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Original Article

PRACTICE OF PATIENT BASED QUALITY ASSESSMENT PROCEDURE IN CLINICAL CHEMISTRY UNIT AT DIAGNOSTIC LABORATORIES IN NEPAL

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ABSTRACT

Background: The clinical laboratory is the major producer of information used to diagnose, treat, and monitor patients. Errors in laboratory testing may occur at many different points in the total testing process (TTP). Application of quality control plays a vital role in recognizing probable errors. The current dominant technique for error identification uses quality control materials has several inherent drawbacks; otherwise, patient based quality control procedure ensures the detection of pre-analytical errors, analytical, post-analytical errors, clerical errors, and random errors that cannot be detected using commonly used quality control methods, thereby improving the reliability of clinical tests. **Objective:** Thus the objective of this study was to evaluate the practice of patient based quality control procedure in clinical chemistry unit at diagnostic laboratories in Nepal. **Materials and Methods:** The questionnaire based study was conducted in clinical chemistry unit of diagnostic laboratories across the country. Questionnaires were personally dropped in 217 clinical biochemistry laboratories and were asked to complete a practice based questionnaire. The responses of 169 laboratories were analyzed using Microsoft Excel 2007 and expressed in terms of percentage. **Results:** In foremost study undertaken, a total of 169 laboratories responded to the questionnaire. A total 65.9 % of the laboratories monitored errors using patient based quality control procedure but not as a part of quality control. Very few of participant's laboratories responded accurately regarding utility and practical aspects of patient based quality control included in the checklist. **Conclusion:** Practice of patient based quality control procedure was not well established to identify possible errors. Hence, the study extent the existing information and explored that the current classical approaches were not adequate to assure accurate patients test results for specific analytes.

Key Words: patient based quality control, delta check, quality control, quality assessment, EQAS

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INTRODUCTION

Decisions about diagnosis, prognosis and treatment are based on the results and interpretations of laboratory tests, and irreversible harm may be caused by erroneous test results.[1] Hence, the accuracy of data generated by the clinical laboratory is critical for optimum patient care, safety, and economy.[2-3] Errors in laboratory testing may occur at many different points in the total testing process (TTP). Most mistakes i.e. 93% of total errors in today's clinical laboratory are made during the pre-analytical or post-analytical phases of the testing process.[4-7] Every clinical chemistry laboratory must have adequate procedures to identify true laboratory errors throughout all phases of TTP and assure quality of the results reported.[8] Quality control (QC) plays a vital role helping to ensure the reliability of laboratory test results, which can be QC based on control materials or QC based on patient data. This approach can be applied in the whole TTP, including pre-analytic, analytic, and post analytic phases.[4]

The current dominant technique for errors identification uses quality control materials which are inadequate for several reasons : are most sensitive to errors in instrument calibration, the expense of the material, appropriate storage of material may present a problem in some facilities, the material may be unstable once reconstituted and put into use, stored material may slowly deteriorate even if maintained in an appropriate manner, constituents such as enzymes and other proteins may be of animal origin and not react with reagents in the same manner as their human counterparts etc.. [4,9] Also, the concepts of Quality Assessment (QA) or QC or external quality control scheme (EQAS) programme, still have to gain widespread acceptance among Nepalese laboratories.[10]

An alternative approach is the use of patient data or patients based quality control that includes the use of: delta checks, limit checks, patient duplicates, discordance checks, multi-parametric checks of individual patient data (e.g. anion gaps) and average of patient results moreover delta check being the commonly preferred method.[11] Delta check is a quality control method that compares the current test result with a previous result for the same test obtained over a short period of time (within 96 hours) from the same patient and detects whether two values exceeds predetermined biological limits. [8, 11-12]

In TTP, the major contributors of pre-analytical causes of errors are: specimen mix-up errors, improper specimen acquisition, specimens altered by dilution with intravenous (IV) fluid, ethylenediaminetetraacetic acid (EDTA) contamination, possible misidentification of a patient or specimen, and clerical errors that can be identified by using delta check method. Importantly, these types of issues cannot be detected by traditional QC methods using control materials.[8, 12- 13]

Many laboratories use 4 delta check methods: delta difference, delta percent change, rate difference, and rate percent change. However, guidelines regarding decision criteria for selecting delta check methods have not yet been provided. [11, 14-17] Thus, does not matter what is used, it should ensure the detection of pre-analytical errors, few analytical errors, clerical errors, and random errors that cannot be detected using commonly used quality control methods, thereby improving the reliability of clinical tests.[11-12,16] Hence, we conducted a questionnaire based study to elicit the status of practicing patients based quality control procedure-delta check method in clinical chemistry unit at hospitals, other health care centers & referral laboratories in Nepal.

