

IFCC Position Paper

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Assuring the quality of interpretative comments in clinical chemistry

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Abstract: The provision of interpretative advice on laboratory results is a post-analytic activity and an integral part of clinical laboratory services. It is valued by healthcare workers and has the potential to prevent or reduce errors and improve patient outcomes. It is important to ensure that interpretative comments provided by laboratory personnel are of high quality: comments should be patient-focused and answer the implicit or explicit question raised by the requesting clinician. Comment providers need to be adequately trained and qualified and be able to demonstrate their proficiency to provide advice on laboratory reports. External quality assessment (EQA) schemes can play a part in assessing and demonstrating the competence of such laboratory staff and have an important role in their education and continuing professional development. A standard structure is proposed for EQA schemes for interpretative comments in clinical chemistry, which addresses the scope and method of assessment including nomenclature and marking scales. There is a need for evidence that participation in an EQA program for interpretative commenting facilitates improved quality

of comments. It is proposed that standardizing goals and methods of assessment as well as nomenclature and marking scales may help accumulate evidence to demonstrate the impact of participation in EQA for interpretative commenting on patient outcome.

Keywords: clinical chemistry; continuing professional development; interpretative commenting; postanalytical quality; quality assessment.

Introduction

The need for interpretative comments

The correct clinical interpretation of laboratory results is a desired outcome of laboratory services. The brain-to-brain loop cannot be closed until the laboratory information is captured by the physician brain and the right interpretation is used to allow the correct diagnosis and treatment. Recently published data highlight the vulnerability of the so-called “post-post-analytical phase”, the source of problems identified not only before and during the reporting of laboratory results, but also in successive steps. In particular, available data emphasize the vulnerability of some post-post-analytical steps, including the physician’s reaction to the transmission of laboratory data, their interpretation, and the choice of appropriate action to take for the individual patient [1, 2]. Traditionally, laboratory reports have been considered to be valuable if accurate results with the right units and reference intervals are reported, particularly when the requesting physician is familiar with the test(s) required. The current demand for interpretative comments and its desirability spring from both clinical, technical and financial catalysts. Clinical drivers include patient safety, value of interpretative comments, quality requirement in international standards for laboratory

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accreditation, physician satisfaction, new and complex laboratory tests, and doctor education, whereas technical drivers include lack of harmonization of laboratory information and increased electronic data communication; the financial drivers are competition between clinical laboratories and cost-reduction initiatives.

Patient safety

Evidence has accumulated to demonstrate the risk of errors due to misinterpretation of diagnostic tests in different clinical settings (e.g. primary care, emergency departments, internal medicine) and their impact on patient safety. The inclusion of interpretative comments in laboratory reports could decrease error rates, thus improving the quality of laboratory information and patient safety [3].

Value of comments

There are many instances in which the value of a laboratory result can be considerably enhanced by an accompanying comment. Examples include unexpected results due to an interference (e.g. from heterophile antibodies in immunoassays), or particular findings discovered by the laboratory (e.g. macroprolactin or macroamylase), or extension of the original clinician request by reflexive or reflective testing (e.g. the identification of a monoclonal peak in serum electrophoresis). In laboratory practice, we find that many of the verbal (phoned) requests for interpretations are related to the common and routine tests [e.g. iron studies, liver function tests and renal profile (urea and electrolytes)] in addition to hormone profiles (e.g. thyroid function tests) and protein electrophoresis.

Quality requirement

There is a specific requirement in the International Standard for laboratory accreditation International Standards Organization (ISO 15189: 2012) for Laboratory Directors to provide clinical advice in the interpretation of examination results, including the inclusion of “interpretative comments on results” and “where applicable”. The addition of interpretative comments has been recommended in several clinical guidelines to improve the utilization of laboratory data [4]. Monitoring of interpretative comments is now included in the

list of consensually accepted quality indicators for the post-analytical phase [5].

Physician satisfaction

Customer satisfaction of laboratory interpretative service is backed by evidence; contributing factors include a significant reduction of errors and improvement of clinical outcomes [6, 7].

