Ind J Clin Biochem (July-Sept 2018) 33(3):304–313
https://doi.org/10.1007/s12291-017-0679-9

ORIGINAL ARTICLE

Diagnostic Laboratories in India: Investigating Quality Characteristics, Productivity and Time of Reporting

Tony C. Badrick[1] · Anton Gutscher[2] · Daniel Chin[2]

Received: 14 June 2017 / Accepted: 26 June 2017 / Published online: 10 July 2017

Abstract This is the result of a Survey of diagnostics laboratories in the Asia Pacific (APAC) region with perspectives on India, investigating the three key aspects that are central to the success of a laboratory: quality, cost and speed. This Survey provides a comparison in selected performance indicators in a large number of diagnostic laboratories in a broad range of countries in the APAC region. The Survey provides data on some key performance characteristics such as quality improvement activities, staff productivity and Turnaround Time (TAT). This Survey also demonstrates in India the common issues facing all the laboratories surveyed but also common solutions using a Quality Systems approach which involves Accreditation, customer responsiveness, greater use of IT, automation and Lean principles. Indian laboratories reported less automation and fewer laboratories have Laboratory Information Systems. The productivity by various measures in Indian laboratories was less than in other APAC laboratories. TAT was more commonly monitored in the Indian specimens though there were fewer laboratories compared with the APAC specimens where there were separate TATs for Short Turnaround Time and Routine specimens.

Keywords Survey · Diagnostic laboratory · Turnaround time, quality · Customer service

✉ Tony C. Badrick
tony.badrick@rcpaqap.com.au

[1] Royal College of Pathologists of Australasia, Sydney, Australia

[2] Roche Diagnostics Asia Pacific Pte Ltd, Singapore, Singapore

Introduction

Diagnostic laboratories play a key role in the diagnostic cycle and is in a key place to reduce many of these errors [1]. Furthermore, the Institute of Medicine Report recommends that: Health care organisations have programs in place to monitor the diagnostic process and identify, learn from, and reduce errors and near misses in a timely fashion [2]. One important approach to identify areas of potential improvement and monitor success after an intervention is benchmarking against similar laboratories.

Improving the quality of laboratory testing requires the adoption of a system based approach to reducing variation and there is a well-recognised evidence based to suggest that activities linked to Accreditation lead to improvements in patient safety and outcomes [3–10].

However many laboratories in developing countries do not have the capability or resources to achieve accreditations against international standards such as ISO 15189, but they still seek improvement activities that can be measured against their peers. Thus other surrogate activities are necessary in this situation. We have previously reported on a long term survey which sought to provide information to laboratories on quality indicators in the broad areas of quality, cost and turnaround time [11].

In 1997 Plebani and Carraro [12] wrote a seminal paper on the importance of pre and post analytical errors which has led to an increasing awareness of the problem of these extra-analytical errors. Various External Quality Assurance schemes or Benchmarking surveys have been introduced to provide laboratories with information they can use to improve their processes. [13].

The determination of reliable Quality Indicators (QI) in the Total Testing Process (TTP) is a key step in identifying areas where improvement is necessary and these Indicators

of the extra-analytical phases have been developed in some countries [14, 15]. There have been irregular surveys on specific issues but there are few surveys that are conducted regularly and that extend beyond countries borders. In 2008 the International Federation of Clinical Chemistry (IFCC) launched a working group named "Laboratory Errors and Patient Safety" (WG LEPS) to identify a list of valuable Quality Indicators and related quality specifications to be used as a benchmark between different laboratories around the world and to promote the reduction of errors in the TTP which will lead to improvement in quality and patient safety. The preliminary model of quality indicators has been developed, evaluated by some voluntary laboratories at an international level and preliminary results reported [16, 17]. It also been reported that improvement can be achieved by occasional survey [18].

The APAC region is an area of great cultural and economic diversity, with a significant focus on improving healthcare standards. A vital component to these improvements in the capacity to deliver better medical diagnosis and treatment to vast populations is the development of laboratory medicine. To determine the 'State of the Art' and monitor progress, Roche Diagnostics started to survey laboratories in the APAC region from 2011 [11]. The questionnaires were designed to find out information on three key areas of laboratory practice with a focus on, but not limited to, Clinical Chemistry and Immunology. These measures are neither as powerful nor extensive as the Quality Indicators suggested by the IFCC but laboratory improvement is driven by measurement and comparison against peers.

There have been few papers in the literature about the Quality performance of Indian laboratories [19, 20] but this Survey of Indian laboratories appears to be the most extensive. The aim of this study was to report the findings of the Roche Survey of Indian laboratories conducted in 2015, with reference to the previous Survey conducted in 2015. The following quality indicators of the post-analytical phase and laboratory improvement activities: participation in External Quality Assurance (EQA) programs, Accreditation against an external standard, Continuous Quality Improvement activities, Key Performance Indicator (KPI) measurement, TAT definitions and goals, and levels of automation.

Methods and Materials

The Survey

The Survey started in 2011 with 181 laboratories in twelve countries and grew to include 643 participants in 13 countries. The laboratories surveyed were a mixture of laboratories with and without Roche platforms. The questionnaires were distributed by Roche affiliates in the countries. Before 2015, all survey questionnaires were filled in hard copy form but in 2015, an online version was introduced where the laboratories can have an option to fill up the survey online or on hard copy. The survey is carried every alternate year and when the country specific report is ready, it is provided to the participating labs in a de-identified way. The results presented are the results obtained in 2015.

