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Research Article

PERFECTION FROM INCEPTION: STANDARDS FOR BIOCHEMISTRY UNDERGRADUATE CERTIFICATE PRACTICAL

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ABSTRACT

Objectives: The undergraduate biochemistry practical's are the routine test performed in all the medical laboratories. Few of these have been certified practical by competency-based medical education. This will help the teachers access the depth of theoretical and practical knowledge as well as judge their communication skills. To detect the basic concept of quality control in the biochemistry laboratory.

Methods: Quantitative analysis was conducted with a purposive sample, at the Noida International institute of medical sciences by the department of biochemistry. 150 students performed the practical on serum albumin in two batches after the demonstration by the faculty. The results were collected through Google forms. The mean, SD, coefficient of variation, and bias were calculated.

Results: Both batches showed significant improvement in repeating the practical. Batch a performance was markedly improved after disclosing the optical density of the standard.

Conclusion: Teaching basic quality standards used in the biochemistry laboratory and emphasizing the preanalytical errors made during the 1st year of practical's, markedly improved the performance.

Keywords: Competency-based medical education, Quality control.

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INTRODUCTION

The Medical Council of India visualized that the Indian Medical Graduate, at the end of the undergraduate training program, should be able to recognize "health for all" as a national goal and should be able to fulfill his/her societal obligations toward the realization of this goal. To fulfill the mandate of the undergraduate medical curriculum which is to produce a clinician, who understands and can provide preventive, promotive, curative, palliative, and holistic care to his patients, the curriculum must enunciate the competencies the student must impart and must have learned, with clearly defined teaching-learning strategies and effective methods of assessment [1]. It is expected for undergraduates to practice evidence-based medicine. Laboratory medicine is taking the lead and becoming the core specialty in understanding and delivering better preventive, promotive, curative, palliative, and holistic care. To provide high-quality care at minimal cost, educational institutes have to be taken across the continuum of medical education [2]. Competency-based medical education (CBME) curriculum, Objectives of the Indian Graduate Medical Training Programme clause 3.1.11 includes medical graduate objectives as "Demonstrate ability to choose the appropriate diagnostic tests and interpret these tests based on scientific validity, cost-effectiveness, and clinical context" [3]. Medical graduates have recently been allowed to authorize the investigations of basic laboratory setups [4]. The spectrum of investigations performed in a basic laboratory setup comprises routine biochemistry, hematology, and microbiology. These routine investigations are very crucial in determining the overall health management of an individual. A false report may result in a missed diagnosis, under or over-treatment, and delayed medical care. In the CBME curriculum, the biochemistry lab test has 24 competencies, out of which five competencies are to be certified. The students have to perform independently and the holistic knowledge of these competencies is judged according to the precision and accuracy of the results, serum albumin is one of the certified competencies [5]. Laboratory investigation results vary as per test performance characteristics. It becomes an imperative additional objective to make the students understand the acceptable variations in their test results. Quality in laboratory medicine is assurance that total testing process (TTP) is performed correctly and the result is reliable. "Brain-to-brain loop" was used to describe TTP by Lundberg several years ago. He emphasized the 9 steps - Ordering, Collection, Identification, Transportation, Separation, Preparation, Analysis, Reporting, and Action [6]. Now the analytical techniques, reagents and instruments, information technology, quality control, and quality assurance has improved and led to a marked reduction in error. The recent evidence suggests that most errors in the loop are due to pre and post-analytical steps [7].

Hence, it is required that MBBS Undergraduates should learn the pre-analytical, analytical, and post-analytical skills appropriately so that they can handle the basic biochemical investigation independently after completion of the MBBS curriculum along that they should have the concept of the quality indicators like - mean, SD and coefficient of variation (CV) while performing laboratory practical's.

METHODS

This study was conducted at the Noida International institute of medical sciences by the department of biochemistry. Ethical clearance was granted by the institutional research ethics committee at the Noida international institute of medical sciences. 150 MBBS 1st-year students are divided into two batches, A and B. After the demonstration class, the practical test was conducted. After the test, a Google form link was sent to a college student group. Optical density (OD) values and concentration of test samples were collected by the colorimeter. For standardizations of instruments, we have run duplicate samples. Collected data were analysed for Mean, SD, and CV. Bias%. Students who submitted investigation results that were compared with true value

and outside acceptable limits were interviewed and possible errors were noted. The next demo session was arranged for both batches and potential errors were explained and told to perform the test again to all the students. Test results were collected for both batches and compared for any significant difference between results within the two groups and with previous practical results. Test samples and standard samples were run on the fully automatic trans Asia Bio-Medicals analyser Erba chem 200™ to minimize the systemic error. All students performing the test with results within acceptable limits would obtain a certificate marking the performance satisfactory as per NMC standards.

