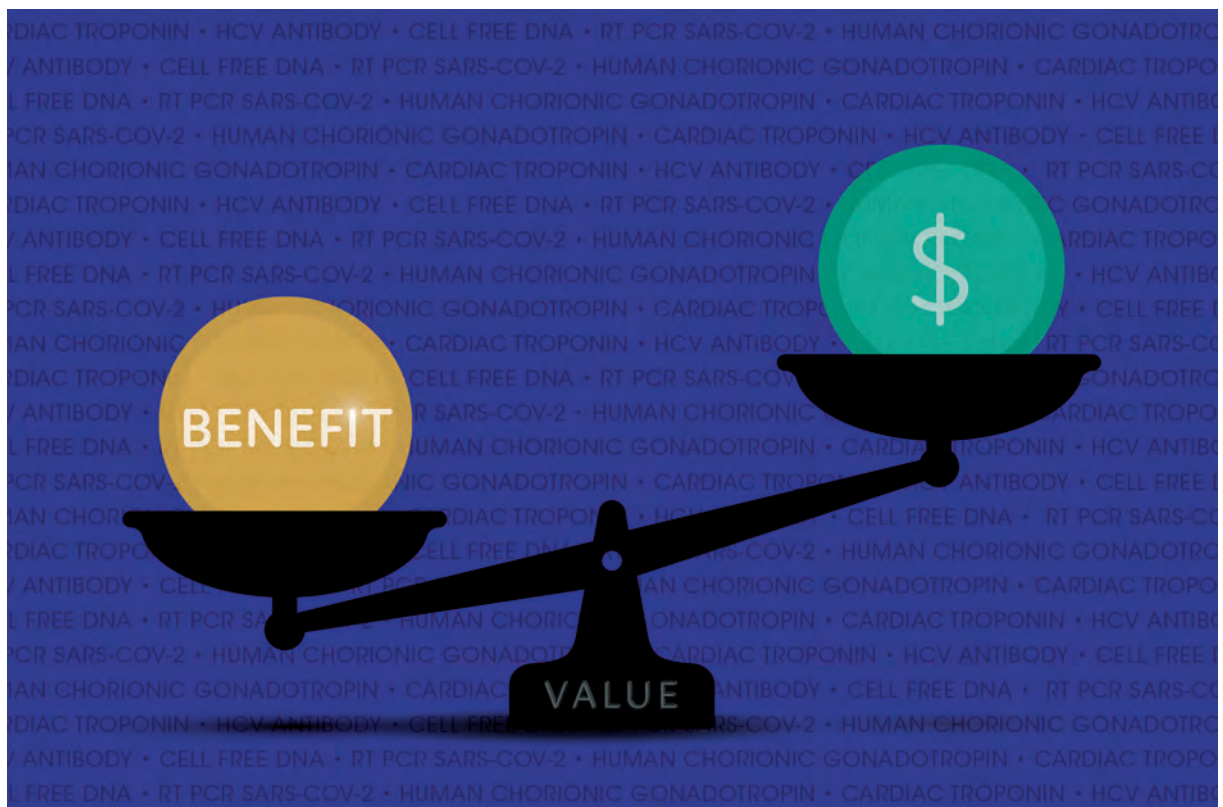


The
Journal
of

APPLIED LABORATORY MEDICINE

An AACC Publication



OXFORD
UNIVERSITY PRESS

AACC

*Better health through
laboratory medicine.*



Special Collection on the Value of Laboratory Medicine

Robert H. Christenson,^{a,b,*} David G. Grenache,^{c,d} and Michael Oellerich^e

A special collection of contributions centered on the value of laboratory medicine is presented in this issue of *The Journal of Applied Laboratory Medicine*. This topic is critically important to the future of laboratory medicine because clinical laboratory tests must be considered for their value in diagnosis, risk assessment, and monitoring, rather than simply focusing on test volume. Major professional organizations including the IFCC, the AACC, the World Association of Societies of Pathology and Laboratory Medicine, and the College of American Pathologists have formed committees and groups that focus on the value of laboratory medicine. This issue's special collection includes reflection pieces about disseminating the value of laboratory testing with approaches for how to promulgate this message. We feel that the focus on value is particularly timely because of the immense impact that the severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) pandemic has had on the health, economic and social well-being of an estimated 3 billion individuals worldwide (1). The value of real-time reverse transcription PCR testing for detection of SARS-CoV-2 viral infection has been profound, and media reports have noted that the supply of testing reagents is