For the purpose of data analysis, the laboratories are categorised by the following main groups:

- Developed* (20%) and developing (80%) countries based on International Monetary Fund advanced economies. These countries (number of laboratories per country) were: Taiwan* (86), Korea* (25), Hong Kong* (12), Singapore* (5), China (153), Philippines (78), Thailand (60), Vietnam (60), India (59), Malaysia (47), Indonesia (32), Pakistan (24) and Brunei (2).
- Government hospital laboratories (50%), private hospital laboratories (32%), private commercial laboratories (16%) and Clinical Research Organisations Laboratories (2%).

There were 59 Indian laboratories in the Survey, with 5% from the government laboratories, 42% private hospital and 48% private commercial laboratories. In general, it appeared that there were more low volume laboratories (<250 specimens per day) in developing countries (36%) compared to developed countries (19%).

The performance characteristics chosen were related to laboratory quality indicators and improvement activities. The data collected in each of the key areas is shown in Table 1 together with a reference to a Figure or Table in this document where the results are presented.

Results

We will describe the results by key areas for Indian laboratories compared to their peers in other APAC sites. In this country specific report, the performance of the Indian laboratories will compared against the APAC group data. The majority of laboratories (74% with 81% of Indian sites) handled less than 1000 specimens per day and 65% (58% Indian) operated twenty-four hours.

Quality—External Accreditation

In the surveyed APAC laboratories 46% were accredited by an external agency with the majority having ISO 15189. Specifically, 71% of all the developed country sites and 40% of all the developing country sites were accredited by

Table 1 Structure of the questionnaire and Figure or Table where these results are presented

Quality	Cost	Speed
External quality assurance (EQA) program (Fig. 1)	Consolidation (Table 2)	Turnaround time (TAT) monitoring (Figs. 6, 7 and 8)
External accreditation (Fig. 1)	Automation (Fig. 12)	TAT target (Fig. 9)
Continuous improvement (Figs. 2, 3)	Staff productivity (Fig. 13)	Specimen handling (Figs. 10, 11)
Information technology (IT) infrastructure (Fig. 2)	Workspace utilisation (Table 2)	Manual aliquoting (Table 2)
KPIs used (Figs. 4, 5)		

