

Importance of interpretative comments in clinical biochemistry – a practitioner’s report

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ABSTRACT

Interpretative comment (IC) from the clinical biochemist is a professional obligation. Most of the Nepalese clinical laboratories use only predefined comments on the report, while few laboratories do not provide comments at all. Apart from doctors, other healthcare professionals and sometimes patients themselves seek laboratory expert opinion in the interpretation of obtained results. The non-availability of patient’s medical record or limited communication with physicians as well as insufficient professional knowledge impacts the quality of interpretative comments in Nepal.

This report is intended to emphasize that the task of providing IC is becoming more important in the context of Nepal. Similarly, this report also guides those who provide interpretative comments.

INTRODUCTION

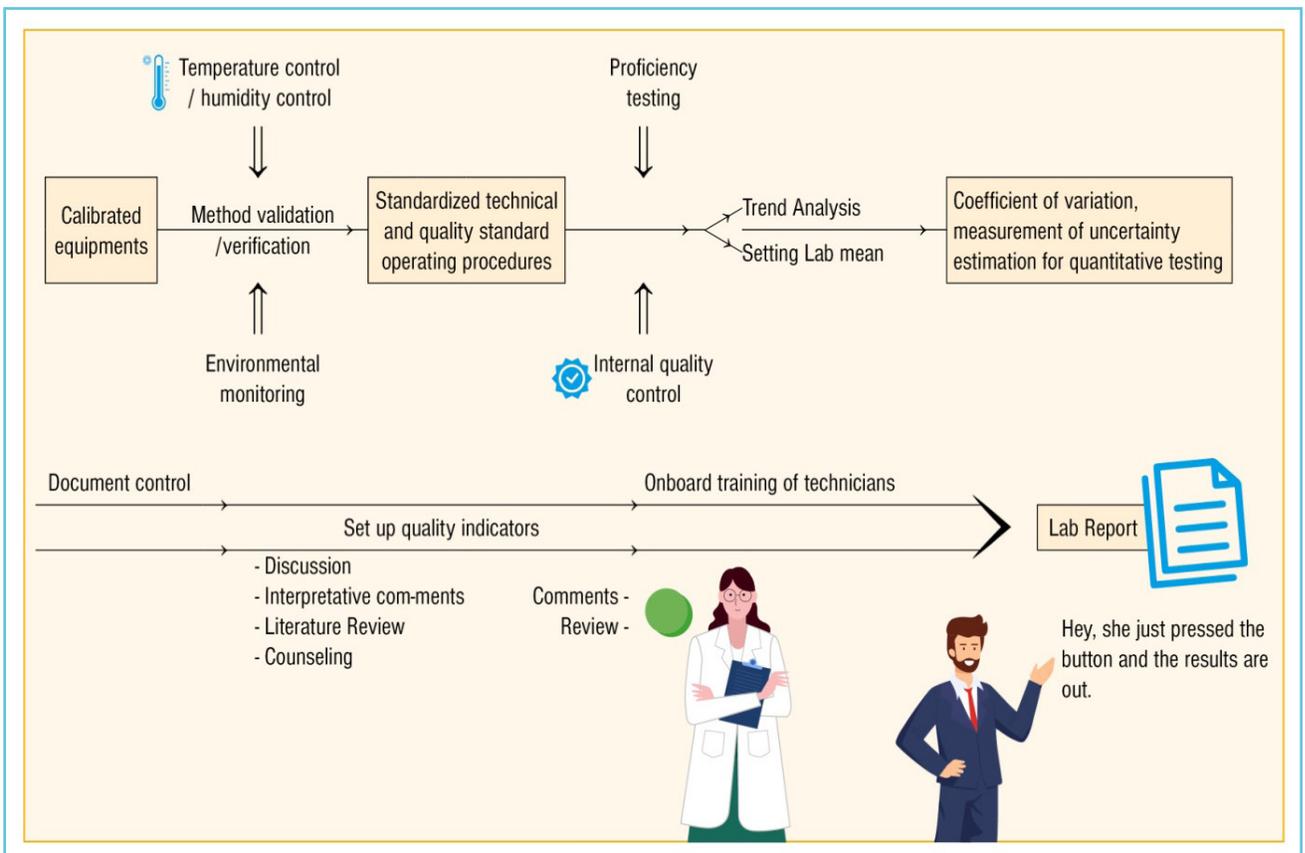
Laboratory professionals can contribute to the test result interpretation to provide other health-care professionals a better understanding of the obtained results. The understanding of analytical part of laboratory work and possible preanalytical influences is required for correct interpretation of test result which also requires the understanding of clinical significance of the results and patients clinical condition. Flagging up of a result outside reference interval is easily appreciated by the reader of laboratory reports, however true interpretation is based on understanding of all aspects of total testing process.

