Original Article

A current analysis of quality indicators in Chinese clinical laboratories

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Background: Improvements in patient safety and outcomes have been linked with systems-based approaches to reduce variation in laboratory testing cycle. Activities linked to laboratory accreditation are also known to improvement in the quality of laboratory testing. Benchmarking is a continuous improvement approach utilised in which errors are identified and outcome of any intervention are monitored against peers.

Methods: Roche Diagnostics started benchmarking surveys of laboratory practice in the Asia-Pacific Region in 2011 by collecting feedback from clinical laboratory managers and directors on their laboratories' operation and performance. The survey is carried every alternate year, and benchmarking report will be released to the participants for their reference. The latest survey was a new edition performed in 2019 via an online platform.

Results: This Survey provides a comparison in selected performance indicators in many Chinese diagnostic laboratories with Asia-Pacific peers. Whilst the performance of Chinese laboratories is generally comparable to those of other Asia-Pacific laboratories, there are some differences with regards to how STAT urgent) samples are handled, enrolment in External Quality Assurance programs and certain turnaround time targets.

Conclusions: The performance of Chinese Laboratories in the main is similar to the performance of Asia-Pacific countries. Some areas of practice identified as unique to Chinese laboratories may reflect laboratory practices that may be mandated or preferred by Chinese agencies.

Keywords: Benchmarking; quality improvement; turnaround time

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Introduction

Information provided by Clinical laboratories are essential in the delivery of healthcare in almost all healthcare settings, including preventative health, diagnosis and monitoring of health status and treatment and in prognosis. Therefore, the activities of the laboratory including diagnostic errors, timeliness of delivery of results and efficiency of the laboratory processes directly impact healthcare delivery and outcomes (1,2). "Improving Diagnosis in Health Care" (3) is a report published by The Institute of Medicine which provides detailed analysis of the causes of diagnostic errors and near misses. It also provides a systematic strategy to reduce these in a timely fashion. Benchmarking against

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similar laboratories is a well-recognised approach to identify the key errors and monitor the outcome of any intervention (4).

Adoption of a system-based approach to improve quality of laboratory testing reduces variation and activities linked to Accreditation have been shown to improve patient safety and outcomes (5-12). However, the capability or resources to achieve accreditation against international standards such as ISO 15189 is a limiting factor for many laboratories in the Asia-Pacific (APAC) region. Thus, other surrogate improvement activities measurable and comparable against peers are necessary. There have been published reports on long term surveys providing data on quality indicators in broad areas such as quality, cost, and turnaround time (13,14). Introduction of some External Quality Assurance (EQA) schemes and Benchmarking surveys have provided laboratories with performance data which can be utilised in process improvement (15).

Reliable quality indicators (QI) in the total testing process (TTP) including Indicators of the extra-analytical phases is vital for identifying areas where improvement is needed, and these have been developed in some countries (16,17). The International Federation of Clinical Chemistry and Laboratory Medicine (IFCC) via "Laboratory Errors and Patient Safety" working group of (WG LEPS) has established a relatively complete model of quality indicators (MQI) and related quality specification available on a specifically developed website (www.ifcc-mqi.com) which can be used as a benchmark by different laboratories around the world. The evaluation of these quality indicators has been performed at a global level and preliminary results have been published (18,19). Occasional surveys have also been demonstrated to achieve improvement (20). There is an Australian QI survey which has been active since 2012 and which has approximately 60% of Australian laboratories represented (21). KIMMS includes a Failure Mode and Effects Analysis FEMA) based risk score as well as frequency of error.

Improvements in healthcare is a major focus in the APAC region despite the great diversity in culture and financial capabilities. Since Laboratory Medicine plays a crucial part in medical diagnosis and treatment, improvement in this field is important for better healthcare delivery to this vast population. Roche Diagnostics sought to determine the 'State of the Art' and progress by surveying APAC laboratories which started in 2011 (13). These surveys gathered data on three key areas of laboratory activities mainly focussing on Clinical Chemistry and Immunology. Although the gathered data are not extensive as the Quality Indicators suggested by the IFCC, they provide useful information on performance compared with peers. National Health and Family Planning Commission of the People's Republic of China suggested a list of 15 QIs in 2015, covering the most error-prone testing processes of laboratory medicine based on the IFCC MQI (22). The debate about the number and type of effective QIs continues (23). The results of an EQA Scheme for 15 QIs established in 2015 by the National Centre for Clinical Laboratories of China (CNCCL) have been published (24-28). However, the Roche survey covers many aspects of not covered by the CNCCL's EQA program is more extensive. We aimed to report on the performance of Chinese laboratories compared with APAC in the 2019 Roche Survey. Comparisons were made on quality indicators on post analytical phase and laboratory activities integral to improvement in quality and safety. These included participation in EQA programs, Accreditation against an international standard, Continuous Quality Improvement activities, Key Performance Indicator (KPI) measurement, TAT definitions and goals, and levels of automation. We present the following article in accordance with the SURGE reporting checklist (available at https://dx.doi.org/10.21037/jlpm-21-19).