The allowable difference from the true values indicates the total allowable error which is taken from clinical laboratories improvement act (CLIA). The systemic difference between the results obtained by the lab test method and the results obtained from an accepted reference method is known to be biased which is calculated from the external quality assurance (EQA) through the formula:

Bias = (Lab Mean - Group Mean) × 100/group mean

Whereas the analytical CV of the test method is known to be the CV which is calculated from 5 months of IQC data [8].

CV% = (Standard Deviation/Laboratory Mean) × 100%

Hence, the total allowable error permitted by CLIA is based on medical equipment, and available analytical methods and is compatible with proficiency testing expenditure. Our target is Total Error <Total Allowable Error.

Hence, we conclude that practical skills play a pivotal role in delivering successful patient healthcare. Practical skills judge the competency of the performer and hence the reinforcement of the skill is a must. Therefore, certain practical has been certified [9].

Statistical analysis

All statistical analysis was performed using SPSS Version 20 software. Variables were presented as Mean±SD, CV% for quantitative data, and percentage for qualitative data. The Chi-square test was used to estimate the statistical significance of differences observed between the groups. $p<0.05$ was taken as statistically significant.

RESULTS

150 MBBS 1st-year students are divided into two batches, A and B. Detailed demonstration class was conducted before the practice for both batches. Results were collected and compared on the basis of the criteria given below: -

Target value	5.6 mg/dL	Standard OD	0.17
Tea	15% or 0.3 mg	Accepted Range of Std OD	0.15–0.19
Standard conc.	3 g/dL	Acceptable Test sample results	5.3–5.9 mg/dL

*TEA: Total allowable error, OD: Optical density

Table 1 shows the comparison between both groups after the first and second demonstrations. Test values of Batch A and Batch B students after the first and second demo practical compared to see how many students performed the test within an acceptable range of test value, that is, 5.3–5.9. It was observed that Group A Mean±SD value in Demo 1 was 5.5±0.6 while in demo 2 5.5±0.2. A further account in Group B has shown Mean±SD values in demo 1 and demo 2 5.3±0.8 and 5.5±0.3, respectively. It has been observed that SD and CV% markedly decreased after the second demonstration in both batches.

Test values of Batch A and Batch B students after the second demo practical compared to see how many students performed the test within an acceptable range of test value, that is, 5.3–5.9. 56 out of 70 students of batch A performed the test within range while 14 out of 70 students performed outside the test value range. 39 out of 73 students of batch B performed the test within the range while 34 out of 73 students performed outside the test value range. A contingency table was prepared and the Chi-square test was applied to know the significance of the difference between the two batches as indicated by Table 2. The Chi-square statistic is 11.31. The P value is 0.0007. The result is significant at $p<0.05$.

List of common errors identified during class practical

1. The most common error observed during the practical was pipetting error. About 25% of the total erroneous results were due to pipetting errors
2. Carryover effect - cuvette not washed by a few students after taking the OD of higher concentration solution
3. Short incubation period - Few students take out test tubes earlier than the stated incubation period
4. Wrong OD reading/Wrong labeling of test tubes - Students interchanged the reading while taking notes from the calorimeter
5. Wrong sample - Students took the water as a sample for a test.

DISCUSSION

The MBBS curriculum has been restructured by NMC to meet the objectives for MBBS graduates. Competency-based education has been defined as an outcome-based approach to the design, implementation, assessment, and evaluation of a medical education program using an organizing framework of competencies. CBME has added a different perspective on the assessment of MBBS students since it plays a crucial role in assessing the implementation of the curriculum. It is not an all or none phenomenon, rather it is incremental. To judge the perfection of the technique and the depth of knowledge, certain

Table 1: Comparison between the results after the first demonstration and second demonstration in both groups

	Group A		Group B	
	Demo 1	Demo 2	Demo 1	Demo 2
Mean	5.5	5.5	5.3	5.5
SD	0.6	0.2	0.8	0.3
CV	0.10	0.05	0.16	0.05

Table 2: Contingency table

	Within range (5.3–5.9)	Out of range	
Batch A	56	14	70
Batch B	39	34	73
Column Total	95	48	143 (Grand Total)

