



The Peer Reviewed Management Source for Lab Professionals since 1969

^{CE} The effects of interval changes on blood donations

The beauty of disk diffusion susceptibility testing

Maintaining excellence in specimen collection

Armed Services Whole Blood Processing Laboratory unites

EXECUTIVE SNAPSHOT

Scott Bush
Chief Executive Officer
SunCoast Blood Bank



The constant evolution and challenges of electronic medical records

By Deanna Shukis, MS, CT (ASCP)^{CM}

Electronic medical records (EMRs) are widely accepted and well-established worldwide. Their benefits are highly intuitive—daily proving an evolving methodology for transmitting patient data across healthcare systems. Patients and their doctors readily subscribe to a simple system: send an order to a laboratory, retrieve results, compile and format data to a certain specification, and report back to a submitting physician or hospital. Each EMR vendor implements its own unique format—each nearly impossible to standardize across the system.

A successful EMR creates a reliable, digital image of a patient's health record from a secure, accessible, and interactive platform. With so many different types of modes for patient data to be captured and conveyed, evaluation of physician-ordered tests leans heavily on laboratory professionals working at all different levels, on unrelated software, and in a broad range of facilities. As they say, accuracy is key. Yet the variables are diverse, unpredictable, and the consistent well-being of patients may be at risk.

The prevailing EMR formats used are HL7 (the world's most common framework for the exchange, integration, sharing, and retrieval of electronic health information) and XML (the Extensible Markup Language developed by the Worldwide Web Consortium (W3C)). Text and PDF formats also apply. While each vendor has a preferred mode, comprehensive patient care is still the goal. How accurate information transmits reliably to physicians ultimately is what counts. Alarming, merging separate laboratory results and multiple formats into a patient's overall EHR (Electronic Health Record) still pose a daily threat.

There are better and safer ways. Connecting physician office EMR and Practice Management systems to the lab without traditional interfaces is one approach. This can reduce—and often eliminate—manual or duplicate data entry. A complete Laboratory Information System (LIS) should include CLIA compliance, and HIPAA-related security and privacy provisions, that combine to make EMRs more efficient.

More innovation is needed to ensure that EMRs continue to evolve and continuously incorporate the latest technology. For example, EMR efficiency will increasingly depend on the dynamic, automated data element integration of molecular testing for PCR (polymerase chain reaction), applications of immunology science, FISH (fluorescence in situ hybridization), karyotyping (pairing and ordering all the chromosomes of an organism), as well as DNA/RNA, and NGS (next generation sequencing).

Technology will drive the trend toward a better and more consistent EMR network, but so will commercial opportunity. Kalorama predicts the EMR marketplace to reach \$36.6 billion by 2021, including revenues for EMR/EHR systems, CPOE systems, and directly related services.¹ Clearly, there's a pressing incentive for providers to get this right. The ultimate goal—ensuring the highest quality patient-centered care—demands it.

Merging EMR data is critical to ultimate patient care

The pivotal challenge to a successful EMR is creating a single record from a diverse assortment of data types and formats. These might include photographs, text, charts, tables, or even videos. Confusion and complexity increase when merging lab results from separate laboratories. The values represented in a test field may have changed since they were entered or they could represent something altogether different from each other. Such LDTs (laboratory developed tests) may fluctuate wildly in value. This is why physicians and clinicians often follow the trends of results, rather than actual values.

Although human error and missed entries always play a role, a reference lab might have changed part of a test, disallowing automatic transmission of results to the EMR. Nevertheless, institutions increasingly realize that quality issues resulting from outside laboratory test results being posted to an EMR drive a need for better policies. Until then, in receipt of incomplete or vague EMR data, clinicians may conduct web searches to find their own normal test result ranges. Inadequately informed, physicians then might make unnecessary referrals.

Some outside laboratories blame frequent differences in reference ranges, claiming that merging test results is unacceptable. But these results may fit an established institution's workflow, or patients might request them directly, making it difficult to follow a chain of custody. It is often unclear who holds legal or regulatory responsibility for making sure that outside results are merged correctly. Despite this, while laboratories have limited control over the results, many clinicians still know that merging test results will help force a more consistent selection of testing protocols in the future.

As time passes, merging lab results will be more important, more necessary, and more complicated. Patients will increasingly rely on home-generated testing and the accuracy of monitoring and reporting vital signs, nutritional, general health, and fitness data. Integrating this data with common protocols and consistent platforms into a reliable EMR will be essential. In just the last month, Geisinger and Merck announced two web-based workflow solutions embedded directly within the EMR for both physician and patient home use, noting their experience that about 70 percent of patient medication lists are inaccurate and can lead to medical errors.² LIS companies within the industry need to be responsive to changes in the EMR marketplace with equal resolve.

Successfully merging laboratory test results and simultaneously maintaining EMR consistency and integrity will be a leading priority for the healthcare industry in coming years. There's a lot at stake—most notably the highest possible quality in patient care.

Why MDx matters for EMR safety, efficiency

Along with the clinical implementation of next generation sequencing NGS, molecular diagnostics (MDx) has transformed greatly over the past 10 years. The combination of both technologies—optimizing a molecular lab while

incorporating genome interpretation and reporting directly into a patient's EMR—will spur even more applications. One of the key future drivers for the growth of MDx testing will be the increasingly widespread public health challenge of resistance to antibiotics. It's a crisis that requires rapid testing, aggressive antimicrobial programs, and consistent public policy action.

