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Editorial

Innovations in Infectious Disease Diagnostics

Nicole V. Tolan, Gary L. Horowitz

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Editorial

Innovations in Infectious Disease Diagnostics

As the result of numerous and rapid innovations, enhanced tremendously by the COVID-19 pandemic, infectious disease diagnostics have expanded well beyond the boundaries of the traditional clinical microbiology laboratory. What began many years ago with the introduction of Hepatitis B Surface Antibody testing on automated chemistry analyzers has now developed to include infectious disease testing not only for antibodies but also for antigens and nucleic acids, and it is no longer limited only to blood specimens. Advancements in new technologies have allowed for growth beyond core laboratories to now include point-of-care and direct-to-consumer testing applications. In this special issue, we highlight innovations in new technologies and alternative workflows that improve infectious disease diagnostic testing capabilities, particularly for SARS-CoV-2, HIV, Influenza, Clostridium difficile, Group A streptococcus, Lyme disease, and sexually transmitted infections. We also highlight current challenges in infectious disease diagnostic testing as a call to action, where further innovation would allow for the advancement in health care delivery and public health programs.

Not surprisingly, among the articles in this issue are seven principally related to SARS-CoV-2. The articles by Peaper *et al.* and Tran *et al.* discuss advances in technology and regulatory oversight, point-of care and over-the-counter testing, alternative specimen types, pooling of specimens, and artificial intelligence and machine learning applications. The articles by Babic et al and Fan show that, with vigorous attention to tests' limitations, even nucleic acid amplification testing with less-than-optimal analytic sensitivity can be 'fit for purpose' and implemented successfully, in one case across a regional network of hospitals and clinics, and in the other for use with emergency room patients in a tertiary care urban teaching hospital. And the articles by Duncan *et al.* and Omosule *et al.* demonstrate validation of alternative specimen types for use in diagnosis (saliva) and surveillance (dried blood spots) of SARS-CoV-2 infections. Tolan *et al.* demonstrate that there are considerable differences in SARS-CoV-2 antibody assays and that their performance must be considered in context of the intended application.

The article by Hainrichson *et al.* describes in detail the analytic validation of a method that measures three proteins simultaneously, combining the quantitative results to predict the likelihood of bacterial versus viral infection in patients with

suspected acute infection. The method has been shown in at least one clinical study to work well, but additional studies are needed. Perhaps more important, even if predictions are confirmed to be reliable in other studies, the ultimate question is whether physicians will act on them accordingly.

The remaining articles in the issue are devoted mainly to infectious diseases other than SARS-CoV-2. The article by Doron and Horowitz points out that, even though nucleic acid amplification testing, and its multiplex/multiorganism incarnations, are now commonly considered the gold standards in terms of sensitivity and specificity, they have several limitations (e.g., detection of carriers, out-of-pocket costs to patients) that too often are overlooked. Xiao and Leung focus on over-the-counter and direct-to-consumer issues, both regulatory and technologic, related to Group A Streptococcus pharyngitis. Improving diagnostic stewardship for Clostridiodes difficile infections (CDIs) is the focus of the article by Khuvis *et al.*, who describe the methods they used to decrease inappropriate ordering by 33% and hospital-onset CDIs by 57%. Chan and Kenyon describe advantages of the current CDC Lyme testing algorithm (Modified Two Tier Testing) and practical considerations for its implementation. Balogun and Slev provide important insights into current HIV testing issues, including the concept of treatment as prevention and the challenges associated with pre-exposure and post-exposure prophylaxis in diagnosing and managing HIV infection. Manabe, citing the estimated global prevalence of curable sexually transmitted infections among people 15 to 49 years old at more than 300 million, describes how changes in regulations and advances in technology (including self-collection, point-of-care and over-the counter testing) make it possible to address this public health crisis more effectively.

Recognizing how busy laboratory professionals have been, and remain, because of the issues precipitated by the COVID-19 pandemic, we wish to thank not only the authors who made time to prepare the articles in this special issue but also to the many individuals who volunteered their time to review these manuscripts. We think the final issue is a testament to the efforts of them all.

Nicole V. Tolan[1], Gary L. Horowitz[2]
[1] Brigham and Women's Hospital, Boston, MA 02115, USA
[2] Tufts Medical Center, Boston, MA 02111, USA