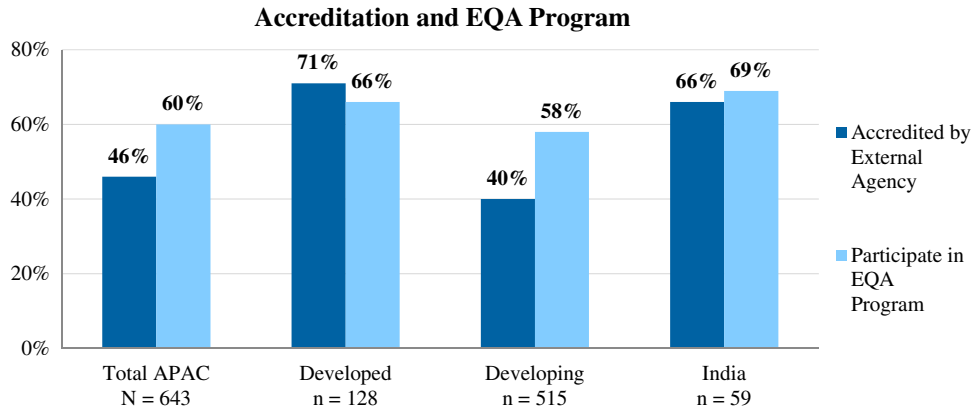


Fig. 1 Participation in external accreditation and EQA program

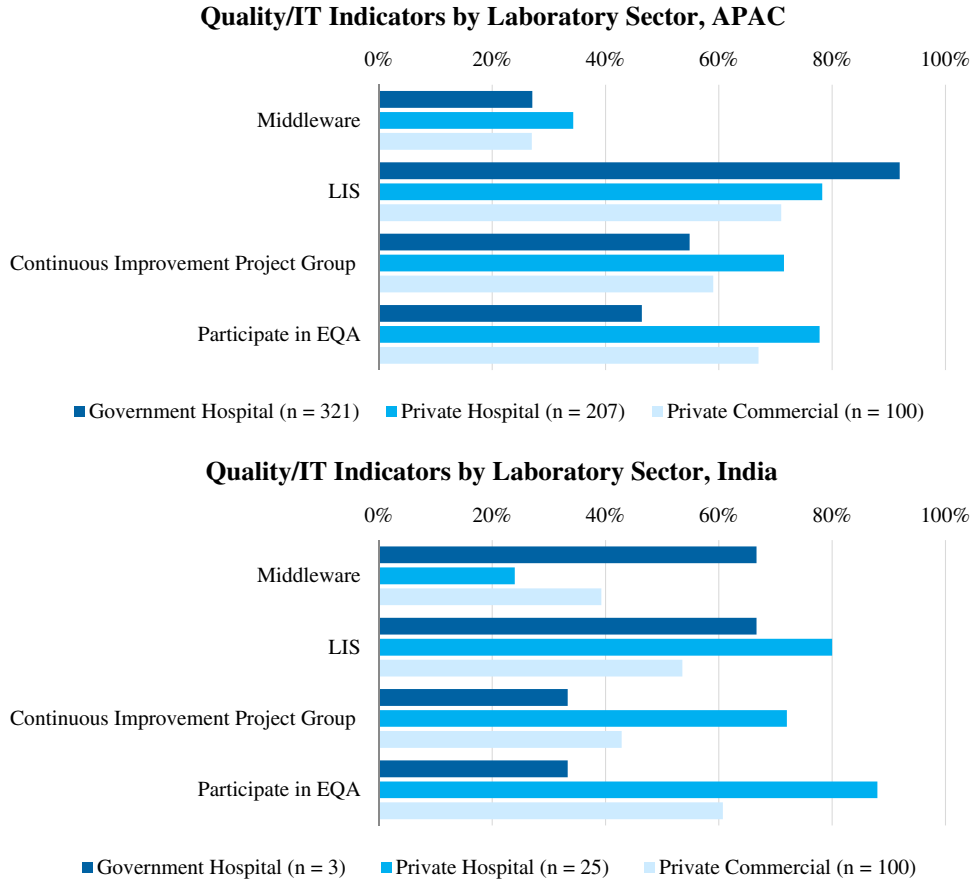


Fig. 2 Details of quality initiatives and LIS/Middleware by laboratory sector

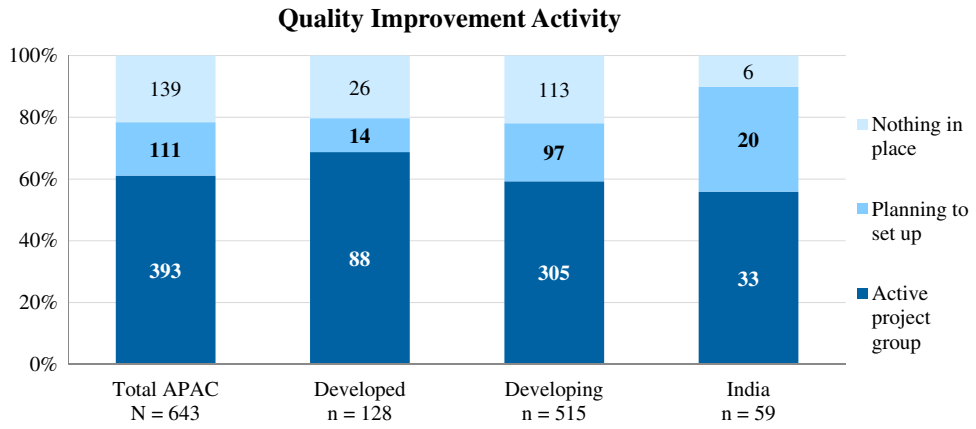


Fig. 3 Specific types and frequencies of continuous improvement activities as reported by participants

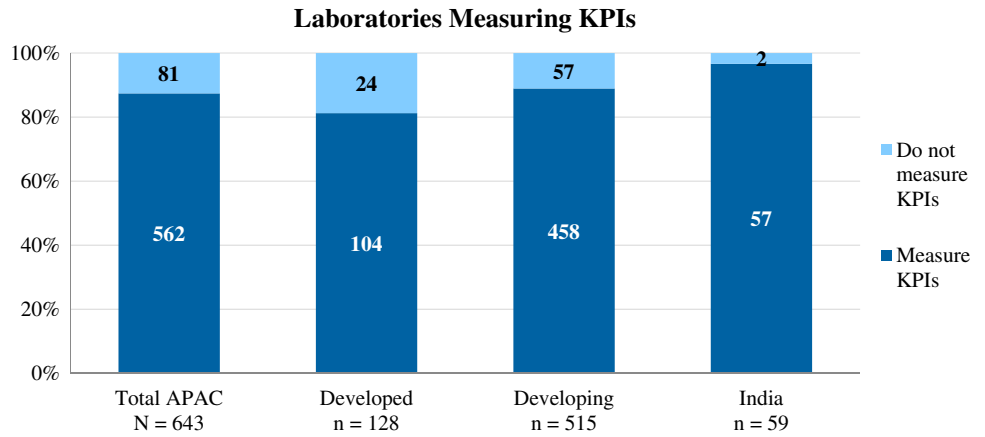


Fig. 4 Comparison of the Indian laboratories measuring KPIs with APAC laboratories

an external agency. As for the EQA program, 60% of all laboratories surveyed participated in EQA Program. The difference in the participation level between developed countries and developing countries is not as apparent as the External Agency Accreditation with 66 and 58% respectively. Interestingly, Indian laboratories perform significantly better than other developing countries where the External Agency Accreditation (66%) and Participation in EQA Program (69%) are comparable to that of the developed countries (Fig. 1).

Figure 2 includes details on Quality and the presence of a Laboratory Information System (LIS) and Middleware in the different categories of laboratory. The main purposes of the middleware were Report generation, Quality Control evaluation and Validation of assays. Middleware was present in 27% of government hospital laboratories, 34% of private hospital laboratories and 27% of private commercial laboratories in the APAC Region whereas the percentage is generally higher for Indian laboratories, at 67, 24 and 39% respectively. In APAC, 92% of government hospitals, 78% of private hospital laboratories and 71% of commercial laboratories reported having a dedicated LIS as compared to 67, 80 and 54% respectively for Indian laboratories Continuous improvement project groups were active in 55% of government hospital laboratories, 71% of private hospital laboratories and 59% of private commercial laboratories in the APAC region and with the exception for private hospital laboratories (72%), the Indian sites were less active in government hospital laboratories and private commercial laboratories, both at 33%.

The specific types and frequencies of Continuous Improvement Activities are given in Fig. 3.

Quality—Key Performance Indicators

Ninety-seven percent of Indian laboratories measured KPIs (Fig. 4). The surveyed laboratories used a variety of KPIs, measuring satisfaction, productivity and quality (Fig. 5).