Methods

The benchmarking survey started in 2011 by collecting feedback from clinical laboratory managers and directors on their laboratories' operation and performance. The questionnaire is provided in the Supplementary data. There were 181 laboratories from 12 countries/regions participated back then. The survey is carried every alternate year, and benchmarking report will be released to the participants for their reference.

In August 2019, a new edition of the survey was launched via an online platform (www.labinsights.com). Participants from APAC can freely access the platform using any internet browser and complete the survey digitally. Participants can also access the benchmarking survey report afterwards on the same platform at any time once it is ready. The questionnaires were distributed by Roche affiliates in hard copy as well for certain countries which translated version is required.

Statistical analysis

The results presented are the data obtained from the survey

Table 1 Participating countries/regions

Country/region	n	%
China	399	34.5%
Thailand	160	13.8%
Vietnam	132	11.4%
South Korea	96	8.3%
Japan	95	8.2%
Indonesia	80	6.9%
Philippines	60	5.2%
Taiwan	40	3.5%
Malaysia	32	2.8%
Pakistan	21	1.8%
India	20	1.7%
Hong Kong	8	0.7%
Sri Lanka	7	0.6%
Nepal	3	0.3%
Cambodia	2	0.2%
Singapore	2	0.2%
Australia	1	0.1%

in 2019. In total, there were 1,158 laboratories from 17 countries/regions in APAC answered the survey. Twenty one percent of the laboratories were from developed countries (using the IMF World Economy Outlook 2018 (https://www.imf.org/en/Publications/WEO/Issues/2018/09/24/world-economic-outlook-october-2018). Fifty nine percent were government laboratories, 32% were private hospitals and 9% were private commercial organisations. Approximately 29% were small (<250 samples per day), 45% were medium sized (251–1,000 samples per day) and 27% were classified as large laboratories (>1,001 samples per day). Surveys were received from the following countries (*Table 1*). Details of the participant laboratory types and sizes are shown on Table S1. No incentives were offered.

Results

We will report on the results by key areas of quality, speed and productivity for Chinese laboratories compared with the overall APAC group data. Further details are available in the Supplementary data provided.

Quality—Accreditation

In total 33.1% of the surveyed laboratories in China were accredited by an external agency compared with 40.3% in APAC with the majority having ISO 15189 accreditation in both China and overall APAC groups. Most Chinese laboratories who participated in the survey were accredited by national or provincial agencies rather than international agencies. More specifically 66.8% and 77.3% of survey participants had accreditation with National Centre for Clinical Laboratories (NCCL) and Province/City Centre for Clinical Laboratories (PCCL) respectively. Interestingly only 34.8% of Chinese laboratories with international accreditation used international EQA and 74.2% of these laboratories had a continuous improvement program for accreditation. Overall, only 15.8% of Chinese laboratories in the survey used international EQA programs compared with 43.2% in APAC, with EQAS and College of American Pathologists (CAP) being most popular in China. Although many Chinese laboratories (79.7%) did not use or plan to use international EQA, the majority did participate in national EQA programs. *Figure 1* shows the participation in external accreditation and EQA programs.

Quality—continuous improvement

As with the APAC region, focus on continuous improvement is evident in China. 57.4% of Chinese laboratories in the survey had a continuous improvement team compared with 68% in APAC. In the 2015 Survey, 61% of APAC laboratories had a continuous improvement team, so the trend is increasing. Overall, the utility of several continuous improvement activities is slightly lower than APAC. Detailed data on types of Continuous Improvement Activities and their frequencies are shown in *Figure 2*.

Quality—key performance indicators

A variety of KPIs were used by the surveyed laboratories which included measures on quality, productivity and satisfaction. The use of KPI and frequency of its use were: Turnaround Time (TAT) (78.9%), Performance in EQA program (75.2%), Customer satisfaction (48.6%), Cost reduction (71.2%), Employee satisfaction (46.4%), Employee productivity (40.6%), Work-space utilisation (27.3%), sigma metric calculation (25.3%) and sample rejection rate (68.7%. Overall, the measured KPIs were

