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Clinical Laboratories – Production Factories or Specialized Diagnostic Centers

Fahad Hassan Algusheri[1] , Ibrahim Abdullah Alraqibah[2] , Ahmed M. Alshehri[3] , Alaa Hassan Almeleihi[4]

[1-4]Clinical Laboratory Sciences.

Abstract:

Since a large proportion of medical decisions are based on laboratory results, clinical laboratories should meet the increasing demand of clinicians and their patients. Huge central laboratories may process over 10 million tests annually; they act as production factories, measuring emergency and routine tests with sufficient speed and accuracy. At the same time, they also serve as specialized diagnostic centers where well-trained experts analyze and interpret special test results. It is essential to improve and constantly monitor this complex laboratory service, by several methods. Sample transport by pneumatic tube system, use of an advanced laboratory information system and point-of-care testing may result in decreased total turnaround time. The optimization of test ordering may result in a faster and more cost-effective laboratory service. Autovalidation can save time for laboratory specialists, when the analysis of more complex results requires their attention. Small teams of experts responsible for special diagnostic work, and their interpretative reporting according to predetermined principles, may help to minimize subjectivity of these special reports. Although laboratory investigations have become so diversely developed in the past decades, it is essential that the laboratory can provide accurate results relatively quickly, and that laboratory specialists can support the diagnosis and monitoring of patients by adequate interpretation of esoteric laboratory methods.

Keywords: Turnaround Time, Clinical Laboratories, Autovalidation, Interpretative Results.

Introduction:

Since about 2/3rd of medical decisions are based on laboratory test results (Laposata, 2004). it is obvious that clinical laboratories need to be organized in the best possible way to meet this demand. Optimizing, in the economic aspect, usually means fusing smaller units into larger ones to save costs, as well as trying to automate as much as possible. Undoubtedly, this has been an ongoing tendency for decades and has resulted in centralized, mega-laboratories that may process 15-20 million tests per year. There are two key concepts in these large laboratories: integration, where analytical instruments or groups of instruments are linked with pre- and post-analytical devices, and consolidation, where different analytical technologies or strategies are combined in one instrument or in a group of connected instruments. However, there is a logical limit to centralization, since no laboratory expert anticipates that a dozen 'ultra-mega-large' laboratories would be enough for a mid-size european country, or that these laboratories would be the best from the point of view of optimal patient care. Politicians and health economists, on the other hand, often tend to think differently, and, as they are unaware of the details of the laboratory profession, such conceptions may actually prevail. The majority of the laboratory tests are basic clinical chemistry, hematology, urinalysis and hemostasis screening tests. In many smaller laboratories this comprises the whole repertoire of the laboratory. There are two expectations from the patients and their caretaking doctors: the results should be accurate and they should be delivered fast. The laboratories are putting a lot of effort in the former by using internal and external controls, investigating interfering factors and linearity values, however laboratories are sometimes not paying enough attention to delivering the results on time. The timely delivery of laboratory results, however, is also very important.

METHODS TO IMPROVE LABORATORY PERFORMANCE:

- The measuring clock of clinicians' satisfaction: turnaround time.

Central laboratories usually have three types of assays based on TAT:

- Emergency testing. Here the complete 'from vein to brain' TAT should be below 60 minutes. In some cases, extra-urgent samples may need to be further prioritized, such as in the case of patients with ischaemic stroke waiting for thrombolysis.
- Routine testing. The TAT for routine test results today may be quite close to the emergency results, but a more realistic maximal routine TAT value is 3 hours. Nevertheless the median TAT for most the routine assays is around 80-90 minutes.
- Special testing. The TAT for these assays may be highly variable ranging from 2-20 working days. It can be assumed that no laboratory test should take more than 20 working days, as it would not be possible to effectively implement those slowly generated results into actual patient care.

The first two types of testing are usually part of the 'production factory' (Janssens , 2013). while special testing occurs in specialized centers. A delicate balancing is required to devote sufficient resources from the laboratory to each of these test groups.