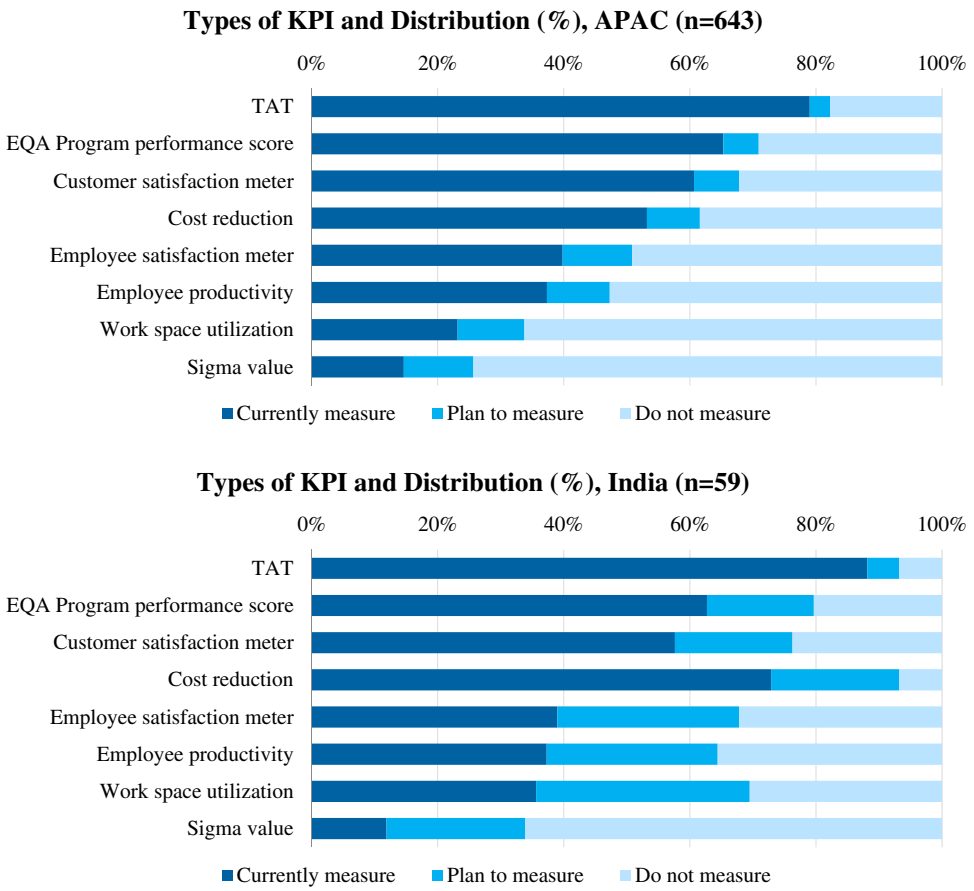


Fig. 5 KPIs measured by participating APAC and Indian laboratories

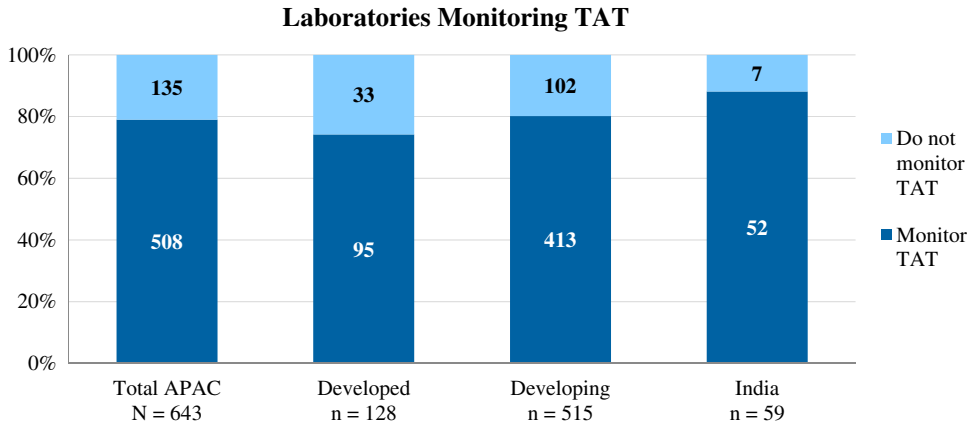


Fig. 6 APAC laboratories monitoring turnaround time

The overall APAC KPI and frequency of its use were as follows: TAT (79%), EQA Program Performance (65%), Customer Satisfaction (61%), Cost Reduction (prescribed cost reduction target) (53%), Employee Satisfaction (41%), Employee Productivity (38%), Work Space Utilization (23%) and Sigma Value (15%) (Fig. 5). Out of these 8 KPIs, more Indian laboratories measure TAT, Cost Reduction and Work Space Utilization.

Turnaround Time (TAT)

88% of Indian laboratories monitor TAT, higher than the overall APAC region. Interestingly, more laboratories from developing countries monitor TAT than that of the developed countries (Fig. 6). In terms of TAT, there is variability in the phases (i.e. pre-analytic, post-analytic, analytic and total) and whether all departments for all

