

Association for Molecular Pathology
Promoting Clinical Practice, Basic Research, and Education in Molecular Pathology

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January 26, 2007

John Agwunobi, M.D., M.P.H., M.B.A.
Assistant Secretary for Health
U.S. Department of Health and Human Services
Room 434E, 200 Independence Avenue S.W.
Washington, D.C. 20201
PHCRFI@hhs.gov

Dear Dr. Agwunobi:

The Association for Molecular Pathology (AMP) is an international medical professional association representing over 1,400 physicians, doctoral scientists, and medical technologists who perform genetic testing, as well as other testing, based on knowledge derived from molecular biology, genetics, and genomics. AMP members practice their specialty in academic medical centers, community hospitals, independent clinical laboratories, and federal and state health facilities.

We would like to respond to the request for information regarding electronic health records and personalized medicine. As practitioners of genetic and molecular medicine, we deal daily with the limitations of current health information systems in managing, collecting, reporting and querying data generated from the laboratory tests that we perform. Specific problems include:

1. Health information systems that are not designed to integrate genetic molecular test management and reporting
2. Partial solutions that are implemented to handle the increasing demands, resulting in a patchwork system unable to integrate with other systems.
3. Variation among institutions and laboratories in reporting and integrating molecular data into a patient's medical record.
4. Lack of standardization to integrate laboratory instruments with laboratory information systems.
5. Lack of consistency between laboratory information systems that transfer electronic laboratory results and interpretations of those results. Information is often lost or truncated.
6. A growing number of laboratories with technology, but not genetic expertise, who report findings in the absence of the patient's clinical scenario or the clinical utility of genetic findings.
7. Lack of disease-specific integrated databases that associate genetic variants with clinical or genetic evidence for causation and/or therapeutic response.
8. Advances in new technologies that outstrip harmonization efforts.

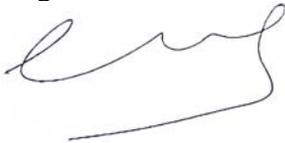
Although initiatives exist to address some of these problems, most efforts are very preliminary and are not ready to give recommendations or guidance. AMP's Clinical Practice Committee is involved with several of these initiatives. For example, a current project is to evaluate the feasibility of synoptic reporting for genetic test results. In another project geared towards interface between laboratory instruments and laboratory information systems, we are working with the Association for Pathology Informatics (API) to determine if specifications can be adopted that companies (both instrument and LIS providers) can strive to meet.

We also support efforts to develop locus-specific databases that would link genetic variants with clinical information. Clinical and laboratory professionals use these databases to help interpret the clinical significance of genetic variants discovered by the laboratory. A worldwide effort has begun which is soliciting support from societies, governments, researchers and clinicians. The enormity of this effort however, can be overwhelming, and may threaten its success.

We recognize the tremendous value in health care information technology. We support these efforts that can improve patient care.

If you would like to discuss the issue further, please contact Dr. Vicky Pratt, Chair of the AMP Clinical Practice Committee at Victoria.m.pratt@questdiagnostics.com or (800) 336-3718.

Regards,

A handwritten signature in black ink, appearing to read 'Andrea', with a long horizontal line extending from the end of the signature.

Andrea Ferreira Gonzalez, PhD
President