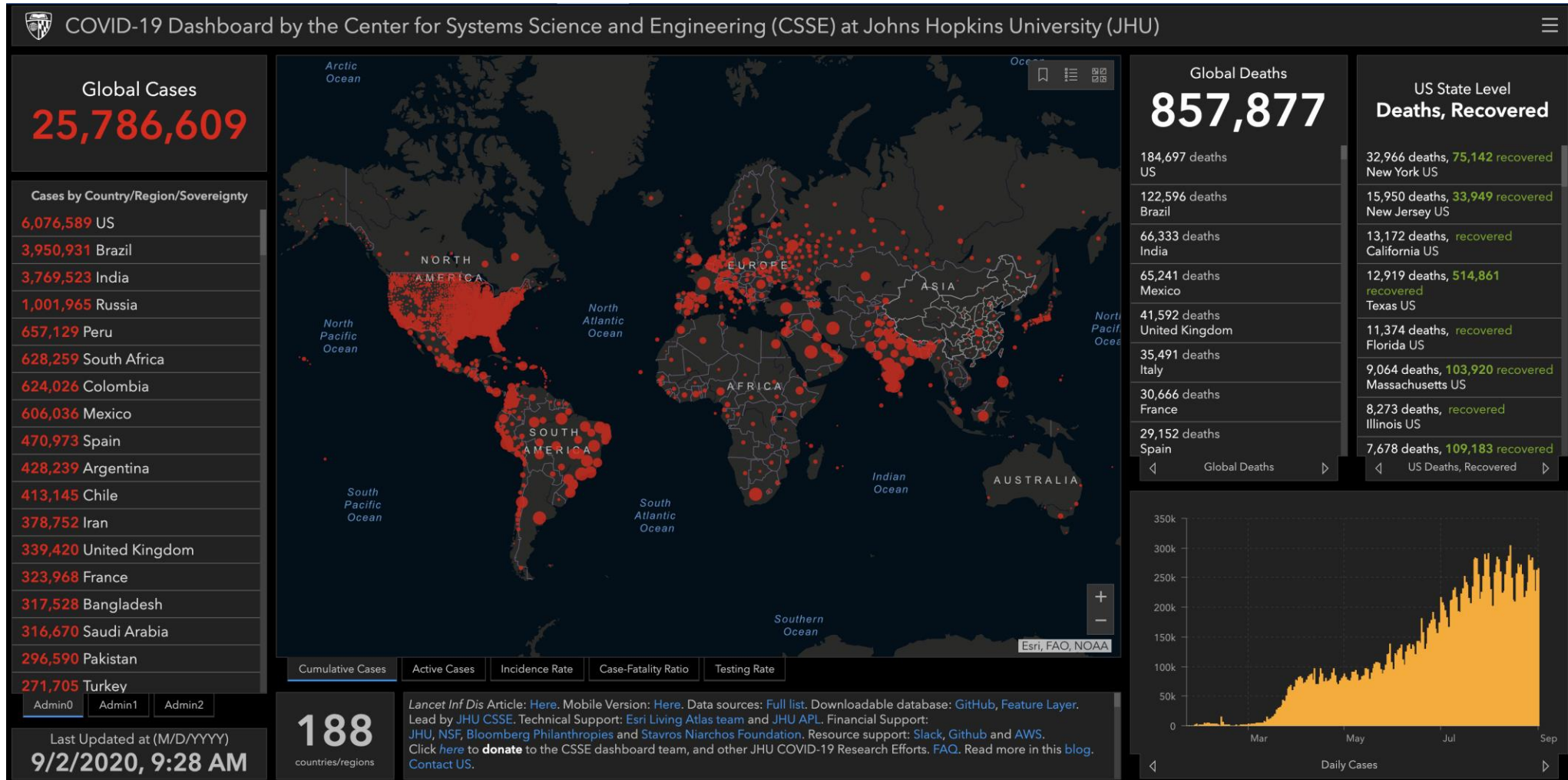




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Total Global Cases (9/2/20)



coronavirus.jhu.edu/map.html

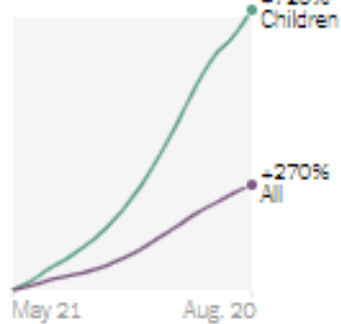


Children and COVID-19: "Some Kids May Not Be Alright"

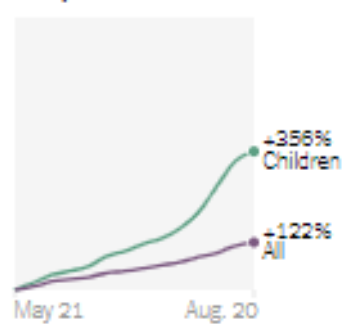
- 7.3% of all cases (as of 8/3/20)