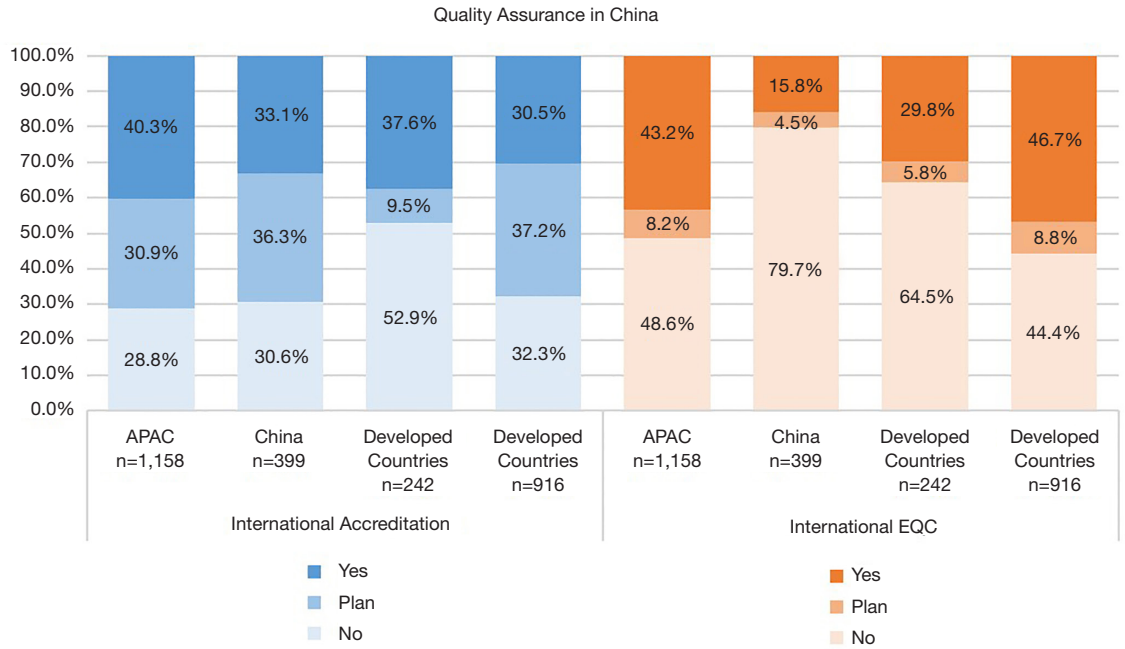

Figure 1 Participation in external accreditation and EQA programs.

comparable with the APAC group (*Figure 3*).

Sample quality

A variety of methods were used to check for sample quality including manual check (86.0%), pre-analytical instrument (44.5%) and analytical instrument (32.9%) (*Figure 4*). The mechanisms employed for notification of sample rejection included phone call (96.2%), QC meeting (55.2%), IT Alert system (46.1%), Instant messaging App (44.7%), SMS (29%) and e-mail (8.3%). Interestingly, the use of instant messaging app for sample rejection notification was higher (44.7%) compared with the APAC group (29.1%) (29). *Figure 4A* and B show the various methods utilised for sample quality check and sample rejection notification.

Quality—IT

Laboratory information Systems have been implemented and in use in 95% of Chinese laboratories compared with 93.8% in APAC. 38.6% of Chinese laboratories use middleware compared with 37.7% in APAC. The survey results with regards to the use of IT functions are summarised in *Figure 5*.

Speed—STAT sample

China invests significantly more resources for STAT samples than the APAC in term of provision of dedicated STAT laboratories, dedicated instrument, and staff to handle these specimens (*Figure 6*).

Speed—critical results

There were three-time intervals given for reporting a critical result. Although only a minority of Chinese labs in the survey 66/399 answered 'No target' for the questions relating to critical results reporting, 22% of the lab had a critical result notification target of <5 minutes compared with 30% in APAC (*Figure 7*).

Speed—TAT (turnaround time)

There was variability TAT monitoring in terms of the phases of the total testing cycle monitored and monitoring for all specimens by departments. Majority of laboratories monitored laboratory TAT (89.7%) whilst total turnaround time, pre-analytical TAT, analytical TAT, and post analytical TAT were monitored by 53.6%, 48.9%, 48.9%, and 46.1% respectively. Most Chinese laboratories in the survey utilised IT function for monitoring TAT (68.5%) with 45.8% of all