A broad new frontier in expanding and improving EMRs, MDx combines the best in genomics (the study of all the genes in a cell or organism), and proteomics (the study of all proteins). Determining how genes and proteins interact in cells, it creates molecular "signatures" (or expression patterns) that greatly improve our ability to expose cancer and other diseases. Molecular diagnostics testing combines qualitative and quantitative values to help form a comprehensive and targeted patient diagnosis. This rapidly evolving technology will help move lab testing toward the greatest point of impact, quickly deploying results that offer the greatest patient-care benefits.

Clinicians and laboratories will need to make sure that laboratory systems can fully support the complexity of NGS and molecular testing. Current laboratory information systems, which typically lack the functionality to handle current or future molecular testing, need to modernize. Given the high standards for patient care that all labs, clinicians, and healthcare practitioners seek, we are certain that the industry will put in place the infrastructure needed to reap the many benefits of molecular diagnostics.

The future of EMR and personalized medicine

The importance of MDx has become integral to the evolution of personalized (or precision) medicine. Personalized medicine enables anyone to build a strategy for healthy living—from data already tailored to their bodies and their lifestyle. A personalized healthcare plan is always at hand and patients have ready daily access to data, whether from sensors, biometrics, or smart devices. In general, analyzing individual cells at a molecular level enables us to better understand the role of heterogeneous cell populations in developing diseases, and how we can best create effective personalized medicine therapies. EMRs have allowed physicians to

track this patient data over time—a highly effective method for identifying patients due for checkups and monitoring patient vaccinations or blood pressure readings. They also have helped improve patient care through access to information from patients themselves.

Another diagnostics field adding value to our EMR and personalized medicine plans is pharmacogenomics—the study of how genes affect an individual's response to certain drugs. Since our genes are critical to metabolizing active compounds, along with drug interactions and environmental factors, we all need to discern how our healthcare system assigns prescriptions. Experts estimate that Americans spend nearly \$300 billion annually on ineffective drugs; clearly there is ample motivation to improve this process.³

Personalized medicine continues to shape the healthcare landscape, accompanied by a rapid rise in frequency and a broad variety of new testing protocols. It is well accepted that genomics-informed medicine

will be fundamental to the future of patient care, giving us a more detailed understanding of how diseases advance and what clinicians and patients can do to influence outcomes. ↻

REFERENCES

1. EHR: Over 30 Billion-Dollar Market and Growing [Online] Available at: <https://www.kaloramainformation.com/about/release.asp?id=4393>
2. News Release [Online] Available at: <https://www.geisinger.org/about-geisinger/news-and-media/news-releases/2018/08/16/21/10/geisinger-merck-unveil-new-applications-to-help-improve-patient-communication-and>
3. How Pharmacogenomics Is Improving American Healthcare [Online] Available at: <https://www.fool.com/investing/2018/08/10/how-pharmacogenomics-is-improving-american-healthc.aspx>



Deanna Shukis, MS, CT (ASCP)™, serves as Vice President of Product Management for **Psyche Systems Corporation**, provider of Laboratory Information Systems for Anatomic Pathology, Molecular Information Diagnostics and Management, Microbiology, physician practice EMRs, Web-based Outreach Integration, and Lab Management Solutions.



When you need SUPER LIS...

WindoPath
AP LIS

NucleoLIS Molecular
MIMS

- Dynamic Comprehensive Patient Reports
- Application Configuration Management
- Laboratory Test-Defined Workflows
- Integrated Management Reports
- EMR Hub Integration

...Psyche Systems is your super hero for AP LIS and Molecular MIMS

Visit our website psychesystems.com/getpsyched for more information or to speak with a Product Engineer.

 **PSYCHE**
Medical Laboratory Software

Psyche Systems Corporation
25 Birch Street, Bldg. B1-#200, Milford, MA 01757
800.345.1514 www.psychesystems.com



NucleoLIS™

Molecular Information Management Solution (MIMS)

NucleoLIS is a fully automated solution designed to support and manage the unique workflow and complex reporting requirements of the clinical, molecular and genetic labs. NucleoLIS allows you to build and fully configure your specific test menus and workflows, supports rules-based logic for reflex testing and features highly customizable report formatting and distribution. You can now streamline the diagnostically diverse complexities of clinical, molecular and genetic testing.

NucleoLIS Attributes

- Handles all clinical and molecular disciplines and workflows (ie: Chemistry, Hematology, Urinalysis, Microbiology, PCR, FISH, Karyotyping, Immunology, Pharmacogenomics, and DNA Sequencing)
- Configurable data tables allow for the capture of required result elements, allowing comprehensive result reporting for each test in your menu, including images and calculated data
- Automated rules-based logic can be applied for reflexive and confirmatory testing
- Define specific bar code-enabled workflows for any sample or batch to quickly and efficiently track location and phase of processing
- Specimen storage manager keeps track of where and when specimens are stored for easy retrieval or access
- Batch/Run Management function creates and manages batches or “runs” for any analysis, including well-plate assignment, mapping, and communication with automation platforms
- The linking of complete patient history, including familial relationships enhances diagnostic and predictive outcomes
- Scan, attach, and link supplemental documents such as external historical patient medical records, lab reports, images, signed consent forms, etc. for each patient and that patient’s linked family members
- Supports multiple signatures on a case based on testing performed, technologist, pathologist, or geneticist
- Integration with Pharmacogenomics (PGx) reporting tools to support personalized medicine initiatives
- Integration with instrumentation that includes result/release capabilities