21st Century Cures: IDSA Diagnostics Recommendations

Diagnostic tests that detect infectious agents are fundamental to high quality, lifesaving care and public health. Tremendous advances are now enabling new tests that combine simplicity, speed, and accuracy. The Infectious Diseases Society of America (IDSA) has compiled several policy solutions to current challenges that impede diagnostics research and development (R&D) and clinical integration. Below is a selection of IDSA recommendations relevant for inclusion in the 21st Century Cures initiative.

Public Private Partnerships: Direct the Department of Health and Human Services (HHS) to establish a public private partnership (PPP) similar to the European Rapid Point-of-Care test Platforms for Infectious Diseases (RAPP-ID) program. In 2011, the European Commission (EC) launched RAPP-ID[1], a PPP bringing together government experts, academia and industry aimed at developing fast and reliable point-of-care tests for the detection of various pathogens. This effort is currently concentrated on diagnostics for blood infections, lower respiratory tract infections (including community-acquired pneumonia and ventilator-associated pneumonia) and tuberculosis. In the U.S., Biomedical Advanced Research Development Authority (BARDA) currently partners with companies on diagnostic R&D, but BARDA does not currently bring together multiple companies with government and academic experts to collaborate and share information. Alternatively, the National Strategy for Combating Antibiotic Resistant Bacterial[2] (CARB) announced the creation of a biopharmaceutical incubator for antibiotics. One way to address the need for new diagnostics could be expanding this initiative, though diagnostic needs exist beyond those that address resistance.

Biorepositories: Direct the National Institute for Allergy and Infectious Diseases (NIAID) 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. A key challenge in clinical trials for new diagnostics is access to clinical samples, particularly those containing rare pathogens. Many clinical laboratories no longer freeze 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. The Antibacterial Resistance Leadership Group (ARLG), a strategic research team funded by NIAID, established a Virtual Biorepository (VB) Catalogue[3], a web-based system that provides researchers with unique access to clinically well-characterized bacteria for the development of diagnostic tests and other research. The bacteria are already being collected through other ARLG research projects and are housed at multiple locations. This approach requires significantly less resources than traditional physically centralized biorepositories. Researchers are able to search the virtual biorepository catalogue to locate the samples they need. This approach could be very useful in other areas of infectious diseases diagnostics development (e.g. virus, fungi, etc.).

Conflict of Interest: Clarify, through report language, that institutions receiving federal funding should implement conflict of interest (COI) policies that appropriately enable transparent industry/institutional research collaborations. Direct the Food and Drug Administration (FDA) to clarify and revise its COI policy to enable more effective recruitment of subject matter experts

[1] http://www.imi.europa.eu/content/rapp-id
[2] http://www.whitehouse.gov/sites/default/files/docs/carb_national_strategy.pdf
[3] https://arlg.org/laboratory-center-strain-access

while retaining objective regulatory review. 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 (NIH) COI regulatory framework[4], 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. Even when an institution does not explicitly ban such activities, policies are sometimes misinterpreted, resulting in a stifling of collaboration between academic researchers and industry. This forces developers to forgo expert input or use laboratories lacking expertise for independent testing. This loss of expert input and the resources diverted to train and supervise testing at labs lacking expertise can add considerable time and cost to diagnostic development. In addition, the FDA is subject to its own strict COI policy[5] 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.

Rapid communication of laboratory data to doctors: Direct the Office of the National Coordinator for Health Information Technology (ONC) to explore ways to promote the integration of diagnostic information into electronic health records (EHR) systems, allowing for more rapid transmission of diagnostic test results to clinicians and, for reportable diseases, to state, local, and federal health departments. The potential of rapid diagnostics can only be realized by improving coordination between physicians, the laboratory running the tests, public health officials, and antimicrobial stewards to quickly relay diagnostic information to inform patient care and public health protocols. A test that can provide results in under an hour cannot fully impact patient care if the treating physician and other appropriate individuals do not receive the test results until several hours later. New electronic health records (EHR) systems have the potential to significantly improve this coordination, but unfortunately many EHR systems do not integrate diagnostics tests and their results effectively.

Strong educational programs to inform physicians about the utility of new diagnostics: Direct the Agency for Healthcare Research and Quality (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. Many physicians and other health care providers may be hesitant to use new diagnostic tests, in part because they are often uncertain of how best to integrate them in their practice and how to interpret results. Physicians often look to education, such as clinical guidelines developed by their professional societies, such as IDSA, and government bodies, such as the 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. The ability to construct useful guidelines is hampered by the lack of clearly designed outcomes studies demonstrating patient benefit when tests are used as part of clinical decision making. CEPI is well-suited to address this need, as the Center is tasked with conducting and supporting research on health care delivery and improvement and advancing decision and communication sciences to facilitate informed treatment and health care decision making by patients and their health care providers.

[4] http://www.gpo.gov/fdsys/pkg/FR-2011-08-25/pdf/2011-21633.pdf
[5] http://www.fda.gov/oc/advisory/conflictofinterest/policies.html