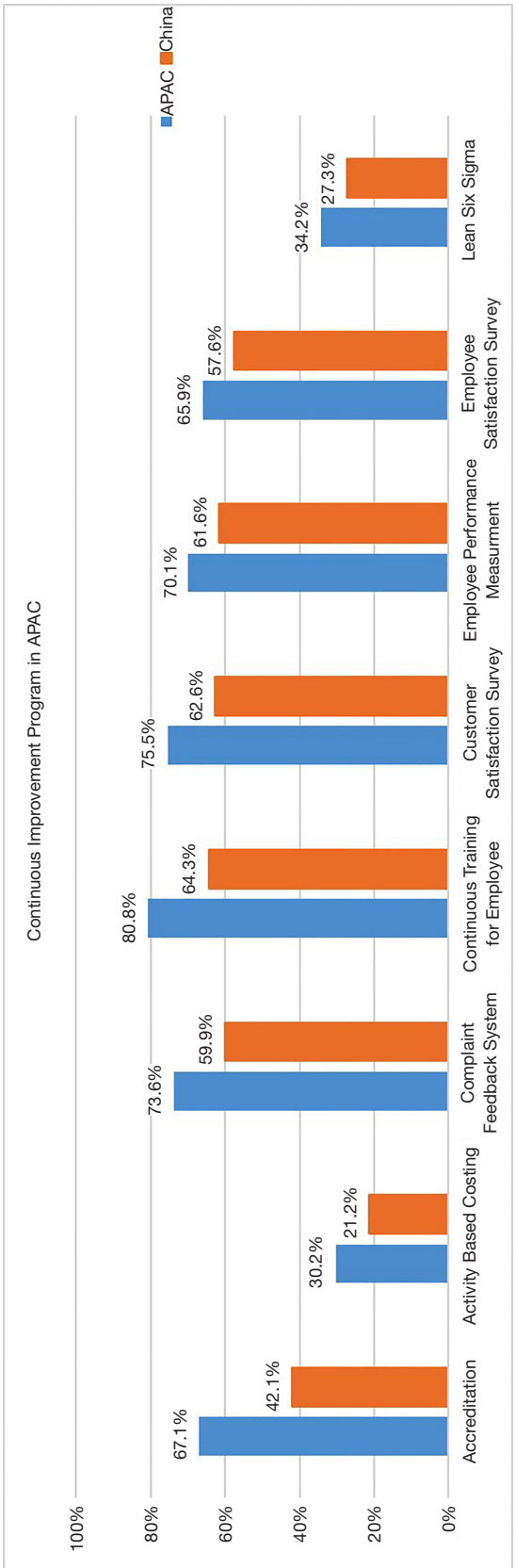

Figure 2 Details of continuous improvement activities.

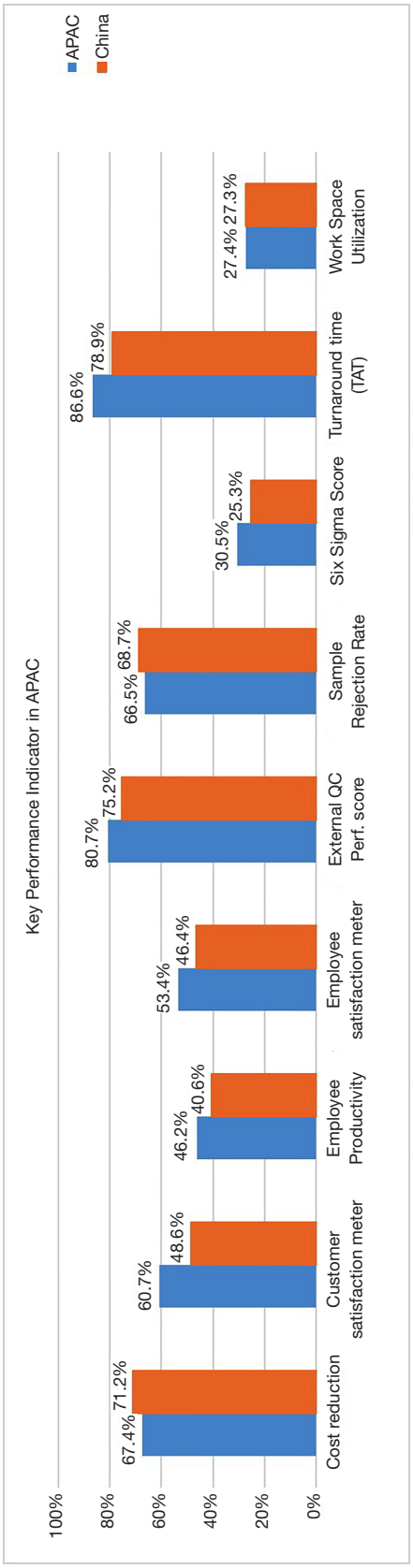

Figure 3 Comparison of KPIs measured by participation APAC and Chinese laboratories.

