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Review

Toward harmonization of interpretive commenting of common laboratory tests

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ABSTRACT

Interpretive commenting (IC) is an integral part of postanalytical activities of laboratories when the clinical interpretation of laboratory results in the context of the clinical situation of a patient is provided. Harmonizing practices in IC can be an approach to ensure high-quality comments, which if followed by adequate clinical actions has a great potential in improving patient outcomes. This paper reviews basic work prior to harmonization of IC of common laboratory test results.

Practices in IC are considerably diverse both within and between countries. The quality of comments is diverse and often clinically misleading in studies that characterize and estimate error prevalence in IC. Systems that can initiate, monitor, and maintain harmonization in IC are in an evolving state. Despite international initiatives, harmonized, implementable performance indicators and goals in IC are not yet available. External quality assurance (EQA) schemes are accessible mainly in English-speaking countries. A proposal for the standard structure of EQA schemes for interpretive comments in clinical chemistry and best practice recommendations for IC are available.

Few studies that demonstrate evidence on the clinical utility of IC are available in the literature. To set a strategy on further steps toward harmonization in IC, well-controlled clinical studies need to be conducted, in collaboration with laboratories and their users on the clinical usefulness of IC. Until enough evidence on the value of IC in patient outcomes accumulates, standards of qualification and training for performing IC and more EQA schemes in native languages of the users are required to improve the quality of IC.

1. Introduction

Interpretive commenting (IC) by definition means the provision of clinical interpretation of laboratory results, either verbally or in the printed report, in the context of clinical situation of a patient [1]. In the total testing process (TTP) concept, IC is designated as an unambiguous postanalytical (PA) task of diagnostic laboratories (Fig. 1) [2,3]. Provision of interpretive comments also forms part of laboratory accreditation [4], although not requested by all accreditation bodies.

IC has become an integral part of result reporting in esoteric fields of laboratory medicine such as leukemia phenotyping by flow cytometry, cytogenetics and molecular genetics, and investigations of bleeding and thrombotic diathesis [5]. Despite that several recommendations on IC have been published in recent years, most recently in 2016 [6], no consensus in the routine work of laboratories seems to exist yet in terms of whether, when, and how the results of common tests should be interpreted [6,7,8,9].

Harmonization is likely to be an important contributor to ensure high-quality laboratory testing, thus potentially improving patient outcomes. Harmonization efforts of international laboratory societies now cover all phases and steps of TTP including IC in PA phase. This paper reviews basic work prior to harmonization of IC of common laboratory test results. Thus, the state-of-the-art practice in IC and the quality of IC by studies characterizing and estimating error prevalence in IC are discussed. Systems that can initiate, monitor, and maintain harmonization in IC, performance requirements and indicators and EQA programs in IC, and the best practice recommendations for harmonizing practices in IC are reviewed. Finally, after considering the existing studies on the clinical utility of IC, potential further directions toward harmonization in IC are discussed.

Abbreviations: APTT, activated partial thromboplastin time; EA, extraanalytical; EQA, external quality assurance; GP, general practitioner; IC, interpretive commenting; LDL-C, low-density lipoprotein cholesterol; uAPTT, unexpectedly detected prolonged activated partial thromboplastin time; PA, postanalytical

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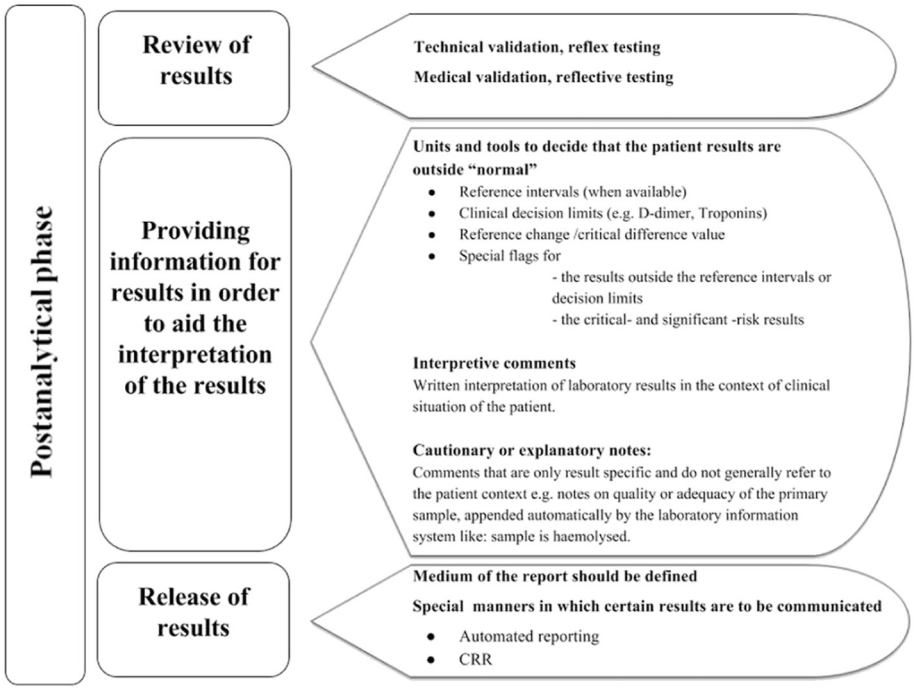