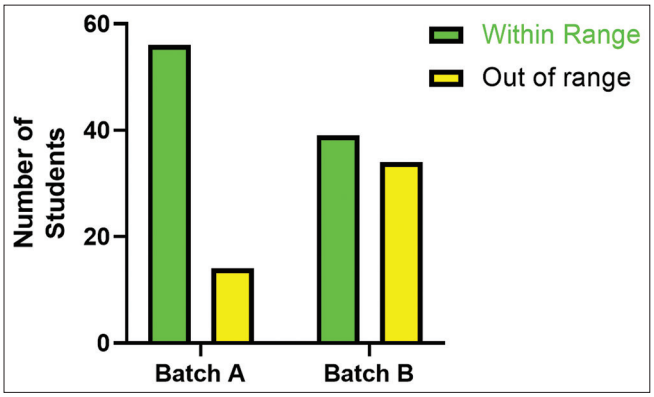

Fig. 1: Distribution of students with test results within range and out of range

biochemical tests have been made mandatory to be certified by the faculty [5]. Evidence-based medicine practice has redefined the role of laboratory work and plays a crucial role in diagnosis, staging of disease, treatment, and prognosis. It is expected from an MBBS graduate to understand the fundamentals of laboratory work, estimation of key parameters, reporting, and interpretation. It has been observed that every laboratory result inevitably has some intrinsic error with it. These errors may be due to analytical variations or individual biological variations. In the past decade, the improvement in the reliability and standardization of analytical techniques, reagents, instrumentation, advances and information technology, quality control, and assurance has decreased the analytical error rate by ten-folds[11]. Biological variation is a component of the performance goal which indicates the change from normal. The biological variation influences total error concepts, analytical goal setting, quality control, EQA practice, through patient-based real-time quality control, and the future of EQA using patient population parameters. Hence to interpret the result of a clinical laboratory test, we require a reference interval from the reference population. Whereas detecting a significant change in consecutive results, we required an understanding of analytical and biological variation[12]. An MBBS graduate is expected to understand what variations are acceptable in laboratory reporting and how to quantify them. It has been observed that SD and CV% markedly decreased (Table 1) after the second demonstration in both batches. Random errors were identified and on explaining the causes of the error and ways to rectify them, the SD and CV% markedly improved in both the batches. On the basis of criteria, during the second demonstration, the students had a better understanding of the types of errors made while performing the practical. OD of the standard solution worked as IQC for batch A in the second practice and helped the students to identify the errors beforehand taking the test OD. This practice ensured the uniformity and reproducibility of test results across the whole batch. The SD and CV% markedly decreased after the second demonstration in both groups. This signifies random errors which are minimized by re-emphasizing the correct methods in the second demonstration. Second, Batch A was provided with standard sample OD and allowed to reattempt the test procedures. The value of standard OD was given to batch A to put check their results and identify the errors. They could make corrections to the preanalytical errors before taking the test sample OD. As a result, 80% of students in batch A achieved the target test value results in comparison to 53.4% in batch B. (Histogram 1.1) The teaching of basic quality statistics used in the biochemistry laboratory and emphasizes the pre-analytical errors made during the first practical, markedly improved the performance. Each student was invigilated while performing the first practical. The preanalytical and analytical errors were noted and explained. The student had a better understanding of the type of error made when they were shown the entire first practical test results during the second demonstration. The significance of random and systematic error was made clear to students. The concept of total error and total allowable error was explained and students were targeted to achieving TE < TEA. This helped the students to discriminate between right and wrong results when the true test value was disclosed to them at the end of the practical.

CONCLUSION

Test results are subjected to variations and it is expected from MBBS doctors to fully understand these variations. A detailed understanding of the causes of possible random and systematic errors helps a laboratory physician to identify these errors timely and correct them. While Quality control practices help to identify errors and make a test run valid. It is customary to make all efforts to achieve maximum accuracy in the test results before releasing any laboratory report. Quality control practices inside the laboratory help to achieve accurate results with acceptable margins of error. The basic concept of quality control was delivered to the students by analyzing the first practical test results. The students had a better understanding of possible systemic and random errors and acceptable lab result variations after the second demonstration. This finally resulted in more homogenously distributed results which can be easily reproduced by the students. CBME has not defined any criteria to assess the performance of students during biochemistry certificate practical's. Hence, we propose that the CBME should add the quality indicators in the practice needed to be certified and the concept should be integrated vertically in all the phases of MBBS.

AUTHORS CONTRIBUTIONS

The manuscript writing had accomplished by Jaspreet Kaur and the data collection and analysis were done byAmit Samadhiya. The research was reviewed and edited by Mithilesh Kumar Singh and statistical analysis was done by Renu Chane and Gitanjali Gupta. The manuscript was finalized and submitted for publication by Jaspreet Kaur and Jaswant Kaur.

CONFLICTS OF INTEREST

None.

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