The introduction of new and complex laboratory tests

New and complex tests represent a major driver for the inclusion of interpretative comments in the laboratory report. This is particularly true in some diagnostic areas such as coagulation, autoimmunity, allergy testing, and molecular diagnostics that present major challenges due to the need of advanced expertise for the correct interpretation of the laboratory data. In addition, interpretative comments are increasingly welcomed by the requesting physicians particularly when they provide clinical advice on “what to do next” [8].

Medical education

Great variation exists in the ways that medical students learn the principles of laboratory medicine in different countries. However, current evidence highlights that medical education on laboratory testing is inadequate and that junior doctors do not feel confident in interpreting even common laboratory tests, at least in part because many medical schools have moved toward newer ways of undergraduate teaching which have reduced the time available for teaching the pathology disciplines [9]. In some surveys, health practitioners have requested the inclusion of interpretative comments in laboratory reports in addition to teaching and education [10, 11]. Healthcare staff other than doctors are increasingly receiving laboratory reports and might especially benefit from any guidance provided.

Lack of harmonization

The lack of harmonization of the laboratory information, not only in analytical methodology but also in measurement units, reference intervals and decision limits, is a further driver for the inclusion of interpretative comments

to overcome these impediments to clinical interpretation of laboratory data [12].

Electronic communication

The increase in electronic data communication requires clinicians to cope with huge data traffic, thus increasing the risk of misinterpretation of laboratory results. This, in turn, increases the desirability of interpretative comments to facilitate the physicians' decision making [13].

Competition

Increasing competition between clinical laboratories that is predominantly based on costs could be better addressed if other variables that provide evidence of the quality of laboratory services are considered. The availability of interpretative comments could represent "added value" to requesting physicians and users.

Healthcare cost

Finally, the need to reduce cost of healthcare, specifically, costs related to laboratory testing, should shift the focus from volume reduction to the reduction of inappropriate requests and, even more important, inappropriate utilization of laboratory information. Current evidence highlights the huge percentage of laboratory results that are poorly acknowledged and misinterpreted, leading to missed or delayed diagnoses and treatments [14].

Together, these drivers require careful consideration of the need for translating the activity of interpretative commenting from a research area to a well-established routine activity of clinical laboratories.

Interpretative comments have clinical value

In countries where the addition of interpretative comments by laboratory staff is prevalent, there is good evidence that the advice is valued by those receiving the reports [15]. For example, in a survey in the UK, 88% of primary care doctors and nurse practitioners found interpretative comments on thyroid, gonadotropin, and glucose tolerance test reports to be helpful [10]. By contrast, evidence that these comments make a difference to patient outcome is more limited, although this gap in knowledge is most likely due to the difficulty in proving

or disproving causality between advice and any change in outcome. One study that sought to establish such a link did so by investigating the changes in the proportion of patients taking levothyroxine who were deemed to be inadequately replaced following the introduction of thyroid interpretative reporting. They found there was a 22% reduction in patients who were under-replaced in the 3 years following the introduction of interpretative comments [7]. In another study, patients with a high low-density lipoprotein (LDL) cholesterol suggesting the possibility of familial hypercholesterolemia showed a greater LDL cholesterol reduction and were much more likely to have undergone specialist review in the 12 months following the initial test if their report included an interpretative comment compared with when it did not [16].

The implications of patients receiving their reports

Even in countries where laboratory reports have traditionally been returned to the requesting physician, there is an evolving recognition that patients themselves should also be allowed direct access to their own laboratory results, either at the same time as their own doctor or soon after. This, in turn, poses both opportunities and challenges to the clinical laboratory. One of the opportunities is that patients may also benefit from the addition of interpretative comments. However, it is important that the language used in these comments then avoids the unnecessary use of medical terms, avoids unsubstantiated or possibly alarming statements, or uses terms which could be interpreted as being pejorative. The important role for interpretative comments, along with potential pitfalls, has given rise to guidance describing best practice in their use [17].