Fig. 1. Laboratory tasks in the postanalytical phase of TTP.

2. Practice of IC in medical laboratories

Only few investigations about the current practice on adding interpretive comments to the common tests are available in the literature. From these sporadic reports, it can be assumed that practices of IC vary widely not only among different countries [10] but also even within the same country [10,11,12].

Findings of a questionnaire-based survey of the Center of Biomedical Research (CRB), EQA provider in Italy, revealed that only a few laboratories (9% of survey respondents) add interpretive comments regularly to medical reports in Italy, mainly supported by clinical findings or in cases of interpretive doubts [12].

Reports differently describe the spread of the practice of IC in the UK. According to a report from 2005, there is a wide variation within the UK with regard to the extent to which individualized narrative interpretive comments are provided on biochemistry reports [13]. Most of the laboratories in the UK report without comments or with computer-generated short verbal explanations according to predetermined rules and algorithms. In some laboratories, only few, if any, individualized interpretive comments are provided because of the concern about the dangers of providing inappropriate advice in the absence of complete clinical information. A secondary concern is that providing such comments may cause delay in the release of results by the laboratory to the detriment of patients. In laboratories that choose not to provide written narrative comments, the interpretation of results is still an important part of the laboratory service, but it is provided verbally by the clinicians. In those laboratories, however, where the IC is part of routine practice, the objective is to assist clinicians in the interpretation of complex data, and comments on dynamic or uncommon tests are reported [13]. Findings of the national survey of interpretive reporting in the UK, which was driven by the National Clinical Biochemistry Audit Group in 2011, described interpretation in clinical biochemistry as being widespread throughout the UK [11]. The majority of the participant laboratories (61–89%) indicated that they provide interpretive comments on most of the routine biochemistry tests that were studied in this survey: urea and electrolytes, liver function tests, lipids, glucose, hormones, HbA1c, and tumor markers [11].

Findings of a study that investigated whether and how laboratories interpret prolongation of activated partial thromboplastin time (APTT) showed large variations both within and between countries among the 990 responding laboratories, 90% of which were in 13 countries. The practice of commenting prolonged APTT results was very different for the 13 countries and varied between countries ranging from 10% to 67% of laboratories which never provide comments [10].

An evolving recognition in many countries that patients themselves should also be allowed direct access to their own laboratory results poses new challenges to clinical laboratories in the practice of IC. IC directly to the patients requires special considerations in the best practice mainly with regard to the language of comments [6].

There are still many unanswered questions related to the practice of IC in laboratories. In which fields of laboratory medicine do individual laboratories in Europe apply clinical interpretation? Does the IC practice vary from country to country? Which clinical requesters are mainly involved in IC service? The Joint Working Group of EFLM and EQALM on Postanalytical phase, which was established with a goal to develop and organize surveys and EQA programs to increase our knowledge about the PA steps of laboratory testing, is actively exploring these questions related to the practice of IC in laboratories [10,14].

3. Quality of IC provided by laboratories (characterization and estimation error prevalence in IC)

Several reports, especially those from different EQA-providing organizations, assessed the quality of IC of common laboratory tests provided by laboratory specialists. With the exception of an Italian survey in which participants had general consensus regarding probable syndromes suggested by the interpretation of the same results of the three case histories with troponin, CK-MB mass, and myoglobin results [12], all other studies [10,15,16,17,18] described a wide diversity of comments including obviously clinically misleading and harmful interpretations.

In the early stages of the UK IC scheme, surveys showed extremely wide divergence of opinions and comments even on apparently straightforward sets of abnormal results. Some comments were regarded as highly inappropriate when they were assessed by peer reviews [15].