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Laboratory Diagnostics and the Journey to Harmonization in the Identification and Treatment of Clinical Disease

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The Affordable Care Act and Medicare and Medicaid reimbursement are topics of daily discussion in the health care environment. But what is often misunderstood is that there are multiple areas in the health care environment that are affected by these policies. There are misconceptions in the general public regarding all of the information and training that goes into providing equitable quality patient care.

As a medical laboratory science professional, the knowledge of what goes on behind the doors of a diagnostic laboratory and the training needed to provide quality care for development of the workforce is quite a mystery to the general public. I cannot recall the number of times I have been asked questions such as; "Well aren't those individuals trained on the job?" Or "Are there really degrees for individuals to do that job?" Unfortunately, there is a serious lack of understanding and frankly, recognition for the knowledge and skill needed to become a qualified laboratory science professional.

Recently, in the national news, there have been multiple stories regarding errors in the laboratory and the poor outcomes associated with patient care. Not to mention the development of what seems to be revolutionizing technologies that are later found to be unreliable. In addition to the lack of quality care, there are many factors currently influencing the need for knowledge and expansion of funding to support the development and training of skilled laboratory science professionals. The National Bureau of Labor and Statistics reports a projected 16% shortage of laboratory professionals over the next decade. That number does not include the 19% shortage of phlebotomists. Seventy to eighty percent of the medical decisions that are made during the course of a patient's care are based on the results provided by the laboratory. So why is it that these problems exist?

There is a huge lack of understanding and respect for the individuals who routinely process and make decisions concerning the validity of diagnostic test results. These individuals are responsible for determining the accuracy of the results, identifying whether or not the specimen was appropriately collected and then interpreting the information prior to releasing the information to the clinician.

In addition to the workforce shortage and need for highly trained laboratory professionals, an improved degree of standardization and harmonization of laboratory testing is needed. Laboratory standardization involves insuring that all diagnostic test results maintain a high level of accuracy and precision independent of the testing system, laboratory and testing personnel. Standardization typically utilizes sample reference materials, a "gold standard" or reference method for comparison, and comparisons across different testing systems over time. A procedure referred to as validation insures that a particular system or procedure meets the standards as related to the reference method. Whereas, verification is a onetime process that determines and evaluates a test system performance for a particular diagnostic test or test panel [1-4].

Despite the efforts of regulatory agencies to standardize diagnostic laboratory tests, a patient who enters any medical facility across the globe cannot insure that a test result will be comparative to one that was completed at a different facility. This is referred to as a lack of harmonization. Interlaboratory comparisons and harmonization of some testing methods has occurred for cholesterol in heart disease and HgbA1c in diabetes. This process will reduce the variability in reporting of diagnostic testing and what is referred to as false positives, indicating the presence of disease or condition in a patient that is not there, and false negative results, failing to detect a disease or condition in a patient that is there. Standardizing laboratory diagnostics across the globe will dramatically improve this factor greatly enhancing patient care. This change will also significantly reduce unnecessary costs in health care by preventing patients from receiving unneeded treatments or failing to receive adequate care early in a disease process, ultimately preventing the need for more drastic and expensive procedures in the future.

Although, harmonizing laboratory diagnostics will greatly improve patient care this alone will not solve the variability that exists in the treatment and management of patients. The harmonization of laboratory testing will also lead to the harmonization of algorithms and treatment formularies for clinicians that will improve the standards of care for patients. For example, harmonizing the definition of a disease or condition such as metabolic syndrome for instance that would include what are the laboratory test results that indicate a mild, serious or life threating case as an example. Different clinicians currently utilize different criteria and treatment options based on their experience and that of colleagues. This may occur in a small health care practice or be as broad as a large health care system. Defining laboratory tests will lead to the definition of diseases and conditions, which will lead to the development of global health care algorithms and therapeutics.

In order for an initiative as large as this to occur, it will require the collaboration and support of private and public entities that will include the development of domestic and international partnerships. Initiatives are currently being developed and supported by the premier laboratory diagnostic professional organizations in the United States that include groups such as the American Association of Clinical Chemistry and the American Society for Clinical Laboratory Science in conjunction with public health authorities (Center for Disease Control) and other prominent members of the medical communities.

On December 14, 2014, he United States Congress passed a bill that was signed into law by the President of the United States entitled the

Consolidated and Furthering Continuing Appropriations Act of 2015. Harmonization of laboratory results was identified as a significant factor in the report as indicated by the following statement: *"Laboratory professionals use a variety of test methods to obtain accurate and informative results to diagnose and treat patients, which may result in the reporting of different numeric values for the same test. CDC is urged to partner with the private sector in "harmonizing" clinical laboratory test results."*

As dedicated health care professionals, researchers and academics, it is incumbent upon this community of individuals to provide information and support to this endeavor. The Journal of Clinical Case Studies is one avenue where information may be gathered and reviewed to document and support the need for such an initiative and provide an avenue for the dissemination of evidence based practices that will lead to the development of harmonization across health care.

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