Interpretative comments vary in quality; implications

The interpretation of laboratory tests is a complex post-analytical activity requiring the understanding of the analytical processes involved in generating the results, and therefore knowledge of performance characteristics of the method(s) used. Interpretation also requires recognition of potential pre- and post-analytical variables, and correlation of results with the clinical status of the patient. In a variable proportion of results, according to the test complexity, attaching a comment adds value to the report and may help the requesting physician to appropriately use the laboratory information. However,

the practice of adding interpretative comments to the laboratory reports varies widely not only among different countries but even within the same country, according to the degree of specialization and complexity of the particular type of test and test panel [18]. This, in turn, highlights the need for appropriate professional qualification and expertise for providing interpretative comments, particularly in specialized areas of laboratory medicine. In addition, for clinical laboratories that provide multidisciplinary services including not only clinical chemistry but also hematology, coagulation, microbiology, molecular pathology, and esoteric testing, interpretative commenting extends beyond a single discipline to an integrated and more comprehensive activity.

The quality system of the individual laboratory provides an appropriate framework to assure the right management of this particular service, but appropriate expertise in a specific field represents an absolute prerequisite. Laposata identified the lack of sufficient specialists in the clinical laboratory as the “largest barrier” to more widespread implementation of interpretive comment programs [19]. Currently, the definition of standards of qualification and training for performing this activity are not harmonized due to global differences in institutions and entities which oversee and regulate the training and qualification of laboratory professionals. Therefore, the laboratory director should take responsibility for defining and monitoring the qualification and competence of his/her staff and evaluating the needs for eventual education and training activities.

Additionally, the quality of interpretative comments often requires the integration of laboratory information with other clinical data. This could be done by providing laboratory professionals accessibility to the patient database through an effective information system.

As yet, there is no gold standard for assessing the quality of interpretative services. Whilst interpretative commenting in clinical laboratories is still in its infancy, evidence has been collected to demonstrate that any interpretation provided by laboratory professionals with inadequate expertise can be clinically dangerous [13] and may impact on the reputation of the clinical laboratory itself. Since 1998, the Royal College of Pathologists in the UK has defined guidelines for interpretative comments in clinical biochemistry but further efforts are needed by professional organization and scientific societies to better define the mechanisms and responsibilities needed to assure quality and safety to this type of interpretation. EQA programs examining the interpretation of laboratory tests have been introduced in the past decade, particularly in the UK, Australasia, Italy, and Asia-Pacific [4, 20–22]. Analysis of proficiency data from EQA programs, together with professional

initiatives to identify the appropriate expertise and ideal qualifications of laboratory scientists issuing interpretive reports, may ensure better quality of interpretative comments and reduce the risk of associated errors.

The role of comments in medical error prevention

In the last 15 years, since the publication of the Institute of Medicine (IOM) report ‘To Err Is Human’ [23], the patient-safety movement has focused on treatment-related harms. However, recent evidence highlights the relevance of diagnostic errors and the need to reduce laboratory-related errors [24]. From the patient safety viewpoint, the communication and interpretation of laboratory results, are increasingly recognized as potential sources of errors both due to the colossal numbers of laboratory test results and their complexity. In addition, according to the current definition of “laboratory error” [25], releasing a correct result is not enough; laboratory professionals share with the requesting physician the responsibility to ensure the right interpretation of the laboratory information [18]. A growing body of evidence demonstrates that interpretative reporting improves the quality of clinical care by reducing medical errors and related costs. The prevention of misdiagnosis and reduction of the time required to make the diagnosis have been demonstrated by Laposata et al. [6] and confirmed by Kilpatrick [7]. The rationale for the added value of interpretative comments in reducing diagnostic errors is clearly highlighted by the data on the nature of diagnostic errors that are largely due to errors in inappropriately requesting and interpreting laboratory results [1].

Technical framework for interpretation

1. Information hierarchy

Interpretative commenting acts in the post-analytical phase when the analytical results (or data) is assessed against other available laboratory and clinical data. The interpretative comment is formulated as guidance that should maximize beneficial impact on patient management. This transition from analytical data to clinical wisdom is achieved through the intermediate steps of assembling all the information and applying medical knowledge. Known as the ‘knowledge pyramid’, the hierarchical transition

data – information – knowledge – wisdom (DIKW), is a well-established model of information hierarchy [26].

I. Highlighting analytical data

While analytical data are often thought of as the quantitative (or qualitative) results of analysis, will focus on the important aspects of the data. For example, all abnormal results should be highlighted as being outside the reference limits; however, some abnormalities may deserve special attention because of the relative clinical importance of that measurand, or the relative risk associated with the degree of abnormality.

