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National External Quality Assurance Program Pakistan (NEQAPP) –a milestone in proficiency testing in Pakistan

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ABSTRACT

Objective

The objective of this study was to highlight current status and importance of National External Quality Assurance Program Pakistan (NEQAPP).

Study Design: Cross sectional study

Place and duration of study

Department of Chemical Pathology and Endocrinology, Armed Forces Institute of Pathology (AFIP) from August to October 2015.

Methods

The study data was extracted from electronic NEQAPP database. Results from 2014-2015 were evaluated for clinical chemistry, hematology, microbiology, and immunoassay programs. Frequencies of unsatisfactory results of individual analytes as well as of all the participating laboratories were calculated.

Results

Failure rate of newly enrolled laboratories were more as compared to those which were participating for the last two years. The percentages of unsatisfactory results of all laboratories were 19% and 15% in 2014

and 2015, respectively. Fifteen analytes were selected according to their increasing percentage of participation. Failure rate was highest for alkaline phosphatase (35%) followed by creatinine (22%) and urea (20%) in two years analysis. Performance of laboratories in each quarter was evaluated depending upon number of analytes in which they fail to pass. The major failures were due to clerical and technical errors as determined during data compilation of results.

Conclusion

There is an increase in trend of participating in NEQAPP by health care laboratories which is a step towards laboratory quality management system in Pakistan. Nonetheless, there is a need for improving quality of laboratory results.

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INTRODUCTION

National external quality assurance programme Pakistan (NEQAPP) is a system designed to objectively assess the quality results obtained by medical laboratories in Pakistan. The primary aim of this proficiency testing (PT) program is to strengthen standards of clinical laboratories in Pakistan by providing medical professionals with a comprehensive quality and cost effective external quality assessment (EQA) scheme at a national level and to reduce the risk of errors in laboratory results. This will help provide better patient care and quality results of clinical laboratories in Pakistan along with fulfilling regulatory and accreditation requirements[1]. Erroneous lab results have great impact in delaying appropriate patient care along with increasing cost of diagnosis and management[2].

NEQAPP program runs in a twelve-month cycle. Samples are sent to registered laboratories on a quarterly basis. Results of a laboratory are judged against a comparator mean of instrument and method, or a pre-determined result as in the case of culture sensitivity for the microbiology program.

The aim of this study is to highlight efforts taken to improve quality of laboratories by inculcating proficiency testing (PT) philosophy through NEQAPP, importance of laboratory PT in medical science and appraise current situation of quality reporting in our laboratories. As such, our study will help all those concerned with medical laboratories in Pakistan and encourage a quality reporting culture according to international standards for better patient management.

METHODS

We conducted this cross section study at the Department of Chemical Pathology and Endocrinology, Armed Forces Institute of Pathology (AFIP), Rawalpindi, Pakistan. The study data was extracted from the electronic NEQAPP database. Results from January 2014 – December 2015 were evaluated for clinical chemistry, hematology, microbiology and immunoassay programs. Frequencies of unsatisfactory results of individual as well as all of the analytes were calculated for different laboratories.

RESULTS

There were 88 laboratories enrolled with NEQAPP in 2011, which increased to 140 laboratories in 2015. Ninety-six percent of the enrolled laboratories participated in the clinical chemistry programme followed by hematology (30%), microbiology (28%) and immunoassay (14%).

Failure rates of newly enrolled laboratories were higher than those which were participating for the last two years. Laboratories were grouped as defence, public and private laboratories. The percentage of unsatisfactory results of participating laboratories was 19%, 15% and 10% in the years 2014 and 2015. Fifteen analytes were

selected according to their increasing percentage of participation. This included ten parameters from clinical chemistry (glucose, alkaline aminotransferase, bilirubin, creatinine, cholesterol, albumin, triglyceride, urea, alkaline phosphatase and amylase), three from hematology (hemoglobin, red blood cell count and white blood cell count) and two from immunoassay (thyroid stimulating hormone and human chorionic gonadotropin). Failure rates were highest for alkaline phosphatase (35%) followed by creatinine (22%) and urea (20%) during the two years of the study period. In clinical chemistry, failure rates of the ten analytes for defence laboratories was 19%, 19.5% for public laboratories and 13.5% for private laboratories in the year 2014. Whereas failure rates declined to 8.5% in defence laboratories, 11% in public laboratories and 10.5% in private laboratories in the year 2015.

Reasons for unsatisfactory results were evaluated and classified into five main categories: methodological (21%), clerical (wrong entry of results or unit) (42%), technical (20%), PT material stability (9%) and random errors (8%). It has been observed that failure rates were low in laboratories which are supervised by technically qualified professionals in laboratory management and quality control, use of automation, standard methodologies and in those laboratories which are frequently participating in national and international proficiency testing programs for quite some time.