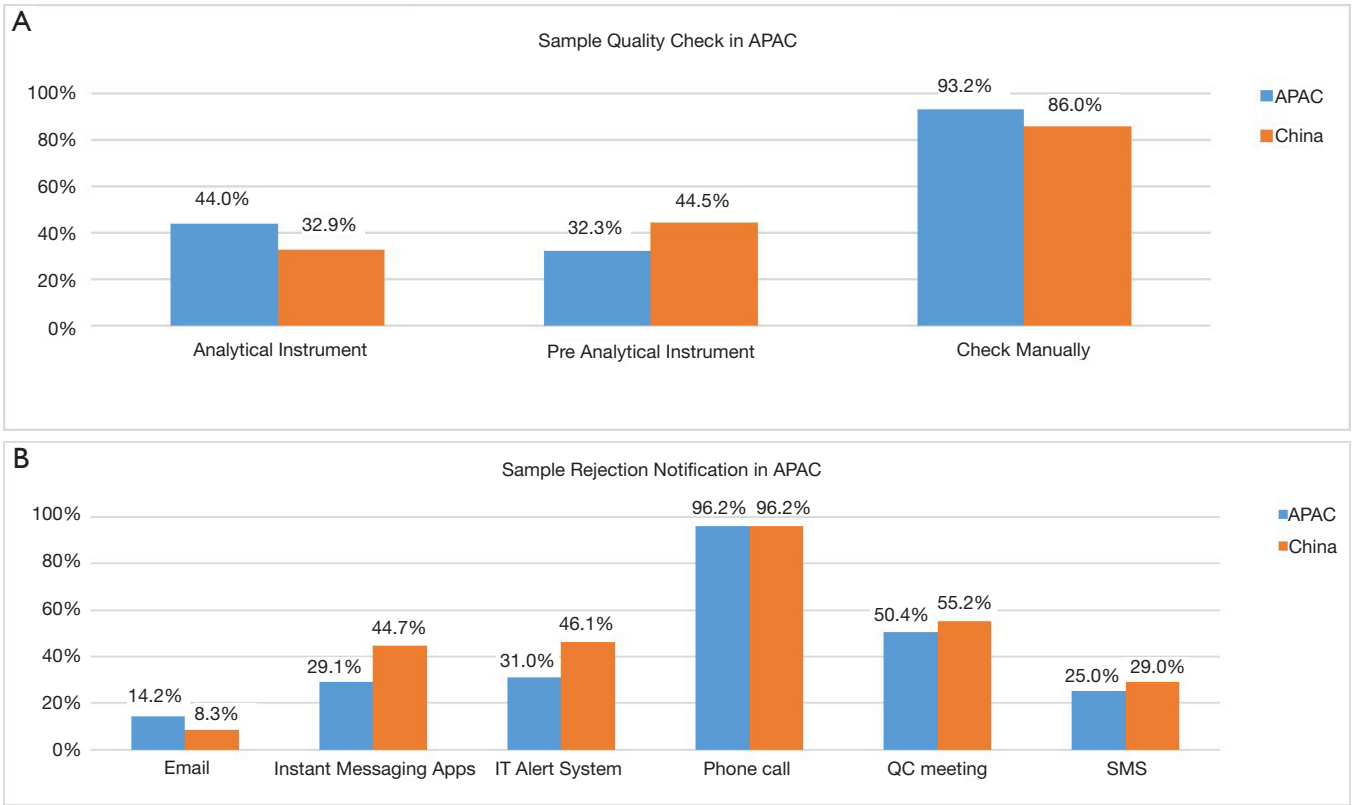

Figure 4 Methods utilized for sample quality check and sample rejection notification. (A) Figure gives data where the sample quality check is conducted. (B) Figure provides details on how sample rejection is transmitted to the referrer.

laboratories monitoring TAT in real time (*Figure 8*).

For STAT specimens, 60% and 48.3% of laboratories have a <60 min target for clinical chemistry and immunoassay specimens respectively. For routine specimens, 63.9% and 42.9% of laboratories have a target <180 min in chemistry and immunoassay respectively. Many laboratories in China also have specific assay turnaround times; 87.5% of laboratories for cardiac markers, 79.7% for liver function test, 81% for renal function test and 73.9% for arterial blood gas. The median TAT target for cardiac markers was 60 minutes (Interquartile range: 30 to 90 minutes). *Figure 9* show routine and STAT chemistry and immunoassay TATs.

Productivity: laboratory automation and consolidation of instruments

Approximately a third of Chinese (32.3%), and 39.8% of APAC laboratories had the chemistry and immunoassay modules consolidated onto the same instrument with 43.4% of Chinese and 33.8% of APAC laboratories having laboratory automation for pre- and post-analytical processes. *Figure 10* show the comparative levels of consolidation and automation in Chinese and APAC laboratories.

In terms of FTE productivity, the median number of samples per full time equivalent (FTE) was 100 compared with 92 for APAC and median number of tests per FTE was 750 compared with 533 for APAC. The median number of samples per FTE increased when instruments were consolidated (133 *vs.* 100) or when there was laboratory automation (143 *vs.* 88). The median number of samples and tests per m^2 in Chinese laboratories were 6 and 38 respectively. In Chinese laboratories the median number of samples and test per instrument were 107 and 750 respectively.

Discussion

The expected varied degree of compliance with the implementation of best practice has been confirmed by this

