Better Tests, Better Care – The Promise of Next Generation Diagnostics

FY 2016 Appropriations Priority Areas

Rapid diagnostics that detect infectious agents are fundamental to high quality, life-saving care. Despite dramatic advances in laboratory technology broadly, many patients continue to receive inaccurate, incomplete, or delayed diagnoses, resulting in suboptimal treatment and outcomes. Several challenges exist to research and development for rapid infectious diseases diagnostic products, including the need for increased federal investments that leverage resources in academia and industry. Current federal budget austerity has created significant challenges in securing funding to cover the high expense of developing innovative diagnostics.

Recommendation: Increase funding to the National Institutes of Health (NIH) and its National Institute of Allergy and Infectious Diseases (NIAID), Centers for Disease Control and Prevention (CDC), and the Biomedical Advanced Research and Development Authority (BARDA) to stimulate R&D for emerging diagnostic technologies.

The federal government has taken some initial steps to promote research and development for new rapid infectious diseases diagnostics. IDSA recommends that increased support be provided the following agencies, programs and initiatives in the FY 2016 appropriations process.

Antibiotic Resistance – In fall 2014, the White House released an executive order with provisions to implement an accompanying *National Strategy for Combating Antibiotic Resistant Bacteria (CARB)*. The CARB national strategy, based on the recommendations of the President's Council of Advisors on Science and Technology (PCAST), lists the development of innovative diagnostics as one of its five goals to address antibiotic resistance. In particular, the CARB strategy recommends federal investment towards developing rapid, point-of-care diagnostic tests that can distinguish between viral and bacterial infection and identify resistance as well as those that will guide treatment of resistant infections and public health responses.

NIH/NIAID, Small Business Initiative Research (SBIR) – Often the best ideas come from small, innovative companies with limited resources. These firms often rely on financing from government sources, such as the NIH SBIR grants, or through partnerships with other companies or academic research institutions.

NIH/NIAID, Mid-Stage Diagnostic Research – Funding appropriated to NIAID is leading to new diagnostic tests to identify reservoirs of latent HIV infection, diagnostic tests that minimize the amount of clinical sample needed, multiplexed diagnostic platforms for the detection of infectious diseases, as well as diagnostics to quickly detect bacteria responsible for antibacterial resistant infections in hospital settings.

NIAID-supported Antibacterial Resistance Leadership Group (ARLG) – The ARLG has supported early clinical research on diagnostics that identify resistant bacterial infection. The ARLG is also preparing a "virtual biorepository" of clinically well-characterized bacterial isolates for use in diagnostic research, which is often hampered by lack of clinical samples for testing. The repository samples will remain at their respective institutions, while the ARLG virtual biorepository will provide a central point of contact

CDC– Advanced Molecular Detection Initiative – (AMD) – The AMD focuses on new diagnostic technologies for infectious diseases. This investment enables public health responses to identify reservoirs of disease, new outbreaks, and tainted food supply sources more rapidly.

CDC – "No Petri Dish Diagnostics Challenge" – Announced in fall 2014, the "No Petri Dish" Diagnostics challenge aims to spur development of innovative tests that can characterize pathogenic organisms from clinical samples without the need to culture them.

CDC – Detect and Protect against Antibiotic Resistance Initiative – The CDC's initiative includes an isolate biorepository bank that could be used for diagnostics R&D.

BARDA – BARDA is supporting advanced clinical development of innovative infectious disease diagnostics. With increased funding, additional awards that spur diagnostic innovation could be made, similar to the CARB NIH/BARDA sponsored rapid diagnostic prize.

FY 2016 Report Language Recommendations

Virtual Biorepositories
A key challenge in clinical trials for new diagnostics is access to clinical samples, particularly those containing rare pathogens. Many clinical laboratories no longer store specimens containing novel or unusual organisms for further use. Even when such critical samples are available, the cost of accessing them has, in many cases, become prohibitive.

Recommendation: Direct the National Institute for Allergy and Infectious Diseases to examine opportunities to support the development of virtual biorepositories for viruses, fungi and other pathogens, utilizing samples already being collected under existing NIAID-funded research, similar to the existing bacteria virtual biorespository. Provide incentives and support for institutions to save de-identified specimens and to participate in virtual biorepository catalogues when possible.

Conflict of Interest (COI)
Often expert input or independent validation of a potential test is needed during development. Institutional COI policies are often much more strict than the National Institutes of Health COI regulatory framework, which was intended to provide guidance to institutions on how to manage COI. Unfortunately, institutional COI policies often bar those best suited for these activities, sometimes even if the expert is willing to work for free on his or her own time. In addition, the FDA is subject to its own strict COI policy designed to avoid bias in review that often creates difficulties in convening expert panels to provide input on device submissions. Even small COI disclosures, unrelated to the matter at hand, can bar subject matter experts from panels, possibly delaying the FDA review process for developers.

Recommendation: Clarify that institutions receiving federal funding should implement conflict of interest policies that appropriately enable transparent industry/institutional research collaborations. Direct the Food and Drug Administration to clarify and revise its COI policy to enable more effective recruitment of subject matter experts while retaining objective regulatory review.

Impact Studies Guiding Appropriate Use
Physicians often look to education, such as clinical guidelines developed by their professional societies, such as IDSA, and government bodies, such as the Agency for Healthcare Research and Quality (AHRQ), to suggest the best methods to diagnose and treat an infection. Little guidance currently exists on the use of diagnostic tests for a particular type of infection, or what bundles of tests should be used if a patient has a particular set of symptoms.

Recommendation: **Direct AHRQ specifically through its Center for Evidence and Practice Improvement (CEPI) to conduct or support research to demonstrate the impact of new ID diagnostics on patient care and outcomes, and to disseminate the results of that research to physicians to encourage them to appropriately utilize new diagnostics.**