MATERIALS AND METHODS

The present study was a prospective assessment of patient based quality control procedure-delta check method, conducted during randomly selected period between May, 2010 to December, 2010 by the Department of Clinical Biochemistry, Dhulikhel Hospital-Kathmandu University Hospital, Dhulikhel, Nepal. A questionnaire was distributed personally to 217 clinical biochemistry laboratories across the country and was asked to complete a practice based

questionnaire. The highest academic qualification and their experience were also asked to fill out.

Evaluation of the practice of patient based QC procedure was performed using inspection sheets that were designed based upon the inspection checklists of College of American Pathologists (CAP), 2006 recommendations. Checklists were detailed series of questions; each question is designed to produce either a 'yes' response (i.e. the laboratory was doing), or a 'no' response (the laboratory was not doing). All applicable questions that cannot be answered "yes" were considered deficiencies.

The checklists chosen were classified into eight groups; each group contained a question/s concerning delta check evaluating the following items: practice of using delta check, type of delta check used, causes for variation, analytes to be used, sample integrity issues, specimen mix-up errors, improper specimen acquisition, specimens altered by dilution with IV fluid, EDTA contamination, clerical errors, and possible misidentification of a patient or specimen. For delta check, the previous result was taken from a specified time interval in the past during which the result was not likely to have changed physiologically. This limitation restricts the analytes that can be used effectively for delta check method. Preferences of parameters for delta check analysis are tabulated in Table 1.

Table 1: Delta checks for analysis[17]

Appropriate parameters	Inappropriate parameters
Electrolyte (Na^+, K^+ & Cl^-)	Glucose
Total Protein	Phosphorus
Albumin	Lactate Dehydrogenase (LDH)
Urea	Creatinine Phosphokinase (CPK)
Creatinine	Aspartate transminase (AST)
Alkaline Phosphatase (ALP)	Alanine transaminase (ALT)

Microsoft Office Excel 2007(Microsoft, Redmond, WA, USA) was used for data analysis and the responses were expressed in terms of percentage.

Patient based QC using delta checks method have been based on: [11, 14]

— Delta difference = current result – previous result.

— Delta percentage change = $\frac{\text{current- previous result x 100\%}}{\text{Previous result}}$

— Rate difference = delta difference/delta time.

— Rate percentage change= delta percentage change/delta time.

[Where delta time is the interval between the current and previous specimen collection time].

RESULTS

During the study period, 169 laboratories responded to the questionnaire. The respondent rate was 77.8 %. Majority of the respondents were with a bachelor degree in medical technology or equivalents, who were handling major responsibilities of the laboratory (in charge).

The study showed 65.9 % of the participant laboratory practice patients based quality control procedure using delta check method. Responses to questionnaires to evaluate practice of delta check are show in Table 2.

Similarly, 92.0% of the laboratory responded that, all of the parameters mentioned in the checklist were used for delta check.

Results showed that knowledge regarding patients based quality control using delta check method were important consideration factors.

Table 2: Responses to questionnaires (checklists) to evaluate practice of patients based quality control-delta check method (n=169)

Checklists		Evaluation response	
		Yes,%	No,%
Practice of using patient based QC procedure using delta check		65.9	34.1
Availability of previous value for comparison		40.1	59.9
	Delta difference	31.0	69.0
	Delta change %	18.8	87.2
Types of delta check method being used	Rate difference	9.05	90.95
	Rate change %	29.15	71.85
Expected cause for variability	Analytes	21.85	78.15
	Time interval	35.15	64.85
	Individuals	35.2	64.8
Does delta check helpful in identifying pre-analytical errors:			
1. Mislabeling		64.0	36.0
2. Specimen mix up errors		53.0	47.0
3. Specimen abnormalities		39.0	61.0
4. Improper specimen acquisition		53.0	47.0
5. Specimens altered by dilution with i.v. fluid		67.0	33.0
6. EDTA contamination		88.0	12.0
7. Possible misidentification of a patient or specimen		38.0	62.0
Do delta check was helpful in identifying Analytical errors		21.9	78.1
Do delta check was helpful in identifying post-analytical error : clerical error		54.0	46.0
Appropriate delta check parameters, (all as mentioned in checklist)		92.0	8.0
Causes of variation that delta check point-out	Laboratory workload	21.9	78.1
	Biological variation	35.2	64.8
	Individual variation	40.1	59.9

DISCUSSION

Our study showed 65.9% of the participant laboratory practice patient based quality control using delta check method based on inspection check list. Majority of the laboratories do not have idea regarding the use of delta check methods and expected cause of variability for delta check. In an attempt to detect pre-analytical errors, only half of the laboratories responded its common practice for their laboratories to use the delta check algorithm, although 67.0 % and 88.0% of the laboratory said specimen altered by dilution with IV fluid and EDTA contamination were commonly identified by delta check method, respectively. Unexpectedly, 21.9 % of the laboratory said they use delta check for error identification for analytical errors of TTP.The previous result is taken from a specified time interval in the past during which the result is not likely to have changed physiologically. This limitation restricts the analytes that can be effectively monitored with a delta check. Consequently, an effective delta check process can be established using a limited number of analytes.[18] In this study, majority of the laboratory responded that they use

all of the parameters mentioned in the checklist for delta check, which was unsatisfactory.

