

November 6, 2023

Centers for Disease Control and Prevention
1600 Clifton Road NE, Mailstop H16-5
Atlanta, GA 30329
Submitted electronically via <http://www.regulations.gov>

RE: National One Health Framework to Address Zoonotic Diseases and Advance Public Health Preparedness in the United States: A Framework for One Health Coordination and Collaboration Across Federal Agencies

The Infectious Diseases Society of America (IDSA) appreciates the opportunity to provide comments to the Centers for Disease Control and Prevention (CDC) in response to its Request for Information regarding the draft One Health framework on coordination across federal agencies.

IDSA represents a community of over 12,000 physicians, scientists, public health experts and other health professionals who specialize in infectious diseases. Our members work across a variety of health care settings. Their wide array of experiences with research and practice informs the need for collaboration across the various practices that make up the One Health space.

IDSA recognizes the strong need for a unified approach to One Health at the federal level. The COVID-19 pandemic, mpox outbreak and growing antimicrobial resistance are just a few examples that demonstrate the global impact that animal health and disease spillover can have on human health. Continued support and a standardized foundation for federal action on One Health issues is needed to prevent and manage further public health threats. The proposed framework provides a strong starting point. IDSA recommends that the goals and objectives include specific metrics or targets wherever feasible to allow progress to be measured over time. Below, we offer recommendations and responses regarding strategies to address core components of the proposed goals and priorities. We welcome continued dialogue and collaboration in promoting robust One Health coordination and addressing emerging zoonoses.

Goal #1: Coordination, Collaboration and Communication: Establish a standing formal, One Health coordination mechanism to provide a common platform and governance structure to address One Health needs.

One milestone to successfully implement the framework is the formal establishment of a coordinating mechanism as laid out in Goal #1. This coordinating mechanism needs to be outlined more formally so that information can be made available for the public, and for One Health stakeholders. IDSA requests more detail on the structure of this mechanism and recommends that it be sufficiently robust, including an interagency task force, federal advisory committee and regular public reporting on challenges and progress and opportunities for public engagement. This mechanism should leverage both domestic and international global health security efforts.

Goal #2: Prevention: Strengthen existing and identify new opportunities for One Health collaboration among federal partners to prevent and control zoonotic diseases.

IDSAs appreciate the work to extend One Health efforts to new collaboration opportunities. One area that is especially novel and requires unified federal guidance is antimicrobial resistance (AMR) in animal medicine. Currently, there is no federal agency mandating standards of care – there is no equivalent of CMS, for example, to develop quality metrics for prescribing or care in this area. There is also little surveillance, despite AMR in animal medicine constituting a One Health risk. IDSA recommends developing a federal standard through interagency collaboration to address this emerging issue.

Goal #3: Preparedness: Strengthen One Health collaborations for preparedness and build new approaches where needed to address priority, endemic, emerging and reemerging zoonotic diseases to improve health for people and animals.

IDSAs support incorporating a strong One Health approach to preparedness plans; this readies a federal response to emerging zoonoses that jeopardize human health. We especially support a stronger evaluation of environmental determinants and climate change impacts on One Health threats, and the overall readiness of the United States to respond to these threats. It will be especially critical to take findings from interagency activities and response exercises and turn them into implementable plans and policies. Often, exercises are held in silos and the findings fail to increase federal preparedness and readiness gaps. Furthermore, these findings should be able to be readily accessed by the public, relevant stakeholder groups and members of the One Health workforce. In order for implementation to occur, the information gathered must be readily available.

Additionally, IDSA recommends the framework seek to develop a strategy for interagency collaboration on clinical trials involving zoonoses impacting human health. COVID-19 demonstrated the need for clinical trials on emerging zoonotic diseases that prioritize diverse participants (including underrepresented groups like Latinx, Indigenous/Native American and Black/African American patients, as well as pediatric and over-65 patients) that can be easily scaled up in the event of a public health emergency (PHE), and that leverage public-private partnerships to reach more participants. This strategy should include clear steps to communicating guidance on conducting clinical trials over zoonoses to the clinical research community. Data gathered from federal trials should be readily available to federal agencies, and to researchers, to ensure clear communication and readily available scientific data.

Goal #5: Surveillance: Strengthen coordinated surveillance and information sharing for relevant zoonotic disease surveillance and reporting systems across sectors.

