Potential for medical error: Incorrectly completed request forms for thyroid function tests limit pathologists' advice to clinicians

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Background. Various publications have highlighted the significance of laboratory errors in the pre- and post-analytical phases and their impact on results. Thyroid-stimulating hormone (TSH) is a first-line thyroid function test and, if abnormal, reflex thyroxine (T4) or tri-iodothyronine (T3) testing is requested, depending on clinical and medication data provided. Interpretative comments are added to all TFT results.

Objectives. In view of the paucity of articles describing such errors, we audited laboratory request forms requesting thyroid function tests (TFT), received from primary care clinics and regional hospitals at our laboratory.

Design. We assessed 482 laboratory request forms for TFT from primary health care clinics for specific parameters.

Results. A total of 482 forms were analysed. Medication/s used by the patient (74.5%) and doctor's contact number (65.1%) were the most commonly incomplete parameters. Of the 123 patients with medication details, 62 (50.4%) were on thyroxine.

Conclusions. There are few studies examining the frequency and impact of incomplete laboratory forms on laboratory errors, and even fewer studies examining interpretative comments accompanying clinical biochemistry results. We studied how pre-analytical errors in completing request forms may lead to incorrect interpretative comments and inappropriate reflex testing, and so influence the quality of the post-analytical phase.

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Laboratory quality has been historically determined by the accuracy of the analytical phase. Following the development of high-quality analytical techniques, analytical error is no longer the main reason for error in the laboratory testing process.[1] Up to 68.2% of laboratory errors occur in the pre-analytical phase,[2] which refers to procedures performed neither in the clinical laboratory nor under the control of laboratory personnel,[3,4] e.g. completion of a laboratory request form, specimen identification, phlebotomy, sample handling and transportation to the laboratory. Post-analytical error refers to the ultimate check on the pre-and intra-analytical quality, including the reviewing pathologist providing interpretative comments, and the clinicians' interpretation and reaction to the results.[3,4] Interest is growing in the assessment of clinical laboratories' contribution to medical outcomes, including the evaluation of pre-and post-analytical errors.[5]

Clinical authorisation of results provides a final quality check of the entire pre-analytical and laboratory process, and is an important addition to standard quality control procedures.[6] Clinical validation of biochemistry results includes the post-analytical addition of comments to a laboratory report; this should be done by a qualified person with knowledge of the potential pre-analytical and analytical variables that may influence the result.[7] Providing interpretative comments, especially to primary care physicians, is an important duty of chemical pathologists.[8] Owing to the paucity of clinical biochemistry training in undergraduate medical training programmes[9,10] and increased specialisation of medical staff, interpretative comments may be useful for requesting physicians.[6] The Royal College of Pathologists has guidelines for the provision of such comments.[11] The Clinical Pathology Accreditation (CPA) Standards state that interpretation of results is an important component of clinical laboratories' services.[12] External quality assessment of interpretative comments is in place in the UK, Australia and Italy.[8,13-17] Clinical diagnoses are often confirmed with the use of laboratory results and, therefore, laboratory errors may lead to increased costs and unnecessary deaths.[18]

According to Price, 'any test will be beneficial only if appropriate action is taken on the results'.[19] Laboratory errors are important because laboratory data influence 70% of medical

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diagnoses and can significantly influence the success and cost of patient treatment.[20] These findings have led to agreement on the definition of a laboratory error as a defect occurring at **any** stage of the laboratory cycle,[21] and this definition has been incorporated in ISO Technical Report 22367.[22]

It was previously thought that interpretative comments had little influence on patient outcome, but a study of numerous thyroid function test (TFT) requests on patients taking thyroxine replacement therapy showed that introducing interpretative comments resulted in a significant decrease in thyroxine under-replacement.[23] A survey of general and nurse practitioners showed that, although interpretative comments of certain biochemical tests, including TFTs, are time-consuming, they are appreciated.[24] Although interpretative comments may be useful for primary care physicians who may not be familiar with the interpretation of test results, the clinical information provided on the request forms may be limited or inappropriate and may influence the interpretative comment provided.[8] Errors in interpretative comments may be attributed to the absence of adequate clinical information on request forms, which may result in comments that are misleading or harmful to patients.[25]

We reviewed the compliance of laboratory request forms for TFTs received in the chemical pathology laboratory at a primary health care laboratory where interpretative comments are provided for all TFT results. We hypothesised that pre-analytical errors would influence interpretative comments and have a further impact on requests for reflex testing.

