Quality and diagnostic perspectives in laboratory diagnostics

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Abstract

Laboratory diagnostics is a medical discipline playing an important part in patient management. In laboratory medicine meaningful, accurate and precise routine measurements are essential for diagnosis, risk assessment, treatment and follow-up of patients. The contribution of the diagnostic laboratory in the overall diagnostic process is app. 40–60%, depending on the kind of disease status investigated. The diagnostic laboratory uses nowadays more than 1.000 different tests mostly provided by the *in vitro* diagnostic industry.

Key words: laboratory medicine; diagnostic process; pre-analytical phase; post-analytical phase

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The laboratorian – a partner of clinical medicine

The contribution of the diagnostic laboratory in the overall diagnostic process is app. 40–60%, depending on the kind of disease status investigated (1). The specialist working in the diagnostic laboratory has to be actively integrated in the relationship between patient and the doctors like the radiologist who does not only produce x-ray, CT- and MR-pictures, but also gives his diagnostic comments. The same has to be true for the laboratorian using pathophysiological and clinical knowledge as basis of his interpretation of laboratory results. Since the number of test results in a patient report is continuously increasing, the quality of the results has to be monitored by a quality system dealing with all steps of the diagnostic process.

The diagnostic process

To achieve these goals, as well as to improve the overall quality, diagnostic laboratories are now implementing efficient quality management systems. Many guidelines for quality management have been published so far (2–6). It is generally assumed that the pre-analytical, the analytical and the post-analytical steps in the overall diagnostic process will be improved and more economically triggered with this approach. In most applied systems, however, the medical, patient-related part which deals with interpretation of complex conditions is lacking.

Basically, the overall quality of the diagnostic process depends on the following steps:

1. **Pre-analytics**
   - rationale, disease oriented test selection, diagnostic algorithms;
   - information about patient's disease status and medication;
   - preparation of the patient;
   - sampling of specimens;
   - pre-analytical handling of specimens (storing, transport conditions);
   - clear identification of patient samples.
2. **Analytics**
   - use of accurate, precise and traceable analytical methods;
   - use of specific methods;
   - knowledge of analytical interferences and limitations;

- maintenance of analytical systems;
- short turn around time;
- internal quality assurance for each test;
- regular participation in external proficiency testing systems.

3. Post-analytics

- structured patient reports:
  - identification of patient (sex, age), date of investigation, clinical diagnosis;
  - test results, reference ranges, biological variation of an individual;
  - clinical decision levels;
  - written diagnostic comments as a summary of complex test results;
- consultation with clinicians on individual patient results in cases of complex conditions;
- follow-up of laboratory reports on treatment of the patients.

The knowledge of the clinical status of a patient is pertinent for the correct selection of a laboratory test. The same is true about the medication of the patient, since this might have an impact on the analytical performance of the test. A wrong or a not performed test might result in a wrong clinical diagnosis and is costly.

Pre-analytics

In several areas of laboratory medicine, diagnostic algorithms are currently used, as outlined in several diagnostic guidelines. This is economically valid and decreases the performance of useless tests. Examples of several diagnostic guidelines in endocrinology, diabetes care, myocardial infarction and infectious diseases are referenced (7–11). The application of algorithms gives responsibility to the laboratory and speeds up the analytical process, since a single sample is used for the step by step measurements. E.g., one EDTA-blood can be used for cell counting, followed by microscopic cell differentiation and in case of the presence of pathological cells by immunophenotyping using flow-cytometry.

Analytics

The overall quality of a diagnostic laboratory depends on the collaboration and the mutual understanding between the parties involved, that are the laboratory professional and the clinician. When introducing a new test or changing a system, it is a kind of quality service for the clinicians to inform them about the following characteristics of the new test as well as to give a rationale explanation for the introduction:

- diagnostic usefulness of the test for a certain disease;
  - replacement of an outdated test or procedure;
  - benefits of the new test (diagnostic, economic;)
  - impact on the overall organisation (clinicians, laboratory);
- diagnostic specificity and sensitivity of the test;
- analytical performance of the test (accuracy, precision, interferences);
- age and sex related reference ranges;
- clinical decision levels based on diagnostic-clinical studies relevant for various medical disciplines.

In spite of the European Union (EU) In Vitro Diagnostic (IVD) Directive 98/79 EC (12) and the introduction of traceability in laboratory medicine (13), the same test by different IVD providers might give different results which is certainly confusing and misleading for clinicians. Therefore, laboratory professionals and the IVD industry in collaboration with professional organisations like the International Federation of Clinical Chemistry (IFCC) strive to achieve major harmonisation of laboratory test results (individual results, reference- and decision levels) by standardisation. Standardisation of all these important aspects will improve the overall diagnostic quality, will have an enormous economic impact, and will contribute to uniform test results over time and space (14). As long as this is not achieved, the laboratory specialist has to explain these differences to the patients and the clinicians, especially when confronted with a report from another laboratory.

Post analytics

The interpretation of test results is a key-element in laboratory diagnostics. The laboratory professional has to inform the clinician immediately and personally about critical, life threatening results. A correct interpretation depends on the information about patient's conditions. In institutions with electronic patient records this tool has to be used by the

laboratory to improve the quality of its reporting and make it more specific for the individual patient.

Future: integration of the diagnostic laboratory in clinical medicine

All kind of individual health data are stored electronically within a good functioning health system. This should be true not only for the laboratory data, but also for clinical informations like history of diseases, treatment, medication, specific allergies, and genetic dysfunctions. All parties involved in the treatment of a patient should use this following strict data privacy rules to obtain the highest therapeutic and diagnostic quality for the patient.

Professionals in laboratory medicine have been long focused on the analytical part of the total testing process. It is time to go "out of the laboratory" and make closer relationship with clinical staff. Therefore, the re-integration of the diagnostic laboratory into clinical medicine will in essence be the main future goal of our discipline. The integration of laboratory diagnostics and the modern techniques of molecular biology will result in individual treatments based on specific diagnostic test. E.g., pharmacogenetics testing will enable the clinician to select the most accurate drug in an optimal dosage for an individual patient, thus preventing toxicity and side effects (15,16). With these new possibilities, the diagnostic laboratory will add to clinical medicine a new quality.

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Kvaliteta i dijagnostičke perspektive u laboratorijskoj dijagnostici

Sažetak

Laboratorijska dijagnostika je medicinska disciplina koja ima važnu ulogu u obradi bolesnika. U laboratorijskoj su medicini svrhovita, točna i precizna rutinska mjerenja od ključne važnosti za postavljanje dijagnoze, procjenu rizika, liječenje i praćenje bolesnika. Doprinos dijagnostičkog laboratorija cjelokupnom dijagnostičkom procesu kreće se oko 40–60%, ovisno o vrsti statusa bolesti koja se istražuje. Danas dijagnostički laboratoriji primjenjuju više od 1.000 različitih testova koje nudi *in vitro* dijagnostička industrija.

Ključne riječi: laboratorijska medicina; dijagnostički proces; prijeanalitička faza; poslijeanalitička faza