In a situation where sample quality or suitability has compromised the value of the data, the critical interpretative comment is communication of the data, and the clinical action which may be required, such as requesting a repeat specimen if still clinically indicated.

II. Information on patterns

After putting the available analytical data together, it should be possible to recognize important patterns in the data, and this constitutes new information.

The pattern may be ‘temporal’: for example, an abnormality representing a continuing upward trend), or a change that is greater than that expected from normal biological \pm analytical variation. Delta checking is a tool that can be helpful for temporal interpretation.

The pattern may be ‘spatial’: for example, an abnormality in one analyte is correlated with an abnormality, or contrasted with normality in other analytes. This is very common in interpretation of thyroid hormones, iron studies, and glucose tolerance tests.

III. Applying medical knowledge

The patterns of information manifest in the report may be further considered in the light of the patient’s history, including the medical context and clinical question communicated with the request. A fundamental requirement of a comment is that it should answer the question (implicit or explicit) raised by the requesting clinician. The interpretation of laboratory information in the specific medical context of the patient distinguishes “patient-focused” reports from “canned” comments.

Unfortunately, laboratories do not often receive enough clinical information, beyond age and gender, for medical interpretation to take place. Adoption of an ISO 15189 requirement

that agreements to provide laboratory services include the provision of any information needed by the laboratory to ensure appropriate examination and result interpretation, may improve the information flow to the laboratory.

IV. Clinical wisdom and actions

The ultimate aim in the process of converting the knowledge generated from laboratory information is to promote clinical actions that will benefit the patient. While clinical management may seem the realm of the clinician rather than the laboratorian, every diagnosis will have implications on management. Clinical guidelines, established either through evidence-based recommendations or by expert opinion clinical consensus, can be very helpful as reminders to the requesting doctor (e.g. expected follow-up testing in response to the findings in the report).

2. Wording

Like verbal communication, words used in comments can be confusing; therefore, some rigor is required to make comments clear. For example, the pattern of laboratory data supporting a particular diagnosis can be described as being “suggestive of”, “consistent with”, “indicative of”, or “diagnostic for”, and these terms often represent ambiguous levels of interpretative confidence. Similarly, terms such as “possibly”, “probably”, and “definitely” need to be used with care. Some of these terms, e.g. “diagnostic” or “definite”, may convey a greater confidence than intended and should be avoided, or only be used with great caution.

Medical science has some common norms regarding confidence, including statistical 95% confidence and likelihood ratios (i.e. >50:50 chance), which can be considered as a basis for terminology (Table 1).

3. Length of interpretative comments

Comments that are succinct are more likely to be appreciated and fully absorbed. Long comments may lead to word skipping and misinterpretation. Often comments are too long because the commentator tries to inform and educate the recipient. The clinician typically seeks further education in a minority of reports and therefore this can be provided by including a reference or electronic links to educational resources.

4. Traceability of commentator

The international standard for quality on medical laboratories (ISO 15189) has a number of requirements for interpretative comments (see Appendix)

Table 1: Suggestions regarding word use.

Confidence	<1%	<5%	<50%	>50%	>95%	>99%
Term	Inconsistent	Improbable	Unlikely	Possible	Probable	Consistent

including (i) an interpretative service is required, (ii) that the personnel making judgments with reference to examinations shall have the applicable theoretical and practical background and experience, and (iii) identification of the person(s) authorizing the release of the report.

Interpretative comments may have major clinical importance. It is vital that the requesting clinician has the opportunity to discuss any ambiguity in an interpretation, as this may have significant impact on patient management. ISO 15189 requires that the person responsible for issuing the report be identified, and that contact details be provided.

5. Comments linked to results

The interpretative comment is typically appended to the end of a series of results. Unfortunately, both paper-based and electronic reports can “lose” their appended comment (for example, through transmission across electronic interfaces). The laboratory needs to verify that their reports are wholly and accurately reproduced in external information systems immediately “downstream” of the original information system.