Design

Ours was a retrospective collaborative study by the Division of Chemical Pathology, NHLS, Tygerberg Hospital, and the Chemical Pathology Laboratory at Green Point Laboratories. Green Point Laboratories receive all requests from primary health care clinics in the Cape Town Metropole and surrounding areas of the Western Cape.

Original laboratory request forms received at the Chemical Pathology division during a 4-day period from 27 - 30 July 2007 requesting TFTs were manually analysed for the presence of parameters provided in Table I. These dates were chosen as they account for all TFT requests between two of the pathologist's visits. Thyroid-stimulating hormone (TSH) is a first-line thyroid function test at this laboratory and is usually the only test requested. The requesting clinician may request a thyroxine (T4) or tri-iodothyronine (T3) test, depending on the clinical situation. All TFTs at this laboratory are validated by a chemical pathologist and released with interpretative comments.

Data were captured on Excel worksheets and patient confidentiality was maintained – patients were identified by a study number only. Data analysis was by basic statistics using the Microsoft Excel programme.

Table I. Pre-analytical quality indicators examined on chemical pathology request forms

Identification by name and surname
Identification by hospital number
Date of birth
Gender
Ward/location where patient resides
Requesting physician's identification
Requesting physician's contact number/pager number
Clinical/diagnostic information
Diagnosis present in an abbreviated form
Medications that the patient is/was taking at the time of specimen collection
Identification of specimen
Date of specimen collection
Time of specimen collection
Illegible handwriting

The study was approved by the Ethics Committee of the University of Stellenbosch and performed according to the Declaration of Helsinki (2000).

Results

During the study period, 482 request forms for TFTs were received. Fig. 1 shows the results of the request forms when analysed for the pre-analytical quality indicators indicated in Table I. The worst parameter completed by requesting clinicians was that of medication details; 359 (74.5%) of the forms lacked this parameter; 349 (65.2%) had no contact details for the clinician; 100 (20.8%) had no diagnosis, and 122 (25.3%) had a diagnosis but in an abbreviated form. Patient and clinic details were relatively well filled in, but this might have been due to most forms being pre-stamped with clinic details, and patient identification stickers are often used. The type of specimen collected was not stated on 16 (3.3%) of forms; 36 (7.5%) did not state the date and 175 (36.3%) did not state the time of collection.

Conclusions

We have previously demonstrated that laboratory forms are not adequately completed by clinicians, and we have illustrated the impact on the communication of critical results in a tertiary care setting.[26] This study shows that laboratory request forms

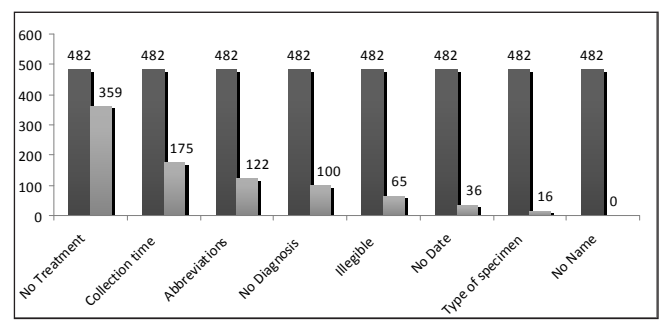

Fig. 1. Absence of parameters on laboratory request forms (N=482).

received from primary care clinics and regional hospitals are also inadequately completed. Interpretative comments are routinely provided with all TFTs. The current use of thyroxine replacement therapy may influence these comments and should therefore be indicated on all forms. For example, a patient with a raised TSH and normal T4 may be reported as a case of subclinical hypothyroidism, when the cause may in fact be non-compliance or inadequate dosage if the patient were using thyroxine replacement therapy.