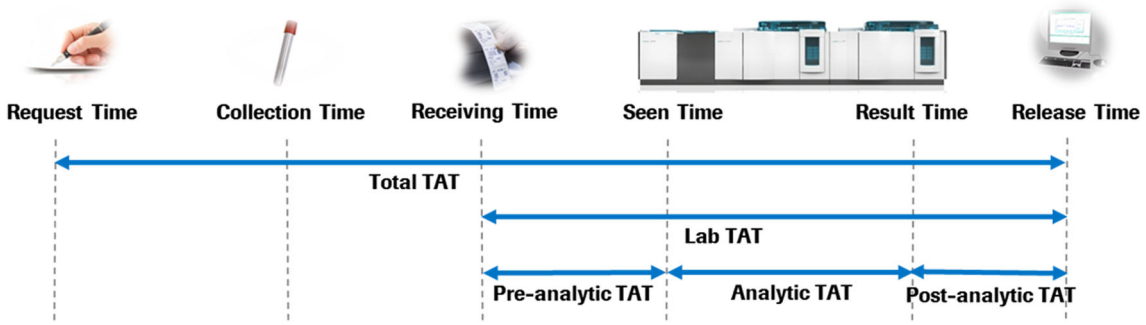
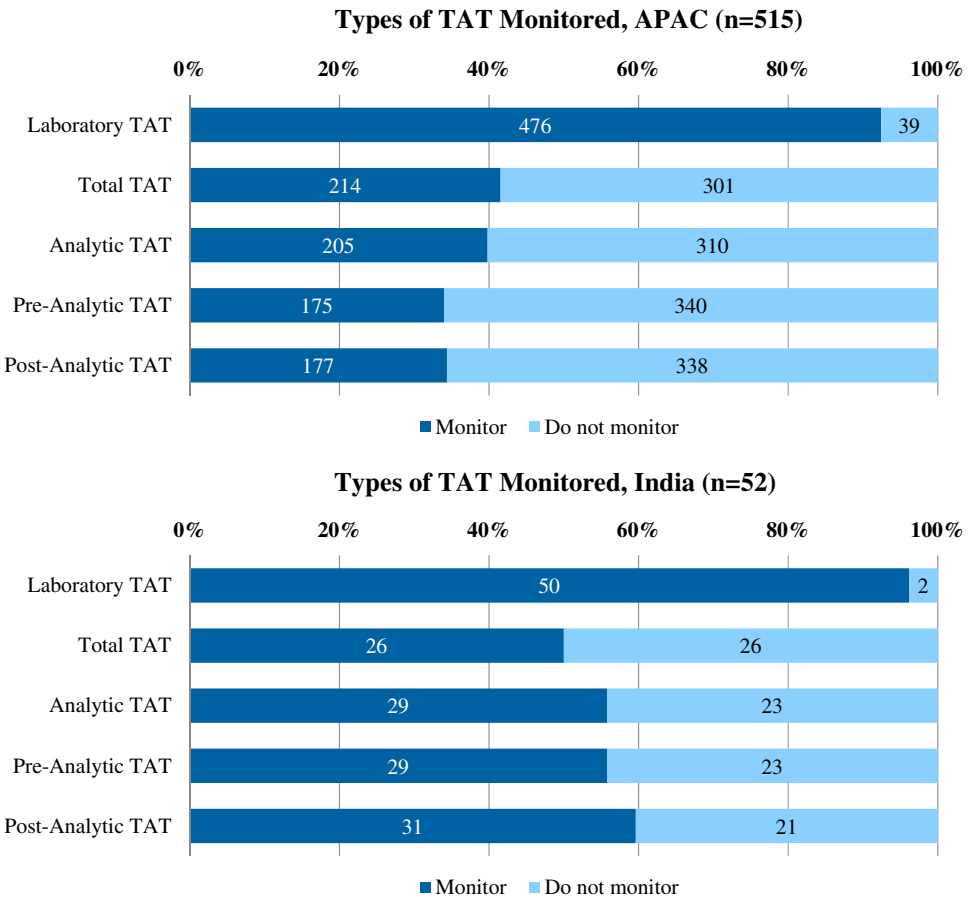


Fig. 7 Different types of turnaround time

Fig. 8 Turnaround time data collection comparison between APAC and India



specimens are monitored (4). Majority of APAC and Indian laboratories measure Lab TAT (Fig. 8).

For STAT Clinical Chemistry specimens, 75% of APAC laboratories have a ≤ 60-minute target whereas only 55% of STAT Immunology specimens have a ≤ 60-minute target. Indian laboratories have comparable ≤60-minute target with 74% and 48% for Clinical Chemistry and Immunology specimens respectively (Fig. 9). When it comes to handling of the STAT and Routine specimens, higher percentage of Indian laboratories (81%) have the same processes or resources as compared to overall APAC laboratories (68%) as shown in Fig. 10. Fifty-three percent of the APAC laboratories will monitor TAT for specific assay as opposed to 47% for Indian laboratories (Fig. 11).

Productivity—Automation

Twenty-two percent of laboratories in the survey have automated pre-analytics. More laboratories in developed countries have automated pre-analytics as compared to