frequently outstripped by the immense need for reverse transcription PCR testing. The value of reverse transcription PCR testing—that is, the benefit or worth divided by cost—to public health worldwide is unquestioned. The special collection includes several pieces on COVID-19 for both acute SARS-CoV-2 detection and the value of anti-SARS-CoV-2 serology testing to assess an individual's immune response, to determine the disease's prevalence, and to establish previous asymptomatic or mildly symptomatic exposure to or infection with the SARS-CoV-2 virus.

This special collection includes reports on a number of important laboratory innovations. One important contribution describes the use of intelligent liver function test strategies for better recognition of hepatic conditions. The quality of this work was acknowledged when the authors were bestowed the prestigious UNIVANTS for Healthcare Excellence award. This competitive award goes through a peer-review process and is a forum for recognizing teams that collaborate across disciplines, transform healthcare delivery, and demonstrate improved patient outcomes (<https://www.univantshce.com/int/en/home>).

^aDepartments of Pathology and Medical and Research Technology, University of Maryland School of Medicine, Baltimore, MD; ^bCore Laboratories and Point of Care Services, University of Maryland Medical Center, Baltimore, MD; ^cTriCore Reference Laboratories, Albuquerque, NM; ^dCore Laboratory, University of New Mexico, Albuquerque, NM; ^eDepartment of Clinical Pharmacology, George-August-University University Medical Center Goettingen, Göttingen, Germany.

*Address correspondence to this author at: University of Maryland Medical Center, Laboratories of Pathology, 22 South Greene St., Baltimore, MD 21201. Fax 410-328-5880; e-mail: rchristenson@umm.edu.

Received June 29, 2020; accepted June 30, 2020.

DOI: 10.1093/jalm/jfaa120

© American Association for Clinical Chemistry 2020. All rights reserved.

For permissions, please email: journals.permissions@oup.com.

PREAMBLE

A special collection targeting value would be incomplete without considering the economics and principles of evidence-based laboratory medicine involved with changing practice and implementing innovations. Economics is the primary topic of a contribution that uses a scoping strategy to address the question of who should conduct health economic evaluations of laboratory tests. Another article applies economic principles, using a value proposition format, to justify genomic testing as part of personalized medicine interventions. Value-based healthcare is an opportunity for laboratory medicine. Healthcare systems are pressed to be cost-effective. Consequently, there is growing acceptance of value-based assessments and judgment of outcomes relative to costs. For laboratory medicine, value-based strategies are essential to providing cost-effective precision diagnostics. A value proposition for individual test utility must be assessed in the context of a patient-centered care pathway. Use of evidence-based laboratory medicine is an essential tenet for generating the value required to make policy and health delivery decisions. Applying evidence-based laboratory medicine adoption and implementation of medical tests is reviewed as part of the collection in this issue. Furthermore, many of these principles are discussed in the context of a managed care organization's comprehensive efforts to deliver services to patients with diabetes mellitus in high-prevalence populations.

Healthcare challenges have numerous drivers and goals for innovation. It will be necessary to improve outcome for patients, quality of care, access to care, and process of care. New biomarkers and new treatments have to be developed while reducing the requirement for resources and environmental damage. We are fortunate to have several very innovative contributions in the field of molecular diagnostics in this collection. These articles describe technology and value propositions for the use of liquid