Cumulative change since May 21

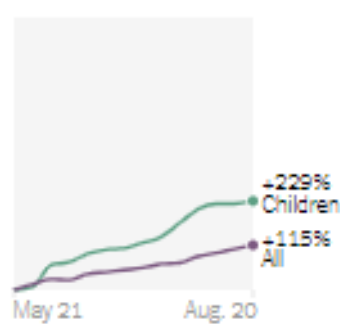
Cases



Hospitalizations

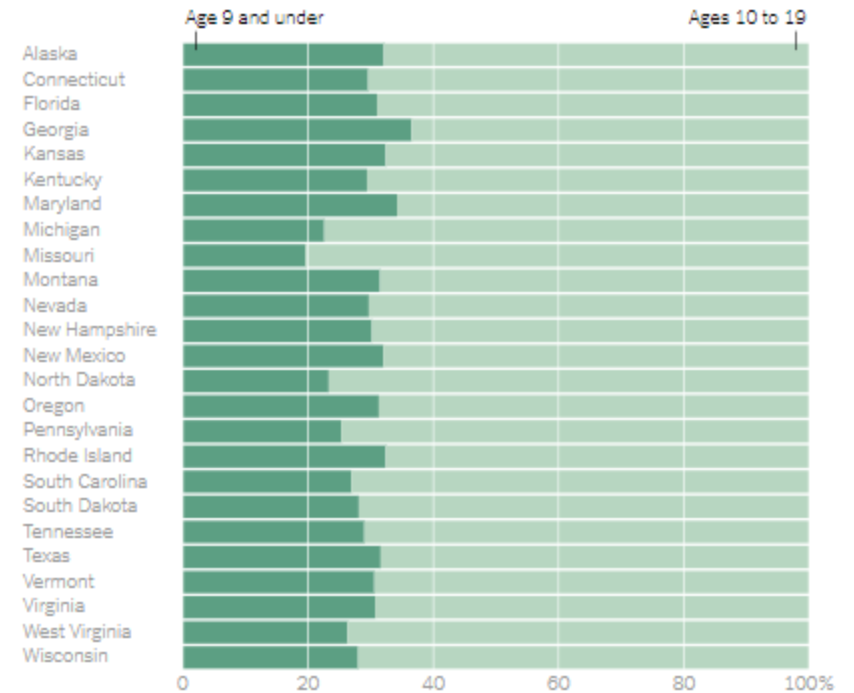


Deaths



Source: The American Academy of Pediatrics

Young children make up fewer of the reported cases than adolescents



Source: State health departments | Note: Data as of Aug. 26. Only states that divide their data at 10 years old are included. Georgia's older range is ages 10 to 17. North Dakota, South Carolina and Tennessee report groups as ages 0 to 10 and 11 to 20.

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





Children and COVID-19: "The Kids May Not Be Alright"

- One-third children hospitalized admitted to the ICU, similar to adults (MMWR)
 - Overall hospitalization rate much lower in children
- 42% hospitalized had underlying condition
- Disproportionate impact
 - Hispanic, Black, low-income children had highest rates of SARS-CoV-2
 - 71% of MIS-C patients Hispanic or Black
- Transmission: mixed data
 - Children < 5 years old w/ 10-100x viral RNA levels than older children and adults (JAMA Pediatrics) - but ability to transmit seems reduced

<https://www.cdc.gov/mmwr/volumes/69/wr/mm6932e3.htm>

<https://jamanetwork.com/journals/jamapediatrics/fullarticle/2768952>





Back to school success?

- Denmark, Germany, others with schools open
 - Low community rates
 - Adequate distancing
 - Mask wear inconsistent
 - Available, rapid COVID-19 testing
 - Contact tracing





Treatment





Remdesivir FDA EUA

FDA NEWS RELEASE

COVID-19 Update: FDA Broadens Emergency Use Authorization for Veklury (remdesivir) to Include All Hospitalized Patients for Treatment of COVID-19

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For Immediate Release: August 28, 2020

<https://www.fda.gov/news-events/press-announcements/covid-19-update-fda-broadens-emergency-use-authorization-veklury-remdesivir-include-all-hospitalized>





