

Evolution of Laboratory Methods



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Ever since the dawn of medicine in the Greek ages, identifying a disease has been of primary concern for all “men of medicine”.

Initially, a diagnosis was only a speculation, with the cause being based on bad luck (the gods have punished his greed with fever), and most of the modern understanding of searching, testing and identifying a disease didn't start until the 17th Century with the likes of Koch, van Leeuwenhoek, and Virchow.

What identifies an abnormal result, and what result is within the “normal” population (diabetic vs. normal glucose), and what are the drawbacks of certain tests (in-accurate result if not fasting) were clearer by the mid-20th Century. The HLA (MHC), antibodies, and therefore transplantation and transfusion all became more successful thanks to the knowledge of how antibodies form, the cells involved (T-cell vs. B-cell), and the classes of antibodies (IgG, IgM, IgE, IgA, and the yet mysterious IgD).

Heredity, genetics and the “thing” that links all living beings, our DNA, was another milestone discovery. Along with the electron microscope, we were able to understand the vast unknown world of viruses, what they are and how they work. We can now “catch” HIV, Hepatitis B, and tuberculosis in 3 hours using their genes rather than wait for days and weeks by older methods.

The past century has therefore seen a tremendous

improvement in our understanding and diagnosis of illnesses. Globalization has added an extra positive point to all this by providing us with better and speedier analyzers, with cheaper prices. We can currently perform >800 tests/ hour/ analyzer, without touching the patient's serum; only 30 years ago, technologists had to pipette biologic samples by mouth. They could only perform 30-40 tests per hour, with possible pipetting errors.

Current advances have introduced automated systems that use a drop of blood to analyze a whole panel (lipids, liver and kidney enzymes, cardiac ...etc.). The use of standardized reagents has also ensured that, for example, a glucose level reached for example, by a Roche analyzer will equal to the level reached by an Abbott machine for the same specimen. **Since a doctor's differential diagnosis will change based on the lab results, it is important that these results are not only correct, but also controlled and final.** An FMF study in one lab can't differ from the same study in another lab, since FMF is a hereditary problem. Even simpler, a blood group/Rh of a person can't change over time.

Current frequency of Lab errors has usually ranged between 0.05%- 0.6%, of which 75% are pre-analytical (phlebotomy, patient preparation and ID), 13% are analytical (lab error, calibration), and 12% are post-analytical (result x given to patient x') (Bonini, 2002). Therefore, international quality guidelines were set to study the above processes, gather data, and then deliver better services to meet &/or exceed customer expectations. These customers can be both doctors and patients. The improvement in this case must be ongoing, in the fields of both management (HR, customer survey) and technologies (Analyzer choice, CME), (Brue, 2002).

Several internationally known organizations are in operation to ensure that laboratories worldwide meet the necessary guidelines, such as CAP (USA), CLSI (former NCCLS), AABB (blood bank), TJC (former JCAHO), ASCP (US), and ISO (9001:2008 for quality management



systems; 17025 for lab accreditation). These are all non-governmental organizations on which many governments depend upon to maintain a baseline of standards for their laboratories (Henry, 2011). Currently in Lebanon, the Ministry of Health has used some of these guidelines to assess the lab quality in local hospitals. It is also planning to do the same for all private laboratories in the near future. **Other than this, the MOH has also placed a minimum of requirements for any lab to open, from the position of the responsible person, to what minimum necessary equipment must be present.** Regardless of this, many private and hospital-based local laboratories have implemented the ISO 9001:2008, which is the base for other future quality measures. This system allows the Lab and its management to:

- Survey customer complaints and suggestions. Use them for improvement
- Internal auditing of staff and methods
- External control of tests, proficiency testing using European or US labs as reference.
- Continual Medical Education of staff (CME)

- Archive all lab data (calibration and patient results), traceability.
- Contacting doctors in case of panic values.
- Documentation of all incident reports, panic values. Notifying the MOH when necessary.

In summary, there has been much advance in the laboratory department in the past century. Most professional laboratories increase their test menu list monthly with newly discovered tests. Standards have also been placed globally so that the criteria for identifying an illness here or in the US or Europe are the same. This also helps so that results completed in Lebanon can be used for treatment/ follow-up elsewhere. All these measures help a physician in his/her treatment with more confidence than compared to 100 years ago. Doctors need to have a good differential, and request the necessary tests to diagnose an illness. It's the laboratory's job then to provide with accurate results in an acceptable timeline to aid in the final diagnosis of that illness.