Amber Mitchell, DrPH, MPH, CPH

UPDATES ON SARS-COV-2 AND COVID19 | TESTING, VACCINES & TREATMENT
Swab Tests; COVID-19 Disease

- Determines if active infection
- Nose, mouth swab
- 13 diagnostic manufacturers in market
  - 5 companies doing distribution kits
- Preferred method for diagnosing active disease/infection
- Point of Care (bedside) or Lab Based
- Uses fluorescent probe to identify nucleic acid of virus
- Fastest test 5 min +, 13 min -
Blood Tests; SARS-CoV-2 Antibodies

- Many determine if current or past infection with any coronavirus
- Some can determine if COVID19 specifically
- Tests whole blood, serum, or plasma
- Over 50 companies offering tests; most in China
- All Emergency Use Authorizations (EUAs); FDA does not clear
- Follow-up testing needs to be done to rule out infection; swab diagnostic
Treatment

• 21 companies with drugs for treatment
• Body’s own immune system over-reacts to virus and damages its own cells; “cytokine storm”
  • Cells to battle causing system inflammation
• Most promising: remdesivir (former Ebola drug; 2013/4)
  • Disrupts viral RNA replication at the enzyme level
• Anti-malaria: efficacy not proven (chloroquine, hydroxychloroquine; 1940s)
  • Creates a toxic cellular environment to prevent replication
• Plasma; convalescent plasma from those who are well.
SARS-CoV-2: Enveloped RNA
Vaccine

• 12 companies working on vaccine
• $1B for Vaccine R&D, testing
  • Gov’t Biomedical Advanced Research & Development Authority
• Moderna first clinical trials with NIAID (RNA)
• Inovio in phase 1 clinical trials (DNA)
Immunity

- Because the outbreak is only a few months old, there are no data on long-term immune response

- While other coronaviruses demonstrate evidence of reinfection, this usually does not happen for many months or years
Outcomes with Patients on Ventilators

• When lungs can’t effectively exchange oxygen with the bloodstream
• Ventilator mechanically exchanges O2
• COVID19 high levels of pressure and O2 because lungs are so inflamed
• Ventilator causes damage
• No effective cure for COVID19 pneumonia
• If extreme, ECMO is done delivering O2 straight into blood
  • Extracorporeal membrane oxygenation; life supporting while lungs heal
• Recovery: 33 out of 98 in UK; 3 out of 22 in Wuhan, China
FDA Industry Hotline: Coronavirus COVID-19 Diagnostic Tests and Shortages

For Industry Questions: COVID-19 Diagnostic Tests, and COVID-19 device shortages, including all Personal Protective Equipment for masks and respirators

• Contact our toll-free line 24 hours a day: 1-888-INFO-FDA, choose option *

Or Email:
• Shortages: deviceshortages@fda.hhs.gov
• Diagnostic Tests: COVID19DX@FDA.HHS.GOV