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IDSA
Infectious Diseases Society of America

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Francis S. Collins, MD, PhD
Director, National Institutes of Health
Bethesda, MD 20814

RE: NIH-Wide Strategic Plan for COVID-19 Research

Dear Dr. Collins:

The Infectious Diseases Society of America (IDSA) appreciates the opportunity to comment on the NIH-Wide Strategic Plan for COVID-19 Research (Strategic Plan). We applaud NIH for its swift and effective mobilization of research, partnerships, and resources in a comprehensive effort to combat COVID-19.

In May 2020, IDSA outlined key COVID-19 research questions for NIH consideration that included the following recommendations:

- Develop common guidelines for research in outpatient settings and establish collaborative research networks in this space. Research infrastructure is needed in the outpatient space, particularly with regard to vaccines and new COVID-19 therapeutics;
- Increase the grants available to early career infectious diseases (ID) investigators to attract necessary new talent to the field. Introduce grants in novel areas, such as social determinants of health and challenges to equity; and
- Develop multi-stakeholder partnerships to address data/specimen collection and protocols for storage and analysis.

We appreciate the Strategic Plan's comprehensive vision and have included additional comments and recommendations on its priorities and cross-cutting strategies below. We urge NIH to consider these additions, as well as the additional questions of how COVID-19 specifically impacts children and the subsequent implications for disease transmission and spread. We appreciate the Strategic Plan's commitment to preventing and addressing COVID-19 health disparities and studying vulnerable populations, including pregnant women, newborns and incarcerated individuals. We also encourage clinical trial support for special populations like immunosuppressed patients and people with HIV. Among all HHS agencies, NIH is perhaps best equipped to study the wide range of COVID-19 manifestations and outcomes that remain central unexplained features of the pandemic.

Priority 1: Improve Fundamental Knowledge of SARS-CoV-2 and COVID-19

- The wide range and potentially sustained manifestations of infection outcomes are central unexplained features of this virus and seem like a theme deserving greater research emphasis.
- There is an urgent need for federal coordination and increased support for pragmatic clinical trials beyond even what is identified in the Strategic Plan, particularly for increased coordination to launch trials more quickly. Improving the speed and breadth of planning and executing well-designed clinical trials will quickly provide actionable data that impact the delivery of care, inform infection control policy and practice, and identify subsequent research needs. Funding from NIH/NCATS/OWS allowed COVID-19 convalescent plasma clinical trials to pivot to new sites quickly and accrue a much larger cohort. An additional model is the UK National Health Service, which was leveraged to get robust data quickly on multiple different therapies for COVID-19.
- Support community-based clinical research trials analogous to HIV community-based research models in which community-based clinicians (including ID physicians) can cooperate to provide answers to clinically relevant questions.
- Consider the importance of antimicrobial stewardship studies related to optimal use of antiviral, antibacterial, and antifungal agents. Several studies suggest initial viral infection in hospitalized patients are mostly monomicrobial by the virus without co-infection with bacteria (yet a high percent of patients also receive antibacterials); on the other hand, patients who remain within the hospital for longer time (especially within ICU) are at risk for recurring bacterial and fungal infections.

Priority 2: Advance Detection and Diagnosis of COVID-19

- For both diagnostic and serologic testing, we recommend a federal oversight strategy vetted by subject matter experts. Current disparate efforts with resulting platforms that cannot be harmonized – and thus lack applicability across research applications and clinical care – are a huge challenge. Coordination at the highest levels will help accelerate progress and improve delivery and quality of care.
- To address the issue of the misapplication of available testing technologies and interpretation of results, investing in the development of tests for specific intent would be helpful (e.g., clinician diagnosis, asymptomatic screening, long-term care environments, pooled vs. individual testing). This will also lead to better utility of limited supplies.
- There is a need for diagnostics that predict severe outcomes to enable early treatment, which is critical in respiratory virus infections. Currently, ID physicians must make decisions based on scarcity without having these types of assays available. This application would benefit from NIH focus.

Priority 3: Advance the Treatment of COVID-19

- The antibody response appears particularly important to host immunity in COVID-19. Antibody therapies, whether convalescent plasma or monoclonal antibodies, should be a focus – specifically, what are the relevant properties of antibodies and are multiple types superior to single monoclonals?
- In resource-limited countries, convalescent plasma may be more available than vaccines or monoclonal antibodies. When is this effective? Can vaccinated individuals serve as plasma donors? Who are the best donors? There is a need to further narrow the specific

populations in which these therapies are more beneficial, since the identified risks for enrollment in current trials are so common in the US population.

Priority 4: Improve Prevention of SARS-CoV-2 Infection

- Consider needs and resource allocation for hospital epidemiology and public health.
- Public health education is critical for influencing preventative measures acceptance and emphasizing the importance of reliable testing. We recognize that communicating public health information for the purpose of impacting behavior is a complex science, and we therefore recommend dedicated investment in this area to achieve impactful outcomes.
- Increase research on the long-term effects of COVID vaccines (e.g., duration of immunity, transmission)
- We recommend developing this section further to support more socio-behavioral research into COVID-19 risk and prevention psychology (e.g., mask-wearing behavior).

Priority 5: Prevent and Redress Poor COVID-19 Outcomes in Health Disparity & Vulnerable Populations

- On page 17, add Native Americans and Hispanics within the parentheses mentioning Africans Americans.
- Invest in subject-area considerations for infection prevention; diagnostics; treatment; epidemiology; vaccines; and translational research that seek to understand impacts of social determinants of health on disease pathogenesis and therapy.

Crosscutting Strategies:

Partnering to promote collaborative science

- Any patient-oriented project, whether basic/translational research or therapeutic trial, will do far better during COVID or a COVID-like outbreak when multiple sites work together, since cases may ebb or fall at any one location. NIH should explicitly encourage this, rather than putting money into single site studies that may or may not accrue a sufficient number of patients.
- Consider research on "one health", as highlighted by the transmission to and from animal sources.

Supporting the research workforce and infrastructure

- In addition to increasing support for early stage investigators, we also recommend support for new investigators and those working toward research independence. COVID-related disruptions such as increased clinical time, caregiving issues, and the prioritization of COVID-centered research have been significant. Current COVID NOSI grants that target established investigators have been extremely competitive.
- COVID-19 and future pandemics paradoxically have the potential to sideline many promising investigators. Of the researchers with the greatest contributions to make, ID physician-scientists are ideally equipped to address many important topics with regard to COVID – yet, when disease is most intense and their responsibilities are amplified, they must jump into the funding pool with a much larger group of furloughed, often non-medical researchers with more time to prepare grants. NIH should consider these disparities and provide opportunities and support for researchers in these cohorts.

- The NCATS Clinical and Translational Science Awards Program has helped train the next generation of ID physician-scientists and should receive increased support.

We look forward to continuing to work with NIH to advance our shared goals in driving critical research to combat COVID-19.

Sincerely,

Barbara D. Alexander, MD, MHS, FIDSA
President, IDSA