Proficiency and training

Each of the steps in the DIKW cascade requires its own level of training. The expression of analytical data for any particular result requires an understanding of what is expected, and what is unusual, from experience with that assay. Recognition of information patterns requires an appreciation of the usual relationships between data in health and disease. Patterns can be categorized according to their common interpretations. In contrast, clinical knowledge, ideally acquired from a broad medical education, allows the interpreter of pathology information to place the current pattern in the overall context of a particular patient. Patient-centered advice may lead to a clear imperative for the management of the patient. Therefore, it is essential that this advice comes from a competent provider with proven knowledge in, and experience with, providing accurate interpretative comments for the tests being validated [17]. Proving such competence, or personal proficiency, is not simple

within laboratory medicine, since those working in it can have widely differing roles and responsibilities, even when working at the same grade. No single means of demonstrating or assessing personal proficiency is applicable to all staff.

It has been recommended that assessment through an interpretative quality assessment exercise needs to be integral to the process of demonstrating personal proficiency [27], but this can prove difficult to achieve in small subspecialties. For the larger ones, such as pediatrics, there may be many general quality assurance (QA) question sets that would not be applicable to everyday pediatric practice.

Even where an interpretative comments QA program is appropriate for the participants, it is only one of a number of factors used to support competence. Examples of these other factors were provided in a recent document published in the UK jointly by the Royal College of Pathologists, the Association for Clinical Biochemistry and Laboratory Medicine and the Institute of Biomedical Science [28]. None of their groupings were intended to be mutually exclusive to the others, nor were the groupings or examples expected to be exhaustive lists.

Evidencing personal proficiency

1. Documenting scope of working
An individual should be able to clearly document the main activities they perform related to the laboratory. Much of this will already be collected as part of the job planning or job description processes. Details should include tests they are tasked to routinely report, areas of the laboratory in which they have specific oversight and other responsibilities such as managerial roles, teaching or research commitments.
2. Demonstrating proficiency in knowledge:
 - Successful recent examination assessment on a topic which forms part or parts of the scope of working
 - Participation and at least satisfactory performance in a personal proficiency assessment such as an interpretative EQA scheme
 - Successful recent peer assessment, if individual performance is provided.

3. Demonstrating continuing learning and professional development

This may include:

- Continuing learning, as evidenced by adequate participation in all forms of relevant professional development and recorded by a formal continuing professional development (CPD) scheme
- Participation in annual appraisal with setting of objectives based on identified personal proficiency needs
- Evidence of reflection on major work or career events.

4. Evidence of service quality improvement or innovation

This may include:

- Involvement in changes to laboratory practice that have benefited patients
- Involvement in initiatives to improve efficiency with no detriment to service quality
- Participation in local and/or national audits, with evidence of completion of the audit cycle
- Research, particularly if relevant to laboratory medicine
- Responding to EQA, safety and other quality alerts.

5. Evidence of effective leadership or teamwork

This may include:

- Leading or being part of a team implementing changes to laboratory practice that have benefited patients
- Leading or being part of a team completing initiatives to improve efficiency with no detriment to service quality
- Leading or being part of a team demonstrating service quality to external accrediting or regulatory agencies
- Participation in leadership or team development programs, including those relevant to management, finance and human resources

6. Demonstrating of valued teaching or trainee supervision

This may include [10]:

- Good student/trainee feedback
- Evidence of updating teaching techniques
- Evidence of updating teaching materials.

7. Feedback from colleagues, other staff and service users

This may include:

- Obtaining feedback, ideally as part of a 360° appraisal, including colleagues (peers, juniors or seniors), support staff and service users/patients

- Evidence that this feedback has been discussed at appraisal and any objectives which may have arisen from it

- Inclusion of complaints and compliments, as below.

8. Complaints and compliments

This may include:

- Formal and informal feedback, either as an individual or as part of a service. This may also include documentation of recent or outstanding disciplinary issues
- Evidence of learning from mistakes, both as an individual and as part of a service.

Therefore, an interpretative comment EQA scheme has an important role in assessing the competence of laboratory staff to provide advice on laboratory reports, but does not represent the single metric by which overall proficiency is to be assessed.

