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ROLE OF INTERPRETATIVE REMARKS IN CLINICAL BIOCHEMISTRY-A PERSPECTIVE OF MEDICAL BIOCHEMIST

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ABSTRACT

It is a professional requirement for clinical biochemists to provide Interpretative Remarks (IR). Few clinical labs give any comments at all, and the majority of laboratories just employ pre-written remarks on the report. In addition to physicians, other medical professionals, and occasionally even patients themselves, seek laboratory experts for guidance on data interpretation. The quality of interpretative remarks is impacted by the unavailability of the patient's medical record, restricted communication with the doctors, and a lack of professional experience. The purpose of this paper is to highlight how crucial it is to provide interpretive commentary in the context of responsibility for medical biochemists. In a similar vein, this paper offers guidance to those who offer interpretations.

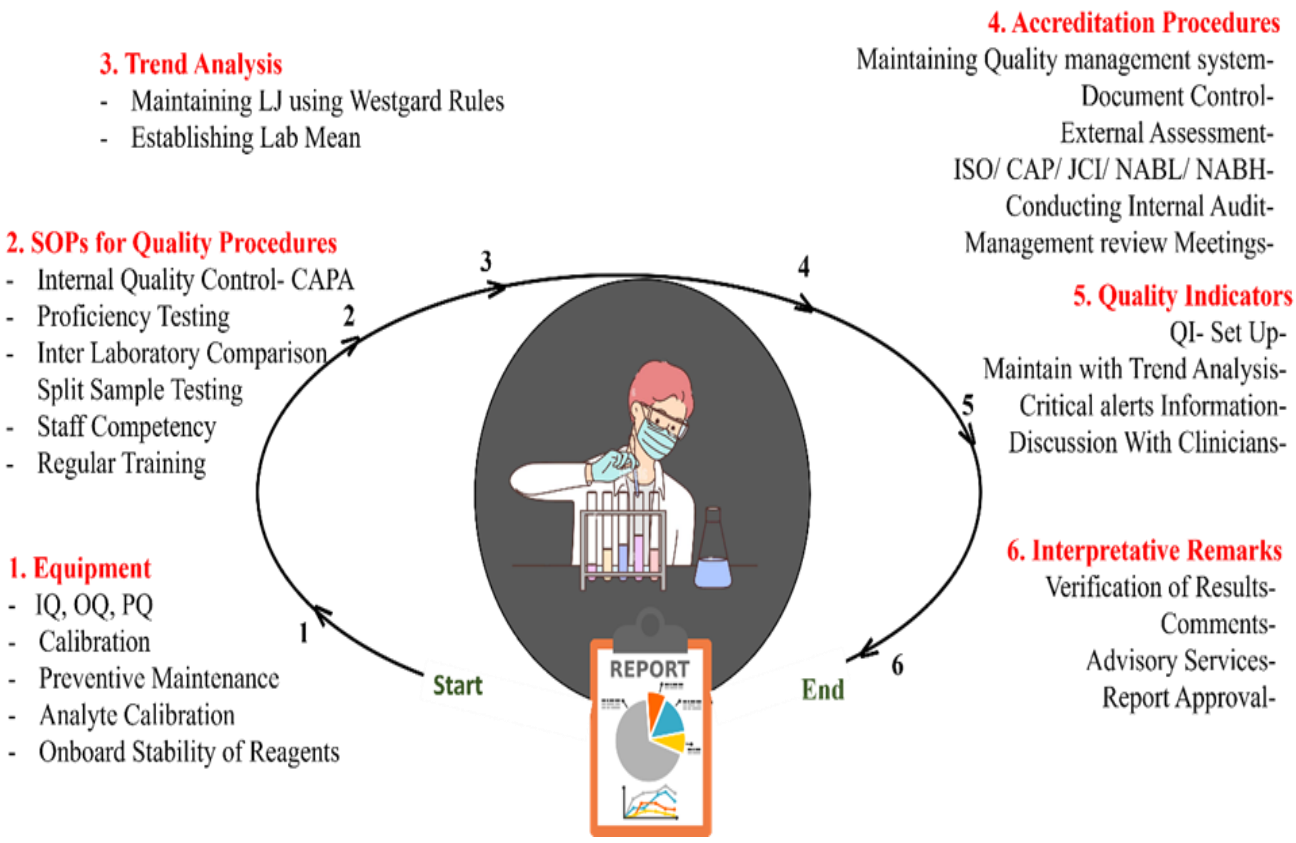
Keywords: Interpretative remarks, Critical alerts, QMS, Biochemistry reporting, Medical decisions