Data sharing poses an issue in implementing these goals. Goal #5 highlights a strong need for better coordination of surveillance in One Health, both federally and internationally, between the U.S. government and the Quadripartite. Stakeholders in surveillance need to be engaged and given adequate support to develop a unified surveillance system that addresses plant, human and animal health. To achieve this, IDSA recommends the following:

- Automate data collection/sharing to the fullest extent possible to reduce burden on providers, health care systems, labs and public health agencies. Public health agencies need resources to automate their data monitoring and reporting systems and better access to patient-level data and demographic information for robust monitoring of human health and possible zoonoses.
- Equip leading federal and independent agencies dealing with One Health threats (including CDC and the U.S. Department of Agriculture) with the coordination authority, capacity and resources to collect accurate global and nationwide data (including patient-level data on subpopulations) and share it back with local communities, including territorial, state and local public health departments, in a timely manner to help inform and strengthen local responses to zoonoses and spillovers.
- Additionally, ensure that this ongoing data surveillance and collection inform research and development of medical countermeasures and vaccines to zoonoses and One Health threats in real time.

Goal #6: Laboratory: Strengthen One Health laboratory capacity (e.g., trained personnel and use of advanced laboratory techniques), coordination and reporting for detection of priority, endemic, emerging and reemerging zoonotic diseases.

The framework highlights the need for laboratories with strong, trained clinical microbiology and diagnostic staff to handle the rise in zoonotic threats. Zoonotic outbreaks need to be handled with unified, national guidelines that are clear and easily carried out by lab personnel. Investments in the recruitment, training and retention of laboratory personnel will be central to the success of this goal. Studies have found that prior to the pandemic, the average percentage of vacant positions in clinical laboratories was roughly 7.2%.⁴ Increasing vacancies due to high attrition and burnout, combined with a high retirement rate and a rapidly increasing demand for testing, has put immense strain on the laboratory workforce. This is especially true in rural areas, where laboratories were overburdened even prior to COVID-19, and in public health labs, where our members have reported vacancies remaining unfilled for nearly a decade due to the high degree of training and education that is often out of pocket for students.

The potential lack of access to laboratory-developed tests (LDTs) also poses a threat to diagnostic capacity and readiness. Academic medical centers and public health laboratories rely on these types of diagnostic tests to conduct routine infectious diseases testing, including antimicrobial susceptibility, specimen identification and HIV testing. In emerging zoonoses, they are often the first tests available to conduct diagnostics; during the mpox outbreak, LDTs were the first available PCR tests and were critical to rapidly scaling up testing capacity at the start of the outbreak. Potential new FDA regulations regarding LDTs would put increased, undue regulations on these tests, and likely stifle diagnostic abilities in many labs. This puts the country

at risk in a new PHE. To increase diagnostic capacity in the One Health space, IDSA recommends the following:

- Direct funding to genomic sequencing efforts especially relevant to emerging zoonoses and surveillance of zoonoses.
- Develop federal tuition plans that support clinical microbiologists and diagnostics-trained staff.
- Urge FDA as a key One Health stakeholder agency to delay LDT requirements associated with 510(k) premarket notification or premarket approval, quality system regulation and labeling until more complete data on LDTs are compiled and made publicly available.
- Develop centralized databases through the framework intended to disseminate successful diagnostic testing protocols for use by other laboratories.
- Ensure laboratories have easy access to biological samples and quantitative assay standards so they can develop and utilize diagnostic tests efficiently. Develop these pathways to access samples and standards in advance of a public health emergency, especially those involving emerging zoonoses, so that testing facilities may easily do diagnostic work.

Goal #7: Workforce: Support and expand efforts to develop a qualified, diverse, equitable and inclusive One Health workforce to address zoonotic disease threats.

The objectives on workforce initiatives outlined in the framework are critical steps to achieve a stronger One Health workforce. The One Health workforce comprises a wide array of disciplines and staff. IDSA's overarching concern in that workforce is that the current capacity of ID clinicians and physician-scientists is insufficient to meet our nation's needs. The ID workforce staffs the front lines of public health emergencies and plays an essential role in stewardship, infection control, diagnostics and development of guidelines for management of novel biological threats.¹ Additionally, the ID workforce coordinates with many other disciplines in One Health, including veterinarians and public health specialists. However, inadequate compensation of ID physicians has led to a limited workforce ill-equipped to handle One Health threats. Nearly 80% of U.S. counties do not have a single ID physician, with shortages in rural areas. In 2023, just over half of ID physician training programs and 43% of pediatric ID training programs were filled; by comparison, most other physician specialties filled nearly all their programs.² ID is one of the lowest reimbursed medical specialties, below even general internal medicine. This, coupled with high medical student debt, makes ID a financially infeasible choice for many. The lack of an ID workforce limits a critical discipline in One Health. We recommend the following to further those objectives:

- Take steps to support staffing and funding, particularly in rural and other underserved areas, for the technical, clinical and public health workforce engaged in One Health efforts, such as infectious diseases clinicians, public health workers and clinical microbiologists and laboratory staff. Rural areas are especially at risk of zoonotic diseases and vector-borne disease due to increased contact with livestock, wildlife and insects.³ These can lead to serious illness, especially in patients who are children, older than 65 or immunocompromised.