A proposed structure for interpretative comments EQA program

Scope of assessment

The scope of a quality assessment program for comments in clinical chemistry would cover general clinical chemistry, endocrinology, tumor markers, trace elements, toxicology, and therapeutic drug monitoring offered by clinical chemistry laboratories. Adult and common pediatric cases could be included. Real-life clinical cases from hospital inpatient and outpatient settings or general practice and specialist practice settings may be de-identified of all identifying characteristics, and utilized. Cases could cover varying degrees of complexity. Investigations for rare entities, such as inborn errors of metabolism and porphyria, may be considered too specialized for the generalist program. The number of cases per cycle and the time intervals between the provision of the cases should be specified at the commencement of the program. The report should contain patient location and requesting doctor details, age and sex, brief clinical notes such as those usually available on a laboratory request form, and a set of biochemistry results for commenting. Additional notes representing other relevant results or information available to the laboratorian could also be included.

Participants

The program should be complementary to analytical external QA programs and would be aimed at individual assessment, rather than laboratory assessment. Pathologists and clinical scientists as well as trainees would be the main participants. Participation should be rewarded with continuing professional development credit or points. Participants should be treated identically, regardless of background or training.

Distribution

The program is ideally suited to web-based presentation, with participants entering comments online. Participants would be notified when a new case is placed on the website, with the deadline for submission of their comment. Participants would be expected to comment on the results as they would do for a routine clinical case assuming the requesting doctor had asked for their opinion. A word or character limit is suggested for the comment (e.g. 250 characters) to encourage brevity. On occasions, participants may be asked to provide a response to a specific question, as would be posed by a healthcare provider. There is no evidence for the optimum number of cases per cycle or frequency of distribution; 10 cases in an annual cycle may be considered a minimum. Twenty-four cases in a year may be considered a maximum number.

Assessment of comments

Assessment of comments should be performed by a panel. Returns should be anonymised before they are made available to the assessor/peer-review panel. The composition of the panel should be specified, ideally a mix of scientific and clinically trained members. A minimum and a maximum number of individuals (e.g. four to seven) on the panel will help ensure the decisions are not dominated by individual opinion, and that the decision-making process remains effective. Qualifications and minimum experience of the panel members should be specified (e.g. qualifications from an appropriate professional organization, current practice in the field, CPD maintenance). Turnover of membership should be staggered to maintain continuity. If the participant number requires more than one panel, measures should be put in place to minimize bias in marking standards between panels. The performance of each panel member should

be monitored over time, as well as compared with other members, and that data shared.

Method of assessment, nomenclature and marking scales

Assessors should mark each comment as a whole, taking into account “technical accuracy, thoroughness, clinical merit and added value” as well as “appropriate presentation (clarity of communication)” of the comment. The assessment may be done individually by each panel member and the mean score calculated. The alternative of marking by consensus by the panel as a whole would require the panel to come together physically or online. In either case, a marking panel prepared and agreed upon in advance by the panel is required, especially if there is more than one panel working in parallel.

The International Standard for Proficiency Testing (ISO/IEC 17043:2010) suggests that ordinal scale responses be divided into a five-point scale [29]. It recommends that performance standards for qualitative data should ideally be evaluated by expert consensus (Annex B.3.2.1 and B.3.2.2) with a suggested marking scale: 5 – very good, 4 – good, 3 – satisfactory, 2 – unsatisfactory, 1 – poor. These scales are similar to ‘Likert’ scales often used to measure agreement between observers (5 – strongly agree, 4 – agree, 3 – neither agree nor disagree, 2 – disagree, 1 – strongly disagree) and have been applied in clinical medicine to compare with expert interpretations (e.g. in radiology and prescribing) [30]. Based on these precedents, we propose the following scale 5: – optimal, 4 – good, 3 – neutral, 2 – unsatisfactory, 1 – poor (Table 2).

The panel should provide an “ideal” or a suggested comment (cf. target value for an analytical EQA program) as well as a brief discussion of the results in order for the program to have educational value. When a participant’s comment is essentially identical to that of the panel, then performance is considered optimal. If the interpretation is not identical but still acceptable, and is compatible with an optimal or acceptable clinical outcome, the comment is classified as good. Comments non-contributory to diagnosis would be classified as neutral. If the comment is different from that of the panel’s and inadequate for appropriate clinical diagnosis, the comment is incorrect or “unsatisfactory”, and if the comment is different and would lead to a major diagnostic error or inappropriate follow-up, the comment is dangerous and assigned the “poor” designation.

Table 2: A proposed marking scale.