Repeating a test for accuracy is a well established practice in laboratories. Monitoring patient's laboratory data can detect pre-analytical, intra-laboratory and post analytical errors and may reflect biological variation and pathological alternations in the patients. There are no published data so far on implementation of error detection based on patient based QC procedure using delta check method for Nepalese laboratories and probably this study will be a step towards further study in delta checks, and implementation of EQAS in Nepal. The result showed, the comparison of current and past test results by delta check method was not well established to identify possible errors.

Delta check methods ensure the detection of pre-analytical errors, clerical errors, and random errors that cannot be detected using commonly used quality control methods, thereby improving the reliability of clinical tests. Opinions on the scope of acceptability of the delta check are not consistent.[8] Worldwide, there have been little or no studies available to date to show the practice of using patient based QC procedure using delta check instead there has been considerable number of studies that recommended the use of delta check method for error identification in TTP.[8,18]

Chima HS et al, 2009 concluded that, the implementation of delta check has improved their laboratories efficiency and turnaround time in critical cases and improved our patient care. [19] Yet from the another study by Lacher DA et al, 1990 concluded that delta checks should be used but the time between consecutive measurements, biological within and between person variability and clinical significance of test change should be considered.[20] Similarly, Kim JW et al, 1990 proposed delta check used in quality control program is a powerful tool for detecting random errors in clinical chemistry analysis.[21]

Similar to our finding, a study by Lehman CM et al, 2010 found that 61% laboratories always repeated critical results and that the median delay in reporting as a result of repeated testing was 10-14 minutes in most laboratories and 17-21 minutes in 105 of the laboratories [22] but our study did not consider the median delay time in reporting the results. A recent study by Park SH et al, 2012 suggested new decision criteria for selecting delta check methods for each chemistry testing and concluded that the new delta check method is highly consistent with the previous delta check method, generally applicable, reflecting both the biological variation of test item and the clinical characteristics of patients in each laboratory that concur our aim for implementations of patient based QC procedure in clinical laboratories.[8]

Many laboratories use 4 delta check methods: delta difference, delta percent change, rate difference, and rate percent change. However, guidelines regarding decision criteria for selecting delta check methods have not yet been provided.[8] Still, a study by Lowerence A et al, 1981 evaluated the performance of 3 delta check methods in clinical use and showed that the 3 delta check methods as applied to individual tests can detect erroneous test results [23], instead we have looked for all 4 methods. Ovens K et al, 2012 have studied about the sensitivity and specificity of the various delta checks for detecting specimen mix-ups and concluded, delta checks are commonly used in a laboratory setting to detect specimen mix-up errors and other random errors [15], conversely, our study have surveyed for practice of using it.

In contrast to our findings, Sampson ML et al, 2007. described a new approach for optimizing delta check rules, in terms of the time interval between tests, as well as their sensitivity and specificity. [24] Another recent study by Toll A et al, 2011 have shown that the practice of repeating tests with critical laboratory values or other results that trigger automated repeating may not be necessary with today's clinical laboratory automated analyzers.[25]

Therefore, the significant finding of the foremost study undertaken in Nepal, showed that patient based quality control procedure-delta check

method is not well established. Laboratory services play a crucial role in both individual and population-based healthcare, and clinical laboratories use many different methods to reduce errors, ensure patient safety, and improve quality including quality control procedures, quality assurance programs, accreditation of laboratories and certification of education programs. Laboratories need to continually improve all their systems including QC. The purpose of a QC system is to identify a situation where erroneous results are reported, and then to identify the cause of the error and rectify it. This can be achieved by participating in EQAS programme or by using QC materials or by random duplicate sampling or by repeat testing of previous day's samples or comparing the current result with previous one during valid period. Some laboratories use patient samples as QC material internally within the network. A patient sample, or pool sample, is sent to all laboratories in the network and the results compared. However, adverse event detection systems and initiatives to reduce error rates by using EQAS programme or quality control materials are in their infancy in Nepalese laboratories. When a formal EQAS program is not available or feasible, laboratories must arrange for an alternate assessment procedure. It is better to do something late than to not do it at all, hence the study extent the existing information and explore that current classical approach is not adequate for clinical laboratories. Delta check alerts provide an additional means to identify significant pre-analytical errors and post analytical errors, in addition to alerting health care providers to true changes in their patient's condition.