Expanded FDA Remdesivir EUA

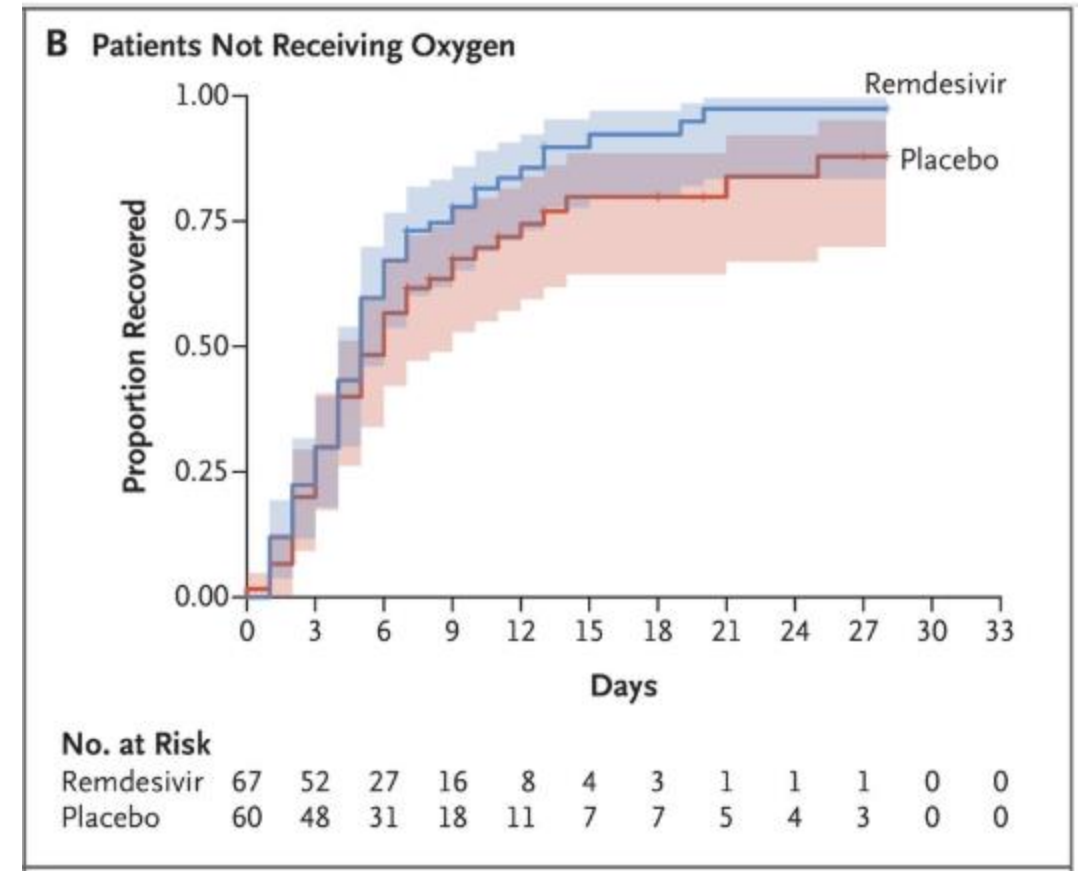
Today, based on the Agency's ongoing review of the EUA, including its review of the totality of scientific information now available, the FDA has determined that it is reasonable to believe Veklury may be effective for the treatment of suspected or laboratory-confirmed COVID-19 in all hospitalized adult and pediatric patients. The Agency's review has also concluded that the known and potential benefits of Veklury outweigh the known and potential risks for these uses.

<https://www.fda.gov/news-events/press-announcements/covid-19-update-fda-broadens-emergency-use-authorization-veklury-remdesivir-include-all-hospitalized>



FDA Scientific Basis

- ACTT-1 trial (28d data pending)
 - Time to recovery median time 10 d v 15 d placebo
 - Trend to reduced mortality 7.1% remdesivir group v 11.9% placebo
 - Most benefit in subgroup analysis for patients requiring oxygen but not mechanical ventilation or ECMO
 - Small group hospitalized, no oxygen



<https://www.nejm.org/doi/full/10.1056/NEJMoa2007764>





Open Label RDV 5 day v 10 day

- Patients with moderate COVID-19, no mechanical ventilation
- 5d superior to standard of care at day 11 AND
- Similar to 10d course, day 14

Goldman May 27, 2020, DOI: 10.1056/NEJMoa2015301





Remdesivir issues

- Modest benefits
- Do these benefits accrue with earlier treatment in less ill patients?
- Liberalizing criteria affect supply?





FDA EUA for Convalescent Plasma

- Operational issues, many taken by “surprise”
 - Blood banks not organized to titer units (high v. low titer)
 - Ortho VITROS SARS-CoV-2 IgG test
 - “Verbal” guidance by FDA during webinar that there will be a grace period allowing non-titered plasma units for administration
 - As of 9/1/20- no written guidance, some concern giving an investigational agent without clear direction

For now, must apply for single-patient eIND until there is clarification by FDA.





Other Issues per EUA

- EUA says it's not standard of care—which was implied in the Remdesivir EUA.
 - Due to insufficient evidence





To submit your own question, please email QA@dkbmed.com





Do cloth masks and surgical masks protect the wearer or just others? If they do protect wearer, what evidence is there to show this?





When should someone who has had potential/likely exposure be tested for COVID-19? (ie, how many days after exposure would a PCR test show a positive result?)





What is the screening process of a COVID-19 convalescent plasma donor?





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