INTRODUCTION

In order to help other medical professionals better comprehend the test results, laboratory specialists can help interpret test data. To correctly interpret test findings, one must understand the examination component of the laboratory work any potential pre-examination impacts, clinical meaning of the results and the patient's clinical state. To make the proper diagnosis and manage the patient, the managing clinician must accurately interpret the results[1]. When a managing clinician interprets laboratory data incorrectly, these procedures may be jeopardised[2]. Ample reports on missed and delayed diagnoses in emergency departments and ambulatory settings highlighted that ordering diagnostic tests incorrectly and misinterpreting them were the main diagnostic process failures. This includes laboratory-based diagnostic testing as well[3,4].

The reader of laboratory reports may readily recognise when a result is flagged as being outside

FIGURE 1: THIRD EYE OF LABORATORY PROFESSIONAL IN RELEASING THE REPORT



of the reference interval, but accurate interpretation requires knowledge of every facet of the whole testing procedure. Pre-Examination procedures (barcoding primary samples, electronic orders, automatic checks for clots, lipemia, hemolysis, and icterus), Examination procedures (using automated advanced assay platforms with low intra- and inter-assay variation), and Post-Examination procedures (auto validation and connecting hospitals with laboratory information system) have all seen significant improvements in recent years. Alongside all these advancements, the function of the laboratory professional has evolved to encompass communication with patients and clinicians in addition to technical duties. Clinical interpretation of obtained test results, however, depends on the extensive practical and theoretical clinical expertise of the laboratory physician. (Figure 1). Everyone agrees that interpretative remarks must be kept an eye on as a post-analytical phase quality measure [5].

VALUE ADDED TO LAB REPORT

Clinical scientists and pathologists are frequently requested to interpret common and routine tests, such as iron studies, liver function tests, and renal profiles (urea and electrolytes), verbally (over the phone or during a "corridor conversation"), thyroid function tests and other hormone profiles[6]. Tests that are semi-quantitative or qualitative, like protein electrophoresis, have always demanded an explanation. Comments can be useful in situations where results are unexpected because of interference (such as heterophile antibodies or macroproteins in immunoassays) or when they propose further or reflexive testing.

While there are no universal guidelines for the use of Interpretative Remarks (IR), the ISO 15189:2022 standard illustrates clinical interpretation through its clause 7.2.3.1b, third lines, which provides informed clinical and technical advice. Clause 7.3.5, which deals with biological reference intervals and clinical decision limits, states that when necessary for the interpretation of examination results, it must be defined and communicated to users. The Post-Examination Processes Clauses, which describe the Reporting of results, provide us with guidance regarding the interpretation of examination results. The report must include all available information necessary for the interpretation of the results[7].

Proper interpretation of test data is essential for an accurate and early diagnosis as well as an appropriate clinical treatment condition. According to research published in Haematology, IR improves communication between the hospital and the laboratory, speeds up diagnosis, lowers the risk of misdiagnosis, and eliminates unnecessary and unnecessary laboratory testing[2,7]. The degree to which IRs are included in biochemical reports varies greatly between countries. IR's goal is to make it easier for treating physicians to understand complicated test data. This is particularly crucial in situations when there are notable anomalies, dynamic or unusual test results, or examination or pre -examination elements that the treating physician may not have recognised that might affect how the results are interpreted. In a pilot study with clinicians and nurses at our hospital in Chennai, 82% of the participants indicated that they were interested in reviewing comments on laboratory findings that assist them in deciding on the course of treatment and procedures.

EXCLUDING IRRELEVANT INTER-PRETATIVE REMARKS

- Restating the obvious, e.g. "normal glucose" or "raised glucose". However, qualifying the degree of abnormality may be useful, e.g. "severe'' or "life -threatening hyperglycemic".
- Remarks should not indicate the same command mentioned in the TRF; a doctor who has indicated (s) he does not wish to receive them (eg, Chronic Kidney Disease), a "hypothyroid" a report comment "consider hypothyroidism" does not add value.
- Comments on specialised reports to a field specialist (e.g., renal function tests submitted to a nephrologist) until requested in writing, with the exception of sophisticated dynamic function tests (e.g., 24 urine protein, uroflometry).
- Suggestions for clinician: “Correlate clinically”, “Suggestive of clinical examination”; “Suggest to check BP”.
- Suggestion for invasive investigations should not be recommended lightly, e.g. “Suggest renal biopsy”[8].