Ways to optimize test ordering:

While we provide a medical service for the patients, whether we like it or not, with a large part of laboratory testing we implement a factory-type work flow, mostly for bulk tests described above (Claustres, 2014). It may be assumed that, indeed, doctors often use too many diagnostic tests, and these tests are requested too frequently. This may be because they

have erroneous expectations of the tests, are unaware of tests carried out previously, or are simply trying to be rigorous. Because these tests can be easily requested, it has been estimated that 8-30% of test requests may be superfluous (Janssens, 2010). Thus, it is plausible that laboratory performance may also be improved by eliminating overtesting. This is, however, somewhat difficult to carry out optimally, and several techniques have been suggested to manage, or rather, to limit the ordering of test requests. One option is to allocate the whole laboratory budget to the requesters or to use a computerized clinical decision support system (CDSS) in medication as well as laboratory test ordering. Most other possibilities refer to tricks that the laboratory can do to prevent overtesting. These may include discouraging or not automatically fulfilling test requests, or creating explorative and reflective testing, such as beginning with a nonspecific, cost-effective but sensitive test, and then performing more targeted and usually more expensive tests only when the results of the initial screening tests are abnormal. A quite useful method could be to exert influence through setup of request forms, or to reduce the availiability of testing at certain times.

How to make the most of the laboratorians' time: autovalidate:

One way to achieve meaningful organization is by automated evaluation of laboratory results for straightforward cases using autovalidation. If a laboratory is not using autovalidation in 2016, it is frustrating for the laboratory specialists, who are under constant pressure to devote their skills to checking the correctness of tens of thousands of numerical values for 'simple cases'**, which may belong to any of the groups below:**

i.each laboratory result is within the age specific reference range;

ii. only minor, clinically insignificant laboratory changes occur or
iii. many laboratory results are pathological, but all are similar to preceding values and are compatible with the diagnosis provided.

Tedious manual validation of simple cases by laboratory specialists carries the risk of serial mistakes, since after a while it is impossible to responsibly evaluate large quantities of data. Additionally, this laborious task takes the expert laboratorian's attention away from quality validation, where their time should be devoted to more complex cases.

In a large laboratory with a wide portfolio, the following simple rule may apply:

- Around 90% of the samples require 10% attention and
- The remaining 10% of the samples require 90% attention.

Expert opinion of simple tests:

If we just consider the basic laboratory portfolio, several complex cases could be mentioned. The automated hematology analyzer reports should be confirmed and validated, since falsely low neutrophil percentage may be reported with erroneously high monocyte numbers in cases with partial or complete myeloperoxidase (MPO) deficiency (Piva, 2009) if differential counts are based on volume and MPO activity . In addition to such cases several other areas exist that require interpretative reports (Vecchio, 2004) that has been shown to contribute to physician satisfaction (Laposata, 2014). Aside from such cases, most of the quality time for general routine analysis is devoted to microscopic investigations of peripheral blood or cerebrospinal fluid samples.

Expert opinion of special tests:

Another area of interpretative reporting is when samples are sent for more esoteric tests, and in many cases no test requests are indicated, rather, a hypothesized diagnosis need to be confirmed or rejected.

These types of investigations mostly, but not exclusively, involve flow cytometric analysis of peripheral blood or bone marrow, cytogenetic analysis for G-banding or FISH, autoantibody pattern description, dynamic endocrine tests and special hemostasis assays for bleeding diathesis or thrombosis. Many of the nucleic acid-based tests can now be easily set up, but in some cases whole-genome sequencing and the interpretation of rare mutations may take many hours, or even days of qualified work from the laboratory specialists to delineate the diagnosis. Many of these techniques also require months or years of experience/training to gain sufficient expertise.

Recommendations:

Upon interpreting the results, the expert draws a conclusion that should contain any of **the five subsequent possibilities:**

- normal finding(s);
- non-specific finding(s) without clinical relevance;
- incidental finding(s) with possible clinical relevance;
- finding(s) of uncertain significance;
- pathognomonic (disease-specific, pathological) finding(s).

Since laboratory tests are usually requested by well-trained clinicians who are aware of the diagnostic, prognostic and monitoring value of the results, the over-interpretation of self-explanatory numerical tests can be useless and harmful. However, laboratory investigations have become so diversely developed in the past decades that in the aforementioned cases, as well as in case of many other special tests, it is essential that the laboratory specialist provides a meaningful interpretation to the laboratory findings.

Conclusion:

A clinical laboratory should be organized in a way so that the clinical pathologist can utilize most of his/her trained skills in evaluating results of specialized diagnostic areas and in interpreting laboratory reports for the physicians. This can be best achieved by introducing automated evaluation in the form of autovalidation in several routine laboratory fields in case of numerous samples that do not require direct medical surveillance. All these measures would facilitate that the laboratorian will become an indispensable part of the medical team.

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