biopsy to detect circulating tumor cells, the use of molecular pathology biomarkers in oncology, and the use of donor-derived cell-free DNA testing in the field of solid organ transplantation. In this context, precision medicine, as per the NIH definition, is an emerging approach for disease treatment and prevention that takes into account individual variability in genes, environment, and lifestyle for each person. Precision diagnostics is required for more accurate prediction of which treatment strategies will be effective for individual patients. Illicit opioid use in the United States is a public health epidemic. According to the CDC, 70% of the 67 367 overdose deaths in 2018 involved an opioid. The United States is in the third of 3 waves: the first was from 1990 to 1999, with the mortality resulting from increased prescribing of opioids; and the second wave, which was the rapid increase in overdose deaths from heroin, occurred between 2010 and 2013 (2). The third wave began in 2013 with substantial increases in overdose deaths involving synthetic opioids, particularly those involving illicitly manufactured fentanyl (3). The market for fentanyl continues to evolve, and illicit use can be found in combination with heroin, counterfeit pills, and cocaine (4). A report from the collection articulates how laboratory medicine can add value to the fight against the opioid epidemic. A second report explains how clinical needs are changing and how to deliver more insightful interpretive data with urine drug panel and toxicology testing. These articles are important to this public health crisis.

We only hope that the readership of *The Journal of Applied Laboratory Medicine* will learn and enjoy reading the content in this special collection on adding value to our profession. This topic requires thoughtful consideration every day and forging of plans for future action in the field. On behalf of the 3 guest editors, we wish to express our sincere gratitude to all of our colleagues who

contributed to this special collection as authors, peer reviewers, and discussants. This special collection in *The Journal of Applied Laboratory Medicine* would not be possible without the AACC

professional staff, which contributes such excellence in ensuring that the processes remain on track and that all included articles are of the highest possible quality.

Author Contributions: *All authors confirmed they have contributed to the intellectual content of this paper and have met the following 4 requirements: (a) significant contributions to the conception and design, acquisition of data, or analysis and interpretation of data; (b) drafting or revising the article for intellectual content; (c) final approval of the published article; and (d) agreement to be accountable for all aspects of the article thus ensuring that questions related to the accuracy or integrity of any part of the article are appropriately investigated and resolved.*

Authors' Disclosures or Potential Conflicts of Interest: *Upon manuscript submission, all authors completed the author disclosure form. Disclosures and/or potential conflicts of interest: **Employment or Leadership:** R.H. Christenson, *The Journal of Applied Laboratory Medicine*, AACC; D.G. Grenache, guest editor, *The Journal of Applied Laboratory Medicine*, AACC; M. Oellerich, guest editor, *The Journal of Applied Laboratory Medicine*, AACC. **Consultant or Advisory Role:** R.H. Christenson, Siemens Healthineers, Roche Diagnostics, Becton Dickinson, PixCell Medical, Beckman Coulter, Quidel Diagnostics, Spingotec; M. Oellerich, Chronix Biomedical, Liquid Biopsy Center (LBC) GmbH. **Stock Ownership:** None declared. **Honoraria:** R.H. Christenson, Siemens Healthineers, Becton Dickinson, Beckman Coulter, Abbott Diagnostics, Roche Diagnostics, Quidel Diagnostics, PixCell Medical. **Research Funding:** None declared. **Expert Testimony:** None declared. **Patents:** None declared.*

REFERENCES

1. WHO. Coronavirus disease (COVID-19) pandemic. <https://www.who.int/emergencies/diseases/novel-coronavirus-2019> (Accessed June 2020).
2. CDC. Understanding the epidemic. <https://www.cdc.gov/drugoverdose/epidemic/index.html> (Accessed July 20, 2020).
2. O'Donnell JK, Halpin J, Mattson CL, Goldberger BA, Gladden RM. Deaths involving fentanyl, fentanyl analogs, and U-47700—10 states, July–December 2016. *MMWR Morb Mortal Wkly Rep* 2017;66:1197–202.
3. Drug Enforcement Administration. *2019 National drug threat assessment*. Washington (DC): Drug Enforcement Administration Strategic Intelligence Section, US Department of Justice; 2019. https://www.dea.gov/sites/default/files/2020-01/2019-NDTA-final-01-14-2020_Low_Web-DIR-007-20_2019.pdf (Accessed March 2020).