DISCUSSION

Proficiency testing program helps in improving and maintaining analytical inter laboratory agreement[3]. Good analytical agreement between laboratories is required as patients/clinicians move from one area/hospital to another. Irrespective of the setting, i.e., large reference laboratory with the latest equipment and professional staff or a small laboratory, a laboratory must report proficiency results of adequate quality to meet the stated guidelines. This can only be ensured by participating in external quality assessment (EQA) and taking appropriate actions when results do not meet acceptable performance. Although once considered a theoretic entity, PT is now a regulatory requirement for laboratory licensing by health authorities[4]. Moreover it is a prerequisite for getting the laboratory accredited as per ISO 15189[5].

Material used for proficiency testing are provided by external agencies, either mandated legislative bodies or voluntary organizations[6]. These materials are used to check the quality performance of a laboratory relative to its peers in terms of standard of performance that is usually expressed as a total variation from a target value for each sample. These samples are intended to reflect the laboratory's performance with patient samples. Erroneous proficiency results indicate that the laboratory is incapable of meeting the accepted standard of performance and can ultimately lead to the loss of the laboratory's license to perform that specific test or entire class of tests.

External quality control program is usually selected by the laboratory and purchased from an external company. It is an external check of the analytical methods performance in an acceptable manner to produce clinically acceptable patient results within the stated criteria[7]. QC samples provide us with data that represent the accuracy and precision of each method at the level of analyte present in each control. A laboratory must interpret that data in order to make daily decisions about the acceptability of each batch of patient samples, and ongoing decisions about the overall acceptability of method performance.

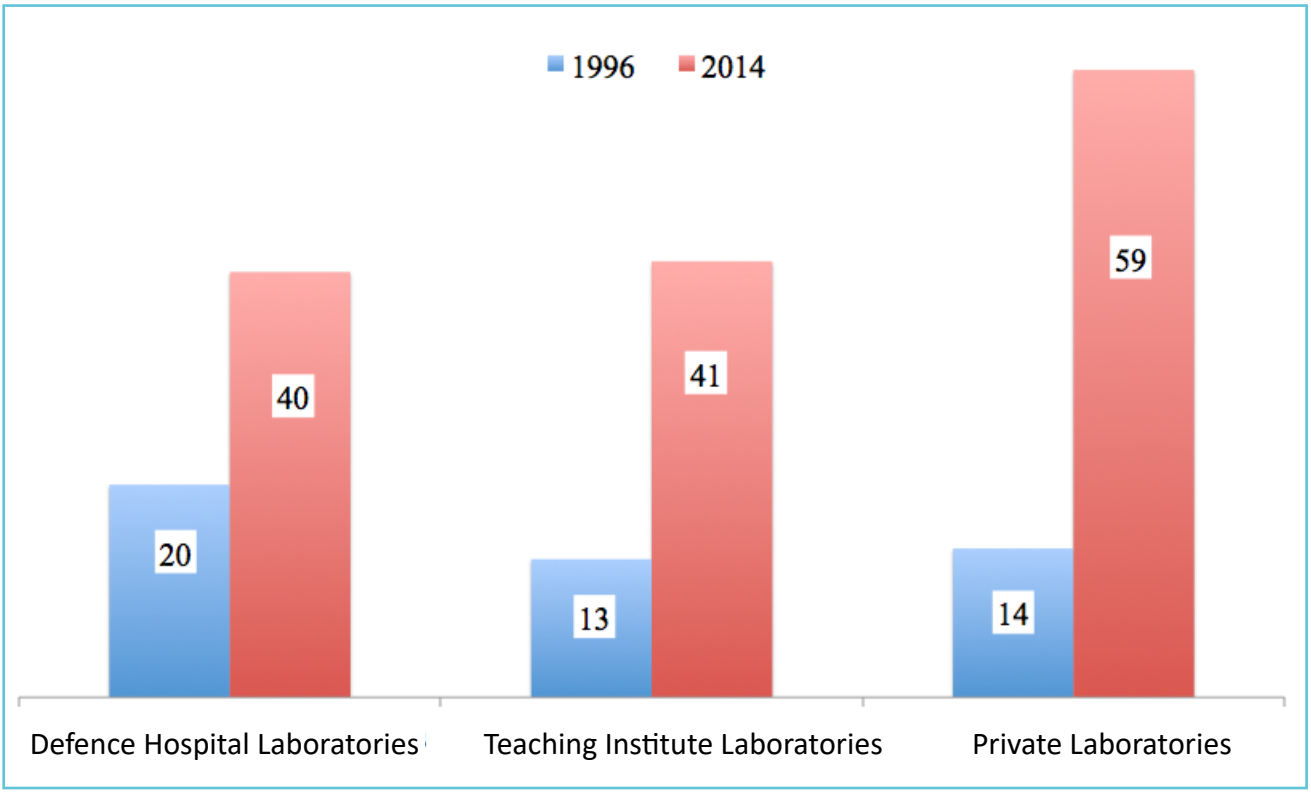
In 1996, at AFIP, Rawalpindi, participation in the clinical chemistry survey of NEQAPP was commenced with the aim to expand it to other

disciplines of Pathology. The Pakistan National Accreditation Council has launched the Medical Laboratory Accreditation Scheme in Pakistan in compliance with international organization of standardization (ISO) 15189 (International Standard for Medical Laboratories). PT is considered mandatory for clinical laboratory accreditation. It was at that time that NEQAPP program was expanded to hematology, microbiology and immunoassay to support the scientific and medical communities in Pakistan. Since then it has gained immense popularity and at present more than 140 clinical laboratories of Pakistan including 40 defence hospital laboratories, 41 teaching institution laboratories (medical colleges and postgraduate medical institutes), 59 public and private sector laboratories are voluntarily participating in this program (Fig. 1).