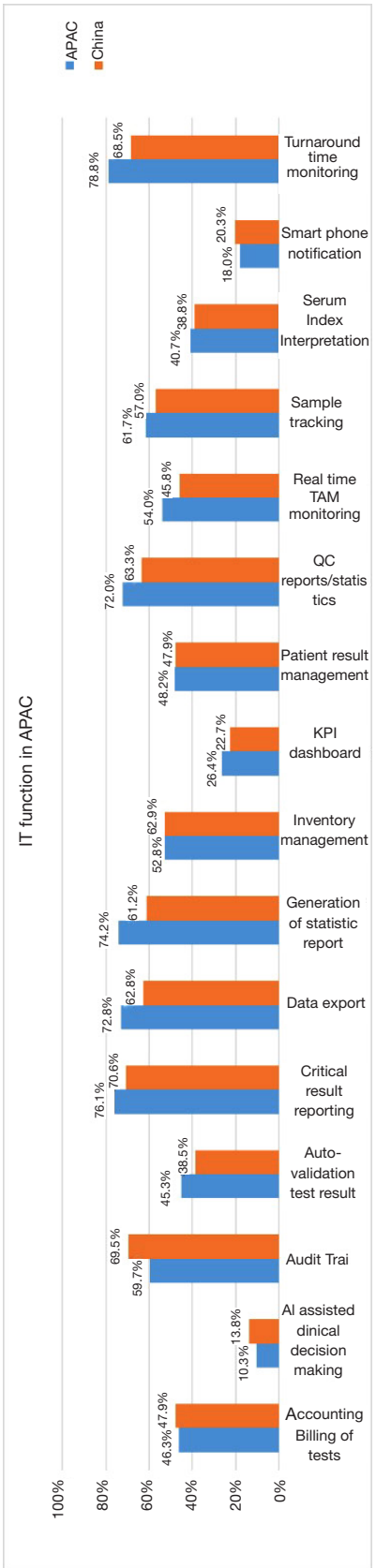

Figure 5 Comparison of use of IT functionality.

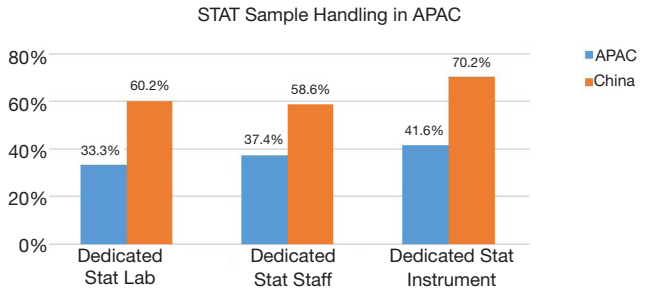

Figure 6 Comparison of STAT sample handling. TAT, turnaround time.

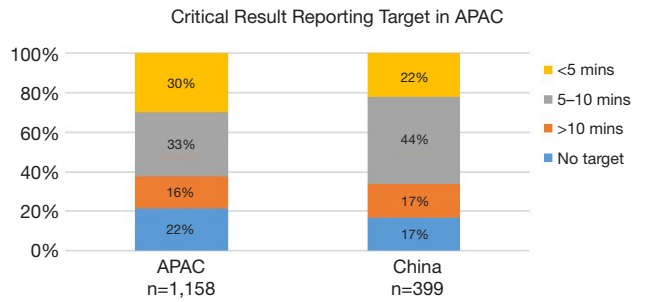

Figure 7 Critical result reporting.

extensive survey of Chinese Laboratories. However, there is a common focus on quality and continuous improvement in various aspects of laboratory practice. These are evident by monitoring of TAT, external accreditation, participation, and performance of the laboratory in EQA. China seems to have invested more resources on STAT samples compared with routine samples. This is evident in the provision of dedicated stat laboratories, dedicated instrument, and staff to handle these specimens as well as the significantly shorter target TAT set for STAT samples compared with routine samples. This suggests a segregation of work and different workflows based on urgency which is not the case in APAC overall.

Most Chinese laboratories are currently enrolled or plan to enrol in international accreditation. However, most have not or do not plan to enrol in international EQA schemes. The fact that most Chinese laboratories are enrolled in national rather than international EQA programs perhaps reflect the fact that although participation in EQA is not mandatory in China, many laboratories recognise the value in participation in a national EQA program which is more practical. However, accreditations such as ISO 15189 which represent the quality level of the laboratory is encouraged

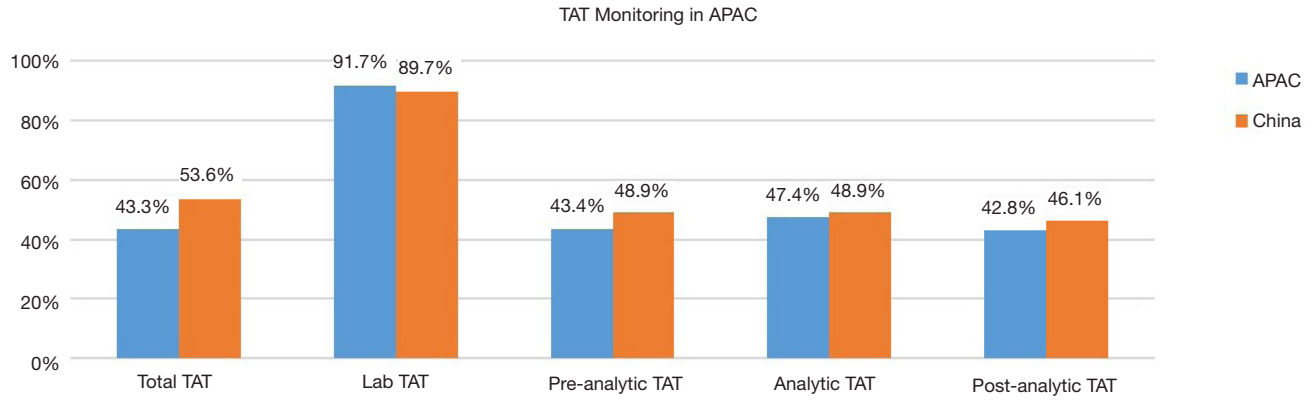

Figure 8 TAT monitoring in APAC. TAT, turnaround time.

by the government which can improve hospital influence.