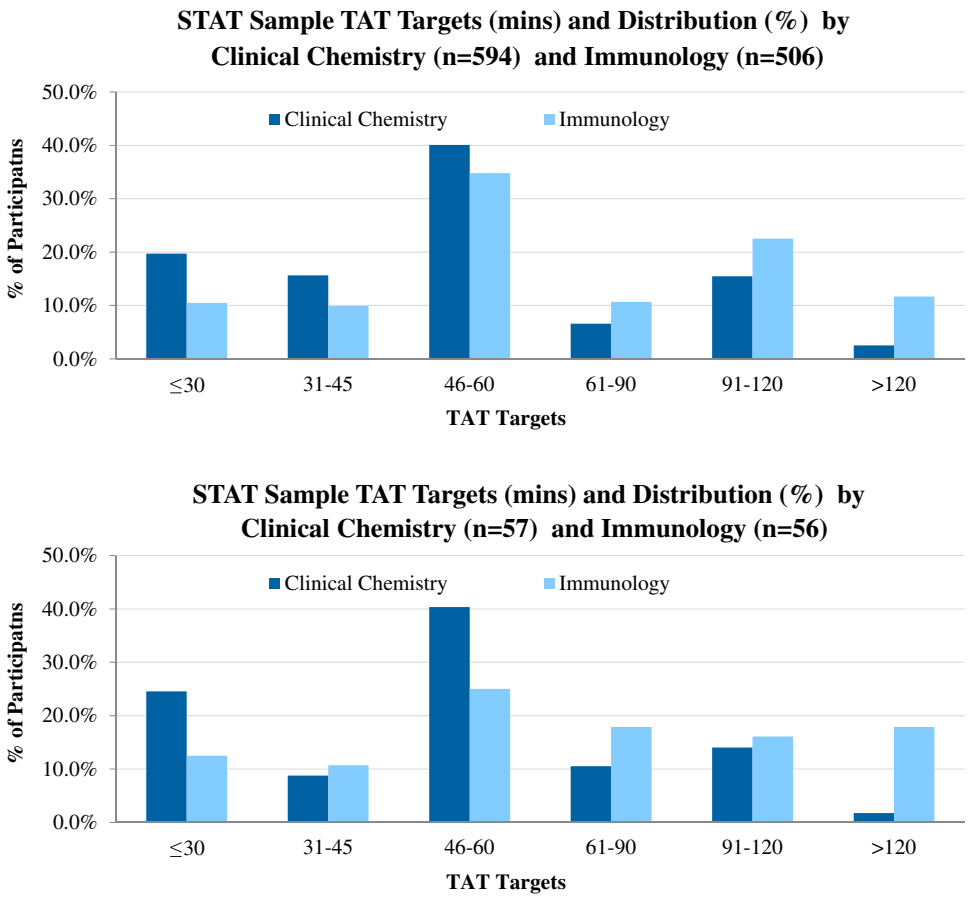


Fig. 9 STAT specimen TAT targets for clinical chemistry and immunology specimens

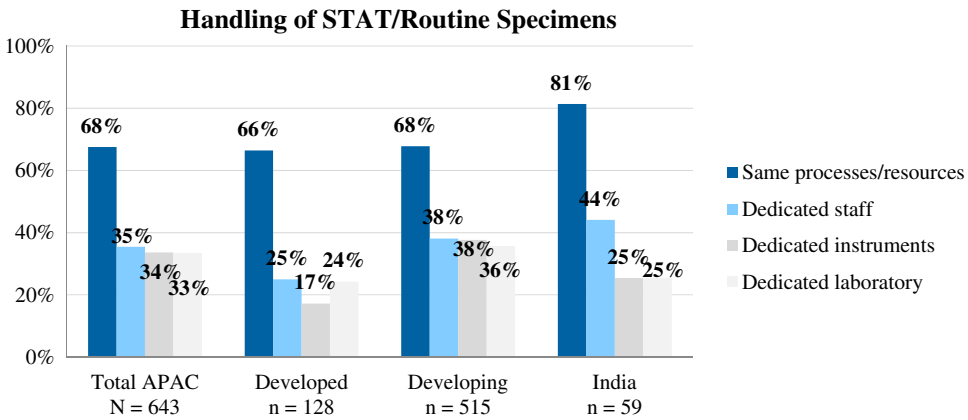


Fig. 10 Processes for handling STAT and routine specimens

developing countries (35 vs 18%) with Indian laboratories having significantly less at 3% (Fig. 12). The same pattern can be observed in the laboratory volume (specimens and tests) per Full Time Equivalent (FTE). The average specimens/FTE and tests/FTE for APAC laboratories are 82 and 573 respectively while that of Indian laboratories are 268 and 49 (Fig. 13).

In Table 2 we compare the results for key questions for Indian laboratories compared to developed and developing countries.

Limitations

The major limitation to these findings is the nature of the Survey, in that it is self-reported. However the sample size is large and the fact that it has been regularly repeated each second year tends to improve the consistency of the data by both familiarity on the part of the participants and construct accuracy by the organisers. There was a change in the delivery form of the Survey in 2015 from paper to electronic and that has impacted on the response rate dropping from