PROFESSIONALS REPORT

Laboratory results are estimated to inform 70% of clinical decisions[9]. When the laboratory report is incongruent with the clinical features, patients tend 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 reports adds uncertainty to the clinician. Recently, the autovalidation and electronic reporting of laboratory results have been a privilege for only a few laboratories in Major Cities. In many cases, the criteria of Hospital laboratory management, lab franchises and different management running labs and hospitals have posed complete disarray. Although the sharing of information is mutual by agreement, in the majority of places, it's not under practice; laboratories face many challenges by information technology, such as limitations in sharing the data and unawareness of what to share and what not to. The patient details of history, medical management, or delta check are not transferable in the Hospital information system to the LIS. Due to the delta check, it takes time to interpret the results. Most of the Clinical biochemistry lab reports contain only computer-generated IR that are present in each report, irrespective of the result, which is pre-defined. Individualised narrative IR for definitive classes of tests is practiced only by a few laboratories.

In recent days, artificial intelligence (AI) has been integrated with the HIS/ LIS, which helps provide concluding remarks on the obtained and available data for the patient at a particular time. This, in turn, is largely attributed to the lack of trained and specialised manpower in all clinical laboratories. The free-flow interpretative remarks are the assessment of diagnostic test results in clinical outcomes, 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 IR added by inexperienced laboratory professionals may add to the 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 help the user to understand the basics of the test and avoid 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.

Table 1: Interpretative remarks in various phases of the total testing process

Phases in the total testing process	Potential sources of error	Interpretative remarks on
Pre- Pre Examination	• Patient preparation • Restricted diet/alcohol/ medicine • Choosing the right lab	• Compromised Sample • The sample may be taken in the basal state (>12 Hrs. of fasting) • The parameter not included in the scope
Pre-Examination	• Incomplete test request form • Patient/specimen misidentification • Sample collected from an inappropriate site • Hemolysis, • Clotted sample • Volume low/high • Inappropriate vacutainers • Improper transport • Not maintaining the cold chain • Error in dispatching to respective departments • Aliquoting error • Error in labelling and Pipetting • Error during centrifugation (11)	• Cold Agglutinins • Platelet clumps induced by EDTA • Icteric, lipemic, hemolysed or sample that could interfere with other analytes • Physiological discrepancies such as fasting condition, age, gender, pregnancy, and diurnal cycle • Any significant context of the test request
Examination	• Equipment breakdown • Sample carryover • Interfering substance • Undetected failure in quality control • Factor changes • Analyte calibration expired • Reagent stability/deterioration	• Sample dilution • Results for corrected calcium/ sodium • Any changes in the Examination platform
Post-Examination	• Erroneous validation of Examination data • Not adhering to turn-around time • Report transcription error • Improper data entry/failure in bidirectional interface • Failure/delay in reporting critical values • Incorrect interpretation • Inappropriate/inadequate follow-up plan • Failure to order appropriate consultation	• Any changes in Biological reference interval • Recommendation for follow-up or expert consultation • Recommendation for further investigation • Any significant change from delta check and evaluation of result from the knowledge of biological variation. • Comments regarding calculations • Interpretation of dynamic tests and molecular diagnostics tests.
Post-Post Examination	• Report issues to the right patient • Incomplete reporting • Not informing you that there are some tests is still pending	• Not verifying the UHID • Mention/report to the patient regarding the follow-up reports

Table 2: Biochemical investigations that should be accompanied by interpretative remarks in the Metropolitan context

S.No	Parameters	Reason for interpretative remarks in the Metropolitan context
1	Cancer markers	Malignancy is not ruled out by a tumour marker concentration that is within the reference interval. False positive tumour marker elevations have a number of sources, and the in-train dividable variation of tumour markers is substantial. Never the less, these tests-which were created by clinical laboratories in the Metropolitan area-are a part of numerous healthcare screening packages that have no demonstrated medical value.
2	Electrolytes	The majority of clinical laboratories' acceptance standards for blood samples obtained remotely lack clarity. Pre-examination errors are common (examples: incorrect draw order, incorrect tube labelling, inadequate tube filling, delayed centrifugation, deterioration during shipment).
3	Hormone Analysis	There are no national guidelines based on evidence for dynamic endocrine tests. As a result, the report should include the proper nomenclature for the dynamic test, the acceptable time for sample collection, and the defined standard for interpretation. It would be appropriate to note the cut-offs and any additional tests that are advised in light of them.
4	Immuno Assays	Conflicting diagnoses may arise from rechecking results in two or more laboratories using distinct immunoassay platforms. Clinicians are ignorant about the following: heterophile antibodies and biotin interference, serial dilution, hook effect, polyethene glycol precipitation test, probable Ayurvedic medicine interference, and cross-reactivity of steroidal hormones with immunoassays.
5	Immunology Markers	The sample screening dilution is not harmonised. The doctor does not fully understand the explanation for any discrepancies in the interpretation of results obtained using multiple methods of determination.

