

Association for Molecular Pathology establishes new standard for clinical utility of molecular Dx

August 17 2016

The Association for Molecular Pathology (AMP), the premier global, non-profit organization serving molecular diagnostic professionals, today announced a new report that addresses the challenges in defining the clinical utility of molecular diagnostics for inherited diseases and cancer. The manuscript titled "The Spectrum of Clinical Utilities in Molecular Pathology Testing Procedures for Inherited Conditions and Cancer: A Report of the Association for Molecular Pathology" has been released online ahead of publication in the September 2016 issue of the *Journal of Molecular Diagnostics*.

Molecular diagnostic procedures are used for a myriad of purposes including diagnosis, prognosis, risk assessment, prediction of future disease, and monitoring and selection of therapies of disease in patients. Future advancements in precision medicine are threatened by drastic shifts in evidence demands and the adoption of very narrow clinical utility definitions that do not address all the important applications of molecular diagnostic testing. Without a correction, treating clinicians could be left to make decisions without an accurate molecular diagnostic result and the clinically valuable information needed for patient management.

In the manuscript, the AMP Framework for the Evidence Needed to Demonstrate (FEND) Clinical Utility Task Force recommends clinical utility definitions that appropriately recognize the full contribution and

value of molecular diagnostic testing to improve patient care. This approach emphasizes that a clinical test result's utility depends on the context in which it is used to classify a patient's disease or disorder and/or guide management. The authors also note that the recommendations can be extended to additional applications of molecular testing.

"Patient access to clinically useful and appropriate [molecular diagnostic testing](#) based upon realistic evidence levels is paramount and clinical utilities beyond therapeutic selection are valuable to patients, providers, and family members," said Elaine Lyon, PhD, 2014 AMP President and FEND Task Force Co-chair. "Ultimately, we need to capture evidence for the clinical utility of [molecular pathology](#) procedures outside of a traditional randomized control trial setting, recognizing that any individual test result is an intermediate outcome that relies on proper clinical interpretation and utilization in context for that specific patient to achieve maximum benefit."

"Molecular pathology testing procedures are vital tools for insight and analysis into various aspects of clinical practice," said Roger D. Klein, MD, JD, AMP Professional Relations Chair. "However, we need a more practical and patient-centered approach for evaluating clinical usefulness before we can truly deliver the promise of precision medicine."

More information: Loren Joseph et al, The Spectrum of Clinical Utilities in Molecular Pathology Testing Procedures for Inherited Conditions and Cancer, *The Journal of Molecular Diagnostics* (2016). [DOI: 10.1016/j.jmoldx.2016.05.007](https://doi.org/10.1016/j.jmoldx.2016.05.007)

Provided by Association for Molecular Pathology

Citation: Association for Molecular Pathology establishes new standard for clinical utility of molecular Dx (2016, August 17) retrieved 24 April 2024 from <https://medicalxpress.com/news/2016-08-association-molecular-pathology-standard-clinical.html>

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