To investigate the effectiveness of current federal guidance towards accelerating availability and development of COVID-19 testings and therapeutics

BACKGROUND

OBJECTIVE

RESULTS

CONCLUSION

These expedited mechanisms have been implemented to approve diagnostic testing and treatments, without a reliable system to accurately and promptly deliver results.

Preliminary study results indicate that current federal guidance has failed to produce reliable diagnostic tools and treatments:

- Inconsistent testing accuracies and high relative percentage of EUA revocations,
- The majority of revocations were for serology antibody tests. These EUAs are more likely to be revoked due to the unreliable nature of antibody testing (the time-dependent detection of the virus complicates both real-time results and subsequent data verification).
- The lack of uniform testing and qualification strategy has been a major setback in terms of holistic pandemic response, and consequently called into question the reliability of subsequent data collection.

**METHODOLOGY**

Comprehensive review of FDA guidances before and after COVID-19

Compile list of authorizations and recalls/withdrawals for COVID-19 developments from FDA database

Compare clinical data from clinicaltrials.gov with approval rates for diagnostic testing and treatment applications

**PART 1**

- **Diag nostic Testings:** Accuracy Parameters (sensitivity, specificity, percentages of false positive/negative results)
- **Treatments:** Treatment Types: antivirals, cell & gene therapies, immunomodulators, neutralizing antibodies

**PART 2**

- In Vitro Diagnostic Products & High Complexity Molecular-Based Laboratory Developed Tests
- Serology Antibody Tests
- Antigen Tests

**RESULTS**

- **270** In Vitro Diagnostic Products & High Complexity Molecular-Based Laboratory Developed Tests
- **76** Serology Antibody Tests
- **24** Antigen Tests

281 Revokals

483 authorized revisions to existing EUAs

**Figure 1:** Breakdown of EUA Standing Approvals for Diagnostic Testings (n = 370)

**Figure 2:** Breakdown of EUA Outcomes for Diagnostic Testings (n = 652)

**Table 1:** Cochrane Review on COVID-19 Antibody Testing

- **Average sensitivity of IgG and IgM antibodies in serology antibody tests (n=7) was >92% when tested 14-25 days after symptom onset.**

**CONCLUSION**

- March 31, 2020 | Coronavirus Treatment Acceleration Program (CTAP) Established
- April 17, 2020 | Accelerating COVID-19 Therapeutics Interventions and Vaccines Partnership (ACTIV) Launched
- July 8, 2020 | COVID-19 Prevention Trials Network (COVPN) Launched
- March 31, 2021 | 370 diagnostic testings and three vaccines authorized for emergency use

**BACKGROUND**

- **February 4, 2020** | In-Effect Emergency Use Authorization Guidance (EUA)
- **March 31, 2020** | Coronavirus Treatment Acceleration Program (CTAP) Established
- **April 17, 2020** | Accelerating COVID-19 Therapeutics Interventions and Vaccines Partnership (ACTIV) Launched
- **July 8, 2020** | COVID-19 Prevention Trials Network (COVPN) Launched
- **March 31, 2021** | FDA announced actions to push out more screenings tools for asymptomatic individuals

**METHODOLOGY**

- Comprehensive review of FDA guidances before and after COVID-19
- Compile list of authorizations and recalls/withdrawals for COVID-19 developments from FDA database
- Assess and compare successful approvals versus unsuccessful approvals

**OBJECTIVE**

- To investigate the effectiveness of current federal guidance towards accelerating availability and development of COVID-19 testings and therapeutics

**RESULTS**

- **270** In Vitro Diagnostic Products & High Complexity Molecular-Based Laboratory Developed Tests
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