The International Organization for Standardization (ISO) 15189:2022 general requirements for quality and competence must be followed by laboratories due to the growing awareness of evidence-based medicine. There are very few hospitals and independent laboratories in Chennai that are accredited by the

current standards, which encourage laboratories to maintain better levels of quality and produce more consistent and trustworthy test results. Similar circumstances apply to other fields, where IRs play a key part in morphological analyses of bodily fluids and peripheral smears, electrophoretic assays, flow cytometry, toxicity, and molecular testing[10]. Adding comments for investigations was initiated for tests like CRP, HbA1c, Cystatin C, high triglycerides, thyroid function, pituitary function, PSA, HbsAg, β-HCG, and other tests where interpretation is regarded to be of support once it was realised how important IR was in authorised labs. Numerous remarks address the sample quality, pre-examination interfering variables, and suggestions made in light of the findings (Table 1). The goal of adding IRs is to assist the requester in selecting the best course of action for the patient's care. Table 2 lists the biochemical assays that should be taken into consideration for the potential inclusion of IRs in an accredited lab setting based on the authors' experience.

According to Hallworth[9], 70% of clinical decisions are influenced by pathology results. This is especially true for endocrine illnesses, where quantification of coupled tropic and effector hormones can help identify the underlying pathology and give objective proof of failure. For an accurate and prompt diagnosis as well as for the proper management of patients, correct interpretation of test data is therefore essential. Physicians depend on the laboratory to conduct tests and deliver results accurately and promptly. To varied degrees, the laboratory also offers an interpretive service[12]. It is not sufficient for laboratory personnel to just release an accurate result; they also have an obligation to work with the physician making the request to guarantee that the laboratory data is interpreted correctly[13].

Note that the IRs may be clinical or technical in nature. Technical remarks, which use electrolytes as an example, are connected to sample quality and pre-examination interfering factors, as listed in Table 2. Similar to this, clinical remarks usually include noting the existence or absence of an anomaly, its severity, a potential reason for an unexpected result coupled with a clinical consequence, and a recommendation for further testing or referral. For instance, suggesting a glycerol blank test to rule out pseudo hypertriglyceridemia in a non-lipemic sample with an extremely high triglyceride value or commenting on a manual count for platelet aggregates when a Coulter counter shows thrombocytopenia[14]. Brief communications and viewpoints from scientists published in national journals to educate doctors and patients about a variety of general routine investigations and links to these articles are mentioned along with IR for further clarification.

GUIDELINES FOR INTERPRETATIVE REMARKS

According to RCPath (UK)'s "Guidelines for the provision of interpretative remarks on biochemical reports"[15], the clinical details provided, the clinical implications of the results, and the likelihood that the requesting clinician is familiar with the tests and their interpretation will determine whether or not a remark is required. Repeats might be required in the following circumstances, per the guidelines:

- a physician has asked for a test that they might not be familiar with;
- a result is unexpected;
- a decision about treatment or management is suggested by the results in conjunction with the clinical information supplied;
- a particular question has been raised, but it's unclear whether the results provide the answer.

Concise observations are crucial because clinicians are loaded with lot of reports, and will lose interest in reading lengthy IRs. Additionally, the statement must be both clear and unambiguous[16].

CONCLUSION

According to ISO 15189, the quality evaluation must cover all aspects of the examination process, including post-analytical operations, which include providing interpretive remarks. Laboratory experts can compare and exchange their knowledge and experience in this field, as well as maintain and advance their abilities, through quality assurance programs for interpretative remarks[17,18]. Interpretive remarks reduce the likelihood of contradictory diagnoses based on disparate laboratory test results. Active involvement in External quality assurance programs and training could guarantee the laboratory professionals' accurate and consistent interpretation of test data. The integration of AI will enhance this process and achieve it to the fullest.

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