NEQAPP is a user friendly, cost effective program with immediate availability of customer service and technical support. Laboratories have an option of submitting their test results electronically (NEQAPP Online) or on paper (Results Forms) via post. Laboratory performance is displayed in each laboratory specific Sample Report. Acceptable performance in this national program is identified as falling within 2 standard deviation index (SDI) from ones comparator mean. Results outside ± 2 SDI are considered as unacceptable and highlighted as 'Fail' (Fig. 2).

In the last three years there is an increasing trend of ISO certification. This program should be adopted as mandatory requirement by regulatory authority for running and scrutinizing quality assurance of medical laboratories in Pakistan. Quality reporting can be ensured by selecting appropriate instrument with test method validation at instrument installment, improving transport and storage of reagents/calibrator/controls, scheduled equipment maintenance and ensuring quality checks[8].

Figure 1 Increasing trend of participation in NEQAPP



There is improvement in quality of PT results due to improvement in pre-analytic steps, laboratory automation, maintaining internal quality control and following standardize protocols for laboratory reporting.

There are certain problems, as follows, which need to be highlighted for running the proficiency program effectively. Laboratories not submitting results on due date, incomplete methodology details, failing to participate in all four quarters of a cycle, submitting results in units other than prescribed by NEQAPP, less use of electronic result submission and failing to update laboratory corresponding details especially in case of public laboratories.

CONCLUSION

NEQAPP program plays a pivotal role in improving the quality of laboratory services in Pakistan. In the last three years there has been a significant improvement in pass percentage of participating laboratories. No health care facility can be totally self-reliant in terms of maintaining quality and this gap can be filled by participating in an external quality program, giving the true picture of level of quality reporting.

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Figure 2 NEQAPP

NEQAPP

National External Quality Assurance Program Pakistan (NEQAPP)

Clinical Chemistry

Report

AFIP Rawalpindi

Your Laboratory No:	A-31	
Report for Cycle:	Cycle 4	January 2013 - April 2014
Sample No:	sample 4	
Sample Date:	01 / 10/ 2013	

AFIP Rawalpindi

Pathologist, AFIP Rawalpindi Cantt Rawalpindi

Coordinator NEQAPP. Dept of Chemical Pathology & Endocrinology AFIP Rawalpindi
For Details of Individual Analyte Report, Please Visit www.neqapp.net

National External Quality Assurance Program Pakistan (NEQAPP)

Clinical Chemistry

LAB	Cycle Name	Sample	Sample Date
A-31	Cycle 4	sample 4	01 / 10/ 2013

Sr.No	Analyte	Your Result	Group Mean	SDI	
18	Albumin	48 g/l	45.54	0.9	Pass
19	Alkaline Phosphatase	235 U/L	375.29	-1.6	Pass
20	ALT	131 U/L	127.56	0.4	Pass
21	Amylase	483 U/L	554.38	-1.2	Pass
22	AST	155 U/L	161.64	-0.6	Pass
23	Bilirubin (Direct)	26.03 umol/l	26.1	-0	Pass
24	Billirubin (Total)	69 umol/L	73.67	-0.9	Pass
25	Calcium (Total)	3.19 mmol/l	3.01	0.9	Pass
26	Chloride	113.7 mmol/l	115.67	-0.6	Pass
27	Cholesterol	6.13 mmol/L	5.93	0.7	Pass
28	Creatine Kinase	382 U/L	407.04	-0.6	Pass
29	Creatinine	532 umol/L	476.95	1.2	Pass
30	Gama Glutamyl Transferase	106 U/L	108.67	-0.2	Pass
31	Glucose	16.1 mmol/L	15.11	1.4	Pass
32	Iron	197 ug/dl	186.2	0.3	Pass
33	Lactate Dehydrogenase	578 U/L	563.65	0.2	Pass
34	Magnesium	1.47 mmol/l	1.32	1	Pass
35	Osmolality	310 mosm/Kg	312.5	-0.7	Pass
36	Phosphate (Inorganic)	2.34 mmol/l	1.95	1.2	Pass
37	Potassium	6.46 mmol/l	6.17	1	Pass
38	Protein (Total)	71 g/l	72.16	-0.2	Pass

Pass; SDI ± 2.0

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