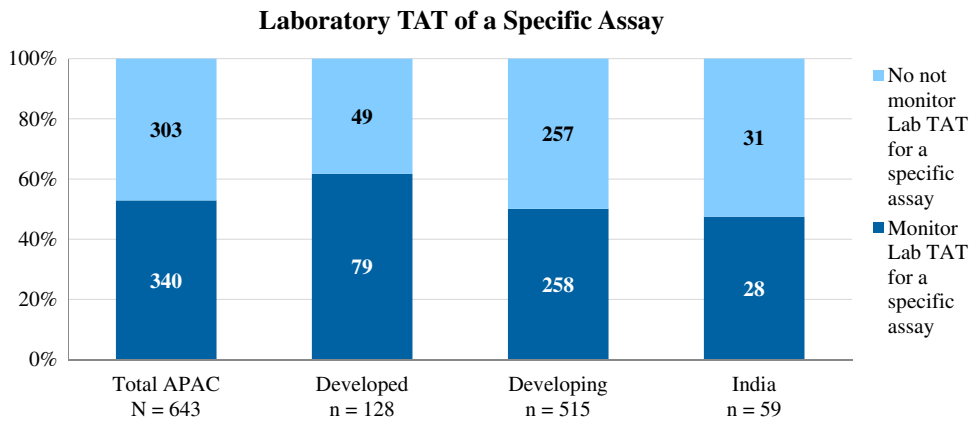


Fig. 11 Monitoring of laboratory TAT for a specific assay

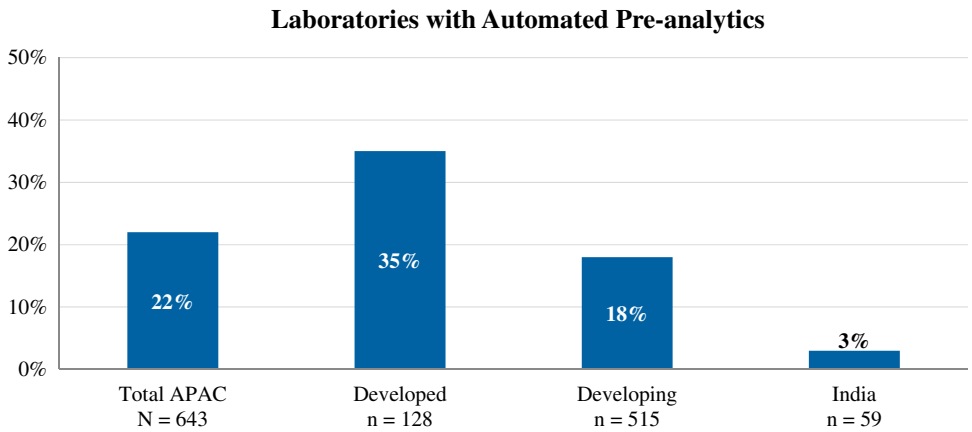


Fig. 12 Laboratories with automated pre-analytic systems

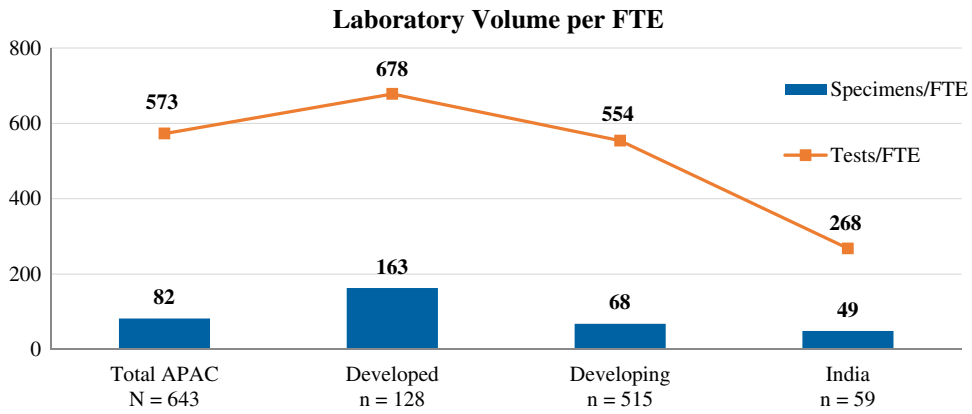


Fig. 13 Daily laboratory volume (specimens/FTE and tests/FTE)

874 to 628. Changing the mode of the survey from paper to electronic should not change the error rate [21] but should make the survey easier to collect. The change in the survey capture from paper to electronic in 2015 that led to drop in response rate was unexpected. The Indian cohort was relatively small with only 59 laboratories submitting results.

The participants are general laboratories in the APAC region and as it is a voluntary Survey there may be some bias in the responders to being the more sophisticated laboratories. This is a Roche Survey and also may have skewed the responders towards Roche users.

The categories used in the survey are often broad such as customer satisfaction and thus may have different meanings in different countries. There is always a balance between the length of the Survey and the detail being collected. With time and feedback the Survey will become more probing and the indicators more closely aligned to the IFCC Quality Indicators.

Table 2 Summary of differences between developed and developing countries and India

Parameter	Developed countries	Developing countries	India
24 h operation	63%	65%	58%
Accredited by external agency	71%	40%	66%
Participate in EQA program	66%	58%	69%
Have a quality improvement activity	69%	59%	56%
Measure KPIs	81%	89%	97%
Have an LIS	92%	82%	68%
Use middleware	54%	23%	32%
Monitor TAT	74%	80%	88%
Have same TAT for STAT and routine specimens	94%	97%	98%
Monitor assay specific TAT	62%	50%	47%
Making manual aliquots	60%	65%	69%
Consolidated clinical chemistry and immunology systems	29%	24%	20%
Automated pre-analytics	35%	18%	3%
Specimens per FTE	163	68	49
Tests per FTE	678	554	268
Tests per square metre	88	47	28

Discussion

As expected the Survey has revealed varying degrees of compliance with the implementation of best practice, however there are common themes in most laboratories. There is a common focus on meeting customer demands and quality improvement. These are apparent through the monitoring of TAT and customer satisfaction on the one hand and performance of the laboratory in EQA and external accreditation on the other. There is greater emphasis on staff training and satisfaction than on cost of service at this time. Most laboratories have set the same TAT for urgent and routine specimens which suggests that there is one system for dealing with all specimens and laboratories focus on improving workflow rather than segregate work on the basis of urgency. This is reflected also in the consolidation of analytical systems (Clinical Chemistry and Immunology) which has occurred in between 24 and 29% of laboratories in the Survey.

We have reported elsewhere that there were no significant differences between developed and developing countries in most of the parameters measured (Table 2) except for the higher number of developed laboratories that were accredited, which may be a national policy in some countries; use middleware; and, have automated pre-analytics. There are more laboratories in developed countries with greater than 2000 specimens per day which may be the reason for the greater automation and use of middleware in this cohort. The productivity parameters are different between the two groups with the laboratories in the developed countries showing more productivity per FTE (specimens and tests per FTE) and less space per FTE.

The Indian laboratory cohort did show a number of differences from the other Laboratories surveyed. More Indian laboratories measured KPIs. Generally Indian laboratories were less likely to have an LIS. In the automation area it is noted that Indian laboratories are unlikely to have pre-analytics and are less productive in terms of tests/FTE, specimens/FTE and tests/square metre than other laboratories in the Survey.

Conclusion

Diagnostic laboratories around the world face the same challenges of increasing workloads, more demanding referrers to reduce turnaround time and improve quality, leading to a greater focus on quality improvement.

