REVIEW ARTICLE

Steering Standardization of Pathology Services Through Centralisation and Consolidation of Laboratory Procurement

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ABSTRACT

The expansion of healthcare services to serve as many people as possible has led to the decentralisation of laboratory testing. Many laboratory tests are now made available at district hospitals and rural health clinics for certain states or provinces. Consequently, there is a proliferation of laboratory