- Support loan repayment programs for animal and human health specialists interested in One Health research or public health practice. Specifically, funding should be provided for the Bio-Preparedness Workforce Pilot Program, which was enacted in 2022 and, once funded, will provide loan repayment for health care professionals who specialize in infectious diseases and work in shortage areas. To ensure stronger diversity and equity, repayment should be targeted at traditionally underrepresented groups like Black, Latinx and Indigenous/Native American students, as well as those students who want to practice or work in rural or other underserved areas.
- Increase reimbursement for ID physicians.
- Support interdisciplinary trainings on One Health topics for students at the collegiate, graduate and medical/veterinary school level. Supporting the development of a standardized One Health elective in medical schools would be especially beneficial for clinicians. As of 2020, only 56% of surveyed medical schools included any One Health curriculum.⁴ This supports a medical workforce ready to treat and manage zoonoses.

How do state, tribal, local and territorial partners, nongovernmental organizations, academic institutions, private-sector partners and other partners want to engage with federal collaborators to advance implementation of this framework?

Engaging collaborators is critical to creating a unified framework and coordinating mechanisms to prepare for, detect and mitigate One Health threats and zoonoses. To this end, the coordinating mechanism should seek to engage the One Health workforce. Collaborators should be reached out to by the coordinating mechanism, and by federal agencies; the initiative should not have to come from them. This will yield stronger guidance and increase the visibility of federal One Health efforts. IDSA recommends the following to achieve successful collaboration and engagement with collaborators:

- Provide opportunities for ID clinicians and veterinarians/animal health specialists to advise on public health and medical guidance for their respective fields in the development phase, especially during PHEs, to ensure guidance reflects on-the-ground needs, capacities and communication preferences.
- When addressing emerging One Health threats, provide short, unified and easy-to-understand documents through relevant federal agencies for use by clinicians as well as the public. Clinicians who are on the front lines of outbreaks require clear and unified guidance from the federal level.
- Provide dashboards for use by health care and public health professionals with real time, accurate data in plain language that can be shared with policymakers and the public.

What additional One Health issues should be prioritized in the future?

While there is mention of antimicrobial resistance (AMR) in the initial background of the framework, we recommend adding specific language regarding coordinated AMR stewardship efforts in the final version of the framework. We recognize the desire to specially address zoonoses in this framework but would stress the importance of resistant infections as potential zoonoses in humans. There is already evidence of animals transmitting resistant infections to humans. From a One Health perspective, AMR is of the greatest threats we face in public health,

which has interconnected root causes in human, animal and plant health. Human antibiotic use has led to growing rates of resistant infections, especially in inpatient settings; rising rates of antibiotic usage for preventative purposes in livestock have been shown through studies to constitute roughly 50% of global antibiotic use⁵; overuse of bactericides and fungicides in agriculture can cause resistance in plant stock, as well as residual effects on those consuming those crops⁶; and the increasing colonization of companion animals with resistant pathogens such as carbapenemase-producing *Enterobacteriales*.⁷ We would encourage language establishing this as a priority to address through the framework so that there can be unified federal action under a One Health lens. Additionally, we would encourage the framework to incorporate a global lens to AMR. Many resistant isolates come to the U.S. from international livestock or patients, and the unrestricted antibiotic use in both livestock and people in many countries accelerates development of dangerous superbugs. This topic can fall under Objective 1.4 as a priority area for One Health science and research and should be incorporated into the priorities for a formal One Health coordinating mechanism at the federal level.

What information or recommendations are needed to ensure the guiding principles of health equity, sustainability, stewardship and a multisectoral approach are adequately addressed in the framework? How can these guiding principles be elevated during follow-up development and drafting of implementation plans?

These principles can be elevated through ample consultation and listening sessions with stakeholders as the framework continues to be developed. Stakeholders involved in these sessions should include representatives from relevant federal agencies, state and local public health personnel, veterinarians, infectious diseases clinicians, botanists and other partner organizations who will likely be involved in carrying out the guiding principles laid out in the framework. The federal government should make a concerted effort to collaborate with organizations that work with and represent underserved communities and populations likely to be disproportionately impacted by zoonotic diseases. We encourage transparency and strong communication throughout this process of drafting and finalizing the framework to ensure all stakeholders stay informed and have ample opportunities to provide input.

IDSAs welcomes continued collaboration on developing these important topics. If you have questions about these comments or would like to connect, please contact Eli Briggs, director of public policy, at ebriggs@idsociety.org.

Sincerely,

A handwritten signature in black ink, appearing to read "Steven K. Schmitt". The signature is fluid and cursive, written in a professional style.

Steven K. Schmitt, MD, FIDSA, FACP
President