Laboratory services have a great influence on clinical decision making: 60–70% of the most important decisions on admission, discharge, and medication are based on laboratory test results. [1, 26] With this high degree of influence, the quality of laboratory testing and reporting is of utmost importance. If we presume the patient care as a cycle of activities or events, errors can occur at any phase starting from the treating physician examining and ordering investigations (pre-analytical phase), the laboratories receiving the sample and analyzing it (analytical phase) and finally while the reports are communicated to the physician for actions pertaining to the management of the patient (post-analytical phase).[5, 27] Errors at any of these stages can lead to a misdiagnosis and mismanagement and represent a serious hazard for patient health. Considerable advances in analytical techniques, laboratory instrumentation, information technologies, automation and organization have granted an exceptional degree of analytical quality over the past 50 years. This, in turn, has resulted in a significant decrease in error rates, analytical error rates in particular. There is consolidated evidence that nowadays, most laboratory errors fall outside the analytical phase, and that pre- and post-analytical process are more vulnerable to error than analytical processes and are source of concern.[1, 6, 28]

The ability to accurately identify true laboratory errors, and take the necessary corrective action when such errors are discovered is difficult in the clinical laboratory setting but every clinical chemistry laboratory must have adequate procedures to ensure quality throughout all phases of testing. The first approaches so far were the use of quality control materials and otherwise to use patient data.[4, 8]

The current dominant techniques for error identification uses quality control materials which is inadequate for several reasons. Among these include: the expense of the material itself, the material may be unstable once reconstituted and put into use, stored material may slowly deteriorate even if maintained in an appropriate manner, are sensitive to the analytical component of laboratory error, are most sensitive to errors in instrument calibration, quality control materials are often animal-based with added stabilizers and surfactants and do not react with analytic reagents the same as human samples, the use of quality control materials does not address the pre- & post-analytical component of laboratory error and quality control checks are performed infrequently -typically once a day. If an instrument falls out of calibration between checks, hundreds

of test results may be erroneous and those samples need to be re-analyzed, or even re-collected. [4, 8-9, 19] In a study on practice of QA and good laboratory practice (GLP) in clinical chemistry laboratory at diagnostic laboratories in Nepal done by Gyawali P et al,2011 have reported that only 20.0% of the clinical laboratories use QC materials for internal quality control (IQC) and proficiency testing (PT), in addition only 46.7% of the laboratories participated in EQAS programme but majority did not responded regarding VIS score.[10] Thus, alternative approach or strict guidelines regarding use of QA should be executed.

Alternative approaches could be patient based quality control procedure that makes use of patient test results as they are produced. Examples of patient based quality control procedure include the use of delta checks, limit checks, multi parametric checks of individual patient data (e.g., anion gap), Bull's algorithm, and the average of normal, delta check being the powerful and recommended tool.[19, 22, 25]

Delta check is a quality control method that compares present and previous test results of patients and detects whether the difference between the two results exceeds pre-defined criteria. If the difference is smaller than the pre-defined criteria, the result is automatically reported; however, if the difference exceeds the pre-defined criteria, the result is transacted only after repeating the test. [8, 11-12] Delta check methods ensure the detection of pre-analytical errors: specimen mix-up errors, improper specimen acquisition, specimens altered by dilution with IV fluid, EDTA contamination, possible misidentification of a patient or specimen, analytical errors, clerical errors, and random errors that cannot be detected using commonly used quality control methods, thereby improving the reliability of clinical tests.[4, 11, 29,30]

There are few limitations for this study; first, this study used only very basic information (pre-analytical factors, aspect of delta check) and simple algorithmic methods for evaluation. Another, the comparison of current and past test results by delta check rules is performed to identify possible errors, but the effect of time on the efficiency of error detection was not considered in this study. Excessive or inappropriate use of delta check methods can, however, delay reporting times and increase workload owing to the need for additional manual validation of test results. Finally, although discrepant results are often identified by delta check alerts but sensitivity and specificity of delta check method for error detection or shortcomings of delta check have not been considered and done in this study.

In conclusion, modern technologies such as bar-coding and automated specimen processing have undoubtedly decreased the incidence of specimen mix-up errors but as a least developing country, Nepal is making advances in the field of technology, research, infrastructure and skilled human resources. The concepts of QA, QC and EQAS still have to gained widespread acceptance among Nepalese laboratories. When a formal EQAS program is not available or feasible, laboratories must arrange for an alternate assessment and it is not sufficient to 'think' that 'my' results are satisfactory. This has to be proved with scientific evidence so even though the delta check methods have little significance short comings it can be an alternative approach. A cultural and educational approach is the essential one in combating the QC in an effective way. So the delta check method or patient based quality control is very useful in this particular case with proper knowledge of all aspects of it.

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