Most Chinese laboratories monitored laboratory TAT (89.7%), many did not monitor total TAT or individual components such as pre-analytical TAT, analytical TAT, and post analytical TAT. The reason for this may be related to IT capability. The IT software installation required for TAT monitoring are often bundled sales with instruments, especially with automation. Thus, laboratories that do not have automation may not be able to monitor TAT.

Whilst there is no significant difference between China and APAC in the proportion of laboratories having TAT target <60 min for STAT chemistry samples, this is not the case for routine chemistry samples. This is despite proportionately similar number of laboratories having adopted instrument consolidation and laboratory automation between Chinese laboratories and APAC. However, the difference may be explained by the significantly a greater number of dedicated STAT laboratories, dedicated instrument, and staff to handle STAT samples in China.

Although the percentage of laboratories with instrument consolidation was similar between China and APAC, a slightly higher proportion of Chinese laboratories seem to have laboratory automation. This may explain the higher median number of tests per FTE in China which was even higher with automation.

Our survey results provide valuable data on a variety of QIs of Chinese laboratories and covers many areas of the laboratory processes which have not been reported in the CNCCL's EQA data on the 15 QIs (22-26).

Limitations

The major limitation to these findings is that this survey is voluntary and self-reported. Therefore, there is a possibility that the responders may be biased towards the more sophisticated laboratories. The number of participants in this survey represents a small proportion of all Chinese clinical laboratories, mainly from users of Roche instruments which may not be representative of all laboratories. However, for the individual participants it provides useful comparative data with their peers. Furthermore, here we report on a snapshot in time rather than comparison of performance over time. Thus, this survey does not allow an assessment of whether there have been improvements in QIs over time.

Conclusions

Clinical diagnostic laboratories are faced with similar challenges of increasing workloads, need for quality improvement and to achieve faster turnaround times. Comparison between Chinese laboratories with APAC highlights the fact that whilst the performance of China is generally comparable to APAC there are some differences in practice that are specific to China. This report provides a useful snapshot of the performance of Chinese laboratories in a number of benchmarking quality indicators.

This Survey reports on a variety of QIs of Chinese laboratories covering many areas of the laboratory processes which have not been reported previously. The Chinese laboratories seem to have invested more resources on STAT