There has been tremendous improvement in the laboratory processes in the past years including preanalytical processes (such as bar-coding of primary samples, electronic orders,

automatic check for clots, lipemia, hemolysis and icterus), analytical processes (use of automated advanced assay platforms with low intra assay and inter assay variation) and post analytical processes (such as auto validation and connection of hospitals with laboratory information system). Together with all these improvements, the role of laboratory physician has changed which includes interaction with both clinicians and patients apart from technical chores. Clinical interpretation of obtained test result however depends on extensive practical and theoretical clinical expertise of the laboratory physician. (Figure 1)

Although there are no universal guidelines regarding the use of interpretative comments (IC), the ISO 15189 standard in its clause 5.8.3 states that the laboratory report should include

Figure 1 Role of laboratory physician in providing reports



IC where appropriate. (1) Correct interpretation of laboratory results is crucial for accurate and timely diagnosis and appropriate management of clinical condition. In two independent studies, authors reveal that IC establish a positive relationship between the laboratory and the clinic, and it reduces time to diagnosis, prevents misdiagnosis and reduces the number of irrelevant laboratory tests. (2, 3)

There is wide variation internationally, as regard to the extent to which ICs are provided on biochemistry reports. The objective of IC is to facilitate clinicians in the interpretation of complex laboratory results. This is especially important when, significant abnormalities are present, dynamic or uncommon tests are reported or where analytical or preanalytical factors not appreciated by the clinician may have influence in the interpretation of the results. In a study conducted at the laboratories in the United Kingdom, 77% of general practitioners and nurses answered that they would like to see comments on laboratory investigations. (4)

PRACTITIONER'S REPORT

When the laboratory report is incongruent to the clinical features, patients have the tendency to visit different laboratories for the same test and compare the results between laboratories. Thus, the number of patients visiting hospitals with conflicting diagnoses based on different laboratory report adds confusion to the clinician. Auto validation and electronic reporting of laboratory results is a privilege for only few laboratories in Nepal. The missing central hospital information system makes it further difficult to trace the previous laboratory reports.

Most of the biochemistry lab reports contain only computer-generated comments that are present in each report irrespective of result. Individualized narrative comments for definitive classes of tests is practiced only by a few laboratories.

This in turn is largely attributed to the lack of trained and specialized manpower in all clinical laboratories. The free flow interpretative comments are the assessment of diagnostic test result in clinical outcome which is highly dependent on clinical context. Therefore, a competent laboratory physician in all aspects of investigation, diagnosis and treatment is required for this procedure. The IC added by inexperienced laboratory professional may add danger of providing inappropriate advice in the absence of complete clinical information. On the other hand, the computer-generated comments that are by default present in each individual report helps the user to understand the basics of the test and avoids delaying the release of reports. However, these comments are very limited in their application and take no account of clinical information provided by the patient. Moreover, the textbook or internet sources on which they are based are questionable.

With the increased awareness towards evidence-based medicine, laboratories are obliged to adhere to the general requirements for quality and competence put forward by the International Organization for Standardization (ISO) 15189:2012. Few laboratories are now accredited by this standard in Nepal that stimulates higher standards of quality within laboratories, thereby leading to more consistent and reliable test data.

There are reports of importance of ICs in diagnosing and monitoring hematological disorder and in facilitating early diagnosis of dyslipidemia associated inherited metabolic disease. (2, 5) The laboratory testing and interpretation of patients with suspected coagulation disorders requires consulting expertise and includes careful assessment of medical history, drug treatment, preanalytical and analytical factors, mixing studies and additional investigations. The situation is similar for other areas, and where ICs have significant role are morphological investigations

of peripheral smear and body fluids, electrophoretic assays, flow cytometry, toxicology and molecular tests. (6, 7)

Realizing the importance of IC in Nepalese context, adding comments for investigations was started for tests such as thyroid function, pituitary function, lipid profile, HbA1c and other test where interpretation is thought to be of help. Many comments are related to the sample quality, preanalytical interfering factors and recommendations based on the results (Table 1).

The motive of adding ICs is to help the requester to make the correct management decision for the patient, therefore it is essential that laboratory professional should contribute their best. As per the authors experience, the biochemical tests that should be considered for the

possible inclusion of ICs in Nepalese context are listed in Table 2.