Score	Interpretation	Definition
5	Optimal	Identical interpretation as the panel leading to optimal diagnosis and/or follow-up
4	Good	A similar interpretation that would lead to the optimal or acceptable diagnosis and/or follow-up
3	Neutral	A different interpretation that may not contribute to diagnosis or follow-up, but no harm either
2	Unsatisfactory	A different interpretation that will lead to an inadequate diagnosis and/or follow-up
1	Poor	A different interpretation that will lead to a major diagnostic error and/or inappropriate follow-up

Participants should receive their report within a specified period (e.g. maximum 4 weeks) for the feedback to be educationally effective. The performance of participants over time should also be presented with individual reports. An annual review may also stimulate education and also provide an opportunity for participants to make suggestions for future challenges.

Scalability

If QA of interpretative commenting is accepted as recognized professional development activity integral to the process of demonstrating personal proficiency, then participation in such programs would increase and administrators of such programs would need to be able to accommodate the large number of participants. Alternative methods of assessment such as key-word translation are felt to be too labor intensive to be scalable; the comparative merits of the different methods have been reviewed elsewhere [4]. Provision of the program online would help minimize the administrative workload. Tailored software for this purpose would be helpful and desirable.

Minimum standards of performance for participants

Minimum standards of performance would need to be established at the outset including a minimum return rate and mean score for each cycle.

Conclusions

Rapid and accurate diagnosis of the patient's presenting condition and progress is essential to obtaining the best outcome, and interpretative comments on laboratory reports may aid this. There is a need for more evidence

to guide the utilization of interpretative commenting in clinical chemistry to improve patient outcomes. Clinicians utilize interpretative services to a greater or lesser extent depending on their knowledge and confidence in interpreting the results themselves, and possibly depending on the availability and quality of the interpretative service from the laboratory. There is also a need for evidence that participation in an EQA program for interpretative commenting facilitates improved quality of comments and ultimately improved patient outcomes. Standardizing goals and methods of assessment as well as nomenclature and marking scales may help accumulate evidence to demonstrate the impact of participation in EQA for interpretative commenting on patient outcome.

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Appendix

ISO15189 requirements for interpretative commenting

4.1.1.4 Laboratory director

(g) Ensure the provision of clinical advice with respect to the choice of examinations, use of the service and *interpretation of examination results*;

4.1.2.2 Needs of users

Laboratory management shall ensure that laboratory services, including appropriate advisory and interpretative services, meets the needs of patients and those using the laboratory services.

4.4.1 Establishment of agreements

Agreements to provide medical laboratory services shall take into account the request—including any information needed by the laboratory to ensure appropriate examination and result interpretation—the examination, and the report.

5.1.2 Personnel qualifications

The personnel making judgments with reference to examinations shall have the applicable theoretical and practical background and experience.

5.4.3 Request form information

(e) clinically relevant information about the patient and the request, for examination performance and result interpretation purposes;

NOTE Information needed for examination performance and results interpretation may include the patient's race/ethnicity, pedigree, family history, travel and exposure history, and other clinically relevant information.

5.6.4 Interlaboratory comparisons

5.6.4.1 The laboratory shall participate in an inter laboratory comparison program(s) (such as an external quality assessment program or proficiency testing program) appropriate to the examination and interpretations provided.

5.8 Reporting of results

5.8.1 Reports shall include the information necessary for the interpretation of the examination results.

5.8.2 Report attributes

(e) Interpretive comments on results, where applicable.

5.8.5 Report content

The report shall include, but not be limited to, the following;

(k) Interpretation of results, where appropriate;

NOTE Complete interpretation of results requires the context of clinical information that may not be available to the laboratory.

(n) identification of the person(s) reviewing results and authorizing the release of the report, and, which, if not on the report, are readily available when needed; and

5.9.3 Information system management

(g) The laboratory shall verify that the results of examinations, associated information and comments are accurately reproduced, electronically and in hard copy where relevant, by the information systems external to the laboratory intended to directly receive the information.

C.6 Reporting of results

C6.3 In addition to the accurate reporting of laboratory results, the laboratory has an additional responsibility to ensure that, as far as possible, the examinations are correctly interpreted and applied in the patient's best interest. Specialist advice with regard to the selection and interpretation of examinations is part of the laboratory service.

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