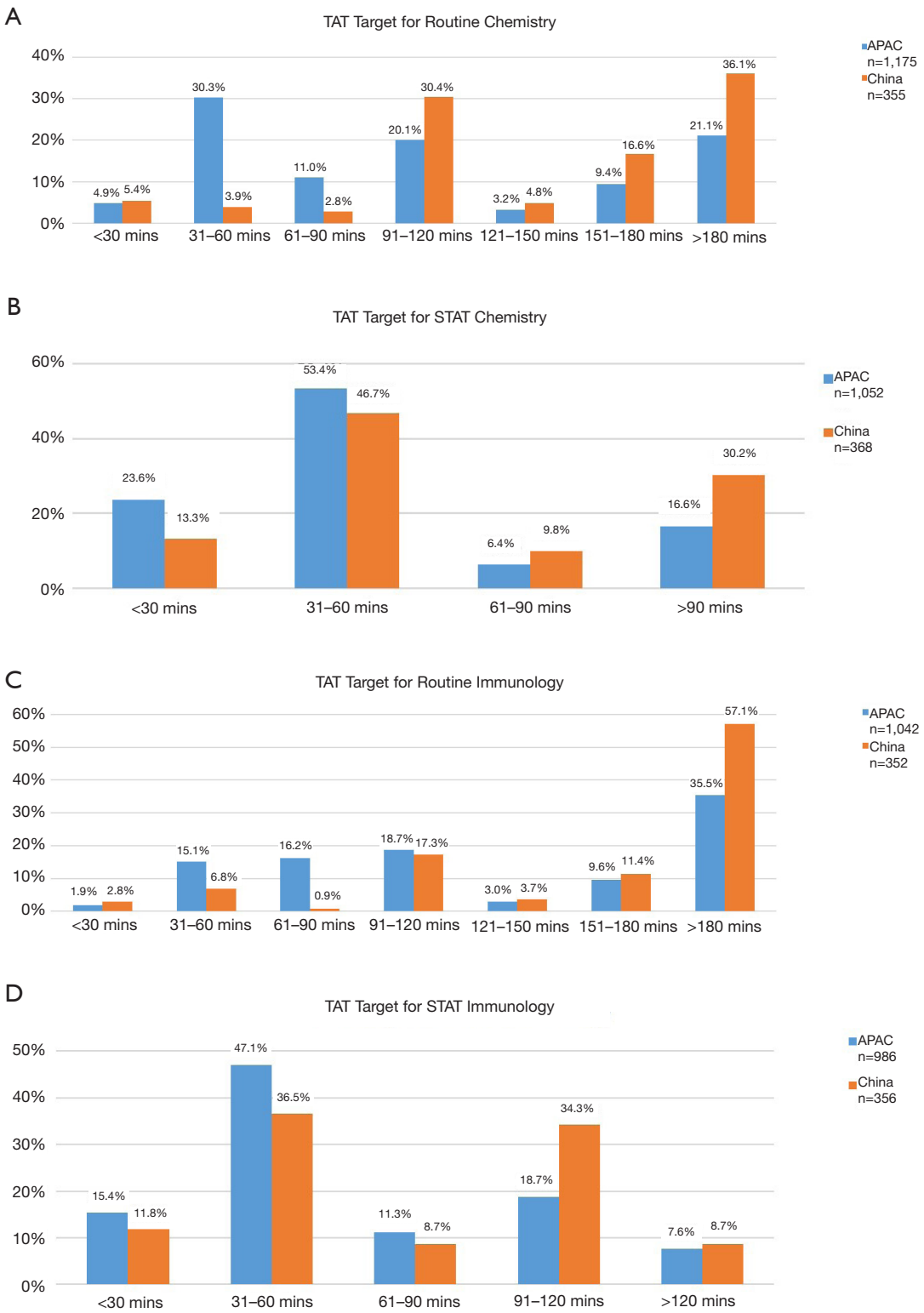

Figure 9 TAT for STAT and routine samples. (A) Figure is TAT for routine chemistry. (B) Figure is TAT for STAT chemistry. (C) Figure is TAT for routine immunoassay. (D) Figure is TAT for STAT immunoassay. TAT, turnaround time.

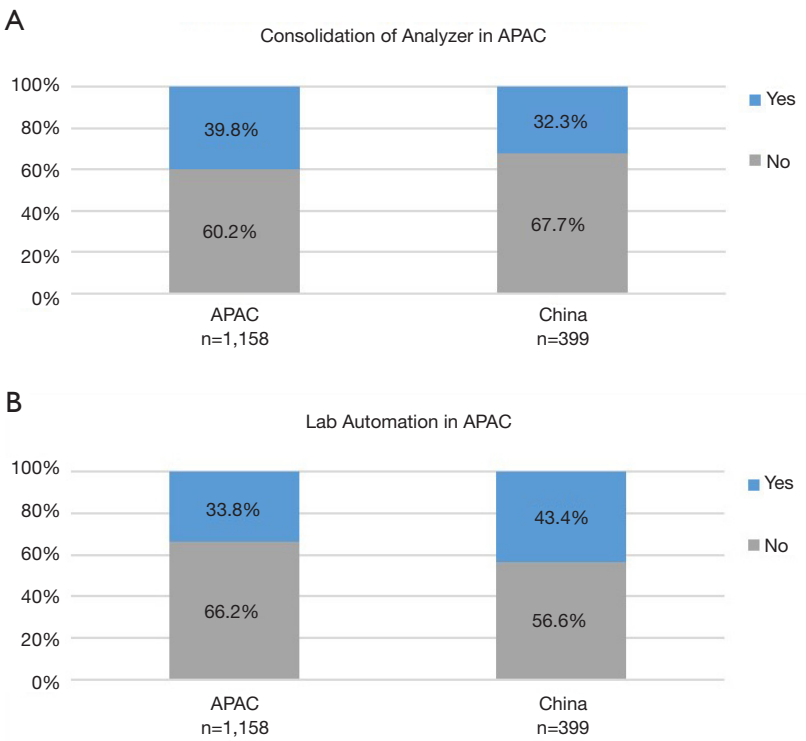

Figure 10 Laboratory productivity: consolidation and automation in China and APAC. (A) Figure is instrument consolidation. (B) Figure is laboratory automation.

samples, enrol in national EQA rather than international EQA programs and have longer overall TAT targets for routine Chemistry results. This may reflect cultural differences in Chinese laboratories compared with APAC in terms of workforce utilisation and expectations of referring Chinese doctors.

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Footnote

Reporting Checklist: The authors have completed the SURGE reporting checklist. Available at https://dx.doi.org/10.21037/jlpm-21-19

Data Sharing Statement: Available at https://dx.doi.org/10.21037/jlpm-21-19

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Ethical Statement: The authors are accountable for all aspects of the work in ensuring that questions related to the accuracy or integrity of any part of the work are appropriately investigated and resolved.

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Supplementary

Table S1 Participant Laboratory types and sizes

	n	%
Country type		
Developed countries*	242	20.9%
Developing countries*	916	79.1%
Laboratory type		
Government hospital	684	59.1%
Private hospital	368	31.8%
Private commercial laboratory	106	9.1%
Laboratory size		
Small Lab (<250 samples per day)	331	28.6%
Medium Lab (251–1,000 samples per day)	517	44.6%
Large Lab (>1,000 samples per day)	310	26.8%

*For the purpose of data analysis, countries are grouped into developed and developing countries based on IMF World Economy Outlook 2018.

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