It should be noted that the ICs could be technical or clinical. Technical comments are related to the sample quality and preanalytical interfering factors as mentioned in Table 2 with electrolytes as an example. Similarly, clinical comments typically comprise of mentioning absence or presence of an abnormality and its severity, possible cause for unexpected result along with clinical implication and a suggested additional testing or referral. Example: Comments on manual count for platelet aggregates when a Coulter counter indicates thrombocytopenia or recommending a glycerol blank test for possibility of pseudohypertriglyceridemia in a non-lipemic sample with a very high triglyceride value. (8)

Table 1 Interpretative comments in various phases of total testing process

Phases in the total testing process	Potential sources of error	Interpretative comments on
Pre-analytical	<ul style="list-style-type: none"> • Inappropriate test request • Patient/specimen misidentification • Sample collected from infusion route • Sample collection (hemolysis, clotting, insufficient volume) • Inappropriate container • Improper storage and transportation • Error in sorting and routing of sample • Pour-off • Pipetting and labeling error • Error during centrifugation 	<ul style="list-style-type: none"> • Cryoglobulins • EDTA induced platelet clumps • Icteric, hemolyzed or lipemic sample that could interfere other analytes • Physiological variation such as age, gender, pregnancy, diurnal cycle and fasting condition • Any significant context of test request

Analytical	<ul style="list-style-type: none"> • Equipment malfunction • Sample mix-ups • Interference (endogenous or exogenous) • Undetected failure in quality control 	<ul style="list-style-type: none"> • Sample dilution • Results for corrected calcium/sodium • Any changes in analytical platform
Post-analytical	<ul style="list-style-type: none"> • Erroneous validation of analytical data • Excessive turn-around time • Improper data entry and manual transcription error • Failure/delay in reporting critical values • Incorrect interpretation • Inappropriate/inadequate follow-up plan • Failure to order appropriate consultation 	<ul style="list-style-type: none"> • Any changes in reference interval • Recommendation for follow up or expert consultation • Recommendation for additional investigation • Any significant change from previous result and evaluation of result from the knowledge of biological variation. • Comments regarding calculations • Interpretation of dynamic tests, coagulation test, autoimmunity test, allergy test and molecular diagnostics test.

Table 2 Biochemical investigations that should be accompanied by interpretative comments in the Nepalese context

S/N	Parameters	Reason for interpretative comments in the Nepalese context
1	Tumor markers	A tumor marker concentration within reference interval does not exclude malignancy. There are various causes for false positive elevation of tumor marker and also the intraindividual variation of tumor marker is high. However, these tests are included in various healthcare screening packages without proven medical benefit, designed by clinical laboratories in Nepal.
2	Electrolytes	Most of the clinical laboratories acceptance criteria for remotely collected blood sample are not well defined. There are high chances of preanalytical error (Example: improper order of draw, mislabeling of tubes, under filling of tubes, delayed centrifugation, degradation during transportation).

3	Dynamic endocrine tests	Evidence based national guidelines for dynamic endocrine tests are missing. Therefore, correct name for dynamic test along with appropriated timing of sample collection and established standard for interpretation should be mentioned in the report. The cut-offs and further recommended test based on those cut-offs should be mentioned.
4	Endocrine tests	Rechecking of results in two or more laboratories with different immunoassay platform may result in conflicting diagnosis. There is lack of knowledge among clinicians about serial dilution, hook effect, polyethylene glycol precipitation test, heterophile antibodies and biotin interference, potential interference from Ayurvedic medicine and cross-reactivity of steroidal hormones with immunoassays.
5	Autoimmunity test	There is no harmonization for sample screening dilution. The clarification for any differences in the interpretation of result obtained using different method of determination is not fully appreciated by the clinician.
6	Test run using Immunochromatography (rapid kit)	Rapid kits require little technical skill and no special equipment therefore highly variable kits are commercialized in Nepal. Alternate confirmatory method of diagnosis should be advised based on sensitivity and specificity of the diagnostic kit keeping in mind the prevalence of disease.

Scientific articles (short communication and perspectives) published in national journals to raise awareness among physicians and patients about various general routine investigations and link to these articles are mentioned along with IC for further clarification.

CONCLUSION

Interpretative comments minimize conflicting diagnosis based on different laboratory test results. Accurate and unified interpretation of test results by the laboratory personnel could be assured through active participation in external quality assurance schemes and education.

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