COVID-19 Prevention

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Preventive Measures

Physical distancing, face masks, and eye protection to prevent person-to-person transmission of SARS-CoV-2 and COVID-19: a systematic review and meta-analysis

THE LANCET

- Meta analysis of 172 studies, 25,697 cases
- Separation by >1 meter decreased rate of transmission 82%
- Face mask use decreased risk of transmission 85%
- Eye protection decreased risk of transmission 75%

Chu DK, Lancet 2020

Vaccines

COVID-19 Vaccine Candidates

Platform	Developer	Current Status
Nucleic Acid	Pfizer	Finishing Phase 3
	Moderna	Finished Phase 3
Viral Vector	Astra Zeneca	Phase 3 enrolling
	Janssen	Phase 3 enrolling
Protein Subunit	Sanofi	Phase 3 pending
	Novavax	Phase 3 pending

Assumptions for COVID-19 Vaccine

- Need about 15,000 in vaccine and control arms based on
  - Level of significance
  - Power of study
  - Risk of being exposed to COVID
  - Vaccine efficacy (70% against infection)
- IF risk of infection is higher or vaccine efficacy is higher, can answer with fewer outcomes
- Doing “interim analyses” at 2-3 time points

Clinical Infectious Diseases

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ACCEPTED MANUSCRIPT

Warp Speed for COVID-19 Vaccines: Why are Children Stuck in Neutral? FREE

Evan J Anderson ✉, James D Campbell, C Buddy Creech, Robert Frenck, Satoshi Kamidani, Flor M Munoz, Sharon Nachman, Paul Spearman

Clinical Infectious Diseases, ciaa1425, https://doi.org/10.1093/cid/ciaa1425

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COVID-19 Vaccine Trials in Adolescents

- Pfizer has expanded age of eligibility down to 12 years of age.
- We began enrollment of 16-17 year olds this week.
- Plan next week to begin enrollment of 12-15 year olds
- If interested in finding out more about the trials contact us at: https://is.gd/covid19researchstudy

Emergency Use Authorization (EUA)

- In 2004, Congress created the EUA to provide access to unapproved medical products during a declared emergency.
- The FDA is required to review and approve the EUA.
- An EUA DOES NOT require IRB review and approval.
- Informed consent NOT required
  - Fact sheets containing information on product safety, available alternative products are required.
- Adverse event monitoring at discretion of FDA
- MEDWATCH and VAERS reporting is required.
- Duration of EUA is up to one year from the date of the declaration or as long as the declaration is in effect, **whichever is shorter**

Possible Distribution of COVID-19 Vaccines Using an EUA

- **Phase 1a (about 5%)**
  - **Front line health care workers, 1st responders**
- **Phase 1b (about 10%)**
  - **Any age with co-morbidity or high risk conditions**
- **Phase 2 (about 30-35%)**
  - **K-12 teachers and school staff, high risk workers**
- **Phase 3 (about 40-45%)**
  - **Everyone else**

National Academy of Sciences, 2020