TSH is a first-line thyroid function test requested by clinicians at primary care clinics and regional hospitals. Our laboratory has its own protocol for subsequent reflex testing; if the TSH is abnormal, a reflex T4 and/or T3 is requested. Studies have found that this reflex testing permits clinicians to obtain a correct diagnosis faster and at less cost.[4] A T4 is requested if the TSH is elevated in a patient not on thyroxine replacement therapy to differentiate subclinical from overt hypothyroidism. If the TSH is suppressed, a T4 is requested to differentiate subclinical from overt hyperthyroidism. If the patient is on thyroxine replacement therapy, these abnormal TSH values may indicate inadequate dosage/non-compliance or overdosage respectively. A slightly decreased TSH may also be found in nonthyroidal illness and secondary hypothyroidism, and the clinical data may hint at the probable diagnosis. Knowledge of patients' clinical and medication details is therefore important, as we do not request a T3 in patients on thyroxine replacement therapy. If this is not provided, unnecessary reflex testing of T3 is requested, resulting in an increased turnaround time and unnecessary cost. Unnecessary repeat tests in a laboratory can comprise up to 16.8% of the total workload in an immunology hospital.[27] Knowledge of **all** medication details of patients, and not only thyroxine replacement, is also important, as many drugs can affect the interpretation of TFT results, and some may even interfere with assays (Table II).[28,29]

We demonstrated that incomplete laboratory request forms may lead to misinterpretation of results, incorrect reflex test requests and inappropriate interpretative comments. Although this study was limited to TFT request forms within a primary care setting, we previously showed similar results n an academic environment.[26] We only examined patients on thyroxine replacement therapy, but it would also have been of interest to examine patients on antithyroid treatment and other drugs influencing thyroid functions.[29]

A limitation of this study is that the impact of incorrectly completed request forms on interpretative comments and reflex testing has not been quantified. This is difficult because of requests from numerous small outlying primary care clinics as well as regional hospitals. A follow-up on how these incorrectly completed request forms affect our services is desirable, but would be difficult to implement in our setting. Education of referring clinicians is required but would also be difficult in our setting as many of them are completing their community service in outlying primary care clinics and hospitals, resulting in lack of continuity in patient care.

Table II. Drugs that influence thyroid function[29]

Drugs that decrease TSH secretion
Dopamine
Glucocorticoids
Ocreotide
Drugs that decrease thyroid hormone secretion
Lithium
Iodide
Amiodarone
Drugs that increase thyroid hormone secretion
Iodide
Amiodarone
Drugs that decrease T4 absorption
Colestipol
Cholestyramine
Aluminium hydroxide
Ferrous sulphate
Drugs that affect thyroid hormone transport
Oestrogen
Tamoxifen
Heroin
Methadone
Androgens
Glucocorticoids
Salicylates
Anabolic steroids
Drugs that increase hepatic metabolism of T4 and T3
Phenobarbitol
Rifampicin
Phenytoin
Carbamazepine
Decreased T4 5′-deiodinase activity
Amiodarone
Glucocorticoids
Propylthoiuracil
Beta-adrenergic antagonists

In conclusion, quality assurance in the clinical laboratory is multifaceted and requires the detection of poor performance in the actions of each process. Errors in the analytical phase have been well-defined and can be compared with a gold standard, whereas errors in extra-analytical phases may be more difficult to study.[30] Pre-analytical errors (e.g. absence of important clinical data on request forms) can have a serious effect on patient care by causing post-analytical errors such as inappropriate interpretative comments, as shown in this study.

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