This Survey is the first of its type to be published and represents a significant number of laboratories in the APAC region. By comparing different countries in the same region we can highlight different issues facing diagnostic laboratories. This is a very valuable snapshot of the performance in a set of quality characteristics and time of reporting diagnostic laboratories in a broad range of countries in the APAC region.

The Survey introduces benchmarking of key indicators such as TAT, and quality improvement activities to a broad range of laboratories. Sharing the results of the benchmarking has led to reductions in the average TAT overall

by a greater recognition of laboratories of what is possible and can be achieved.

The adoption of more sophisticated harmonised Quality Indicators may be a distant hope, but by introducing these laboratories to a form of Benchmarking leads to quality improvement in the non-analytical phases of the Total Testing Cycle and this survey has demonstrated the power of that approach.

The Indian laboratories in the survey have comparatively lower levels of computerisation and equipment consolidation with lower levels of productivity by three measures. There is a higher emphasis on measuring TAT though the laboratories do not monitor separately STAT and Routine specimens. Perhaps the data reflect cultural differences in workforce utilisation in Indian laboratories and different referring doctor expectations than in other APAC countries.

Compliance with Ethical Standards

Conflict of interest TCB declares that they have no conflict of interest. AG declares that he/she has no conflict of interest. AG declares that he/she has no conflict of interest.

Ethical Approval This article does not contain any studies with human participants or animals performed by any of the authors.

References

1. Schiff GD, Hasan O, Kim S, Abrams R, Cosby K, Lambert BL, et al. Diagnostic error in medicine: analysis of 583 physician-reported errors. Arch Intern Med. 2009;169:1881–7.
2. The Institute of Medicine. Improving diagnosis in healthcare. Washington: National Academies of Sciences, Engineering and Medicine; 2015.
3. Sciacovelli L, Aita A, Plebani M. Extra-analytical quality indicators and laboratory performances. Clin Biochem. 2017. doi:10.1016/j.clinbiochem.2017.03.020.
4. Sciacovelli L, Lippi G, Sumarac Z, West J, Garcia Del Pino CI, Furtado VK, et al. Quality indicators in laboratory medicine: the status of the progress of IFCC working group "Laboratory Errors and Patient Safety" project. CCLM. 2016;5(3):348–57.
5. Leatherman S, Ferris TG, Berwick D, Omaswa F, Crisp N. The role of quality improvement in strengthening health systems in developing countries. Int J Qual Health Care. 2010;22(4):237–43.
6. Shin BM, Chae SL, Min WK, Lee WG, Lim YA, Lee DH. The implementation and effects of a clinical laboratory accreditation program in Korea from 1999 to 2006. Korean J Lab Med. 2009;29(2):163–70.
7. Wattanasri N, Manoroma W, Viriyayudhagorn S. Laboratory accreditation in Thailand: a systemic approach. Am J Clin Pathol. 2010;134(4):534–40.
8. Peter TF, Rotz PD, Blair DH, Khine A, Freeman RF, Murtagh RM. Impact of laboratory accreditation on patient care and the health system. Am J Clin Pathol. 2010;134(4):550–5.
9. Tholen DW. Improvements in performance in medical diagnostics tests documented by inter-laboratory comparison programs. Accred Qual Assur. 2002;7(4):146–52.
10. Chaudary R, Das SS, Ojha S, Khetan D, Sonker A. The external quality assessment scheme: five years' experience as a participating laboratory. Asian J Transfus Sci. 2010;4(1):28–30.
11. Badrick TC, Gutscher A, Sakamoto N, Chin D. Diagnostic laboratories in Asia Pacific region: investigation on quality characteristics and time of reporting. Clin Biochem. 2017. doi:10.1016/j.clinbiochem.2017.03.017.
12. Plebani M, Carraro P. Mistakes in a stat laboratory: types and frequency. Clin Chem. 1997;43:1348–51.
13. Kristensen GBB, Aakre KM, Sandberg S. How to conduct external quality assessment schemes for the pre-analytical phase? Biochemia Medica. 2014;24(1):114–22.
14. Khoury M, Burnett L, Mackay M. Error rate in Australian chemical pathology laboratories. Med J Aust. 1996;165:128–30.
15. Mainz J. Defining and classifying clinical indicators for quality improvement. Int J Qual Health Care. 2003;15:523–30.
16. Plebani M, Sciacovelli L, Lippi G. Quality indicators for laboratory diagnostics: consensus is needed. Ann Clin Biochem. 2011;48:479.
17. Sciacovelli L, O'Kane M, Skaik YA, Caciagli P, Pellegrini C, Da Rin G, et al. IFCC WG-LEPS. Quality indicators in laboratory medicine: from theory to practice. Preliminary data from the IFCC Working Group Project "Laboratory errors and patient safety". Clin Chem Lab Med. 2011;49:835–44.
18. Nakhleh RE, Souers RJ, Bashleben CP, Talbert ML, Karcher DS, Meier F, et al. Fifteen years' experience of a college of american pathologists program for continuous monitoring and improvement. Arch Pathol Lab Med. 2014;138(9):1150–5.
19. Adyanthaya S, Jose M. Quality and safety aspects in histopathology laboratory. J Oral Maxill Path. 2013;17(3):402–7.
20. Agarwal R, Chaturvedi S, Chhillar N, Goyal R, Pant I, Tripathi CB. Role of intervention on laboratory performance: evaluation of quality indicators in a tertiary care hospital. Ind J Clin Biochem. 2012;27(1):61–8.
21. Dolnicar S, Laesser C, Matus K. Online versus paper: format effects in tourism surveys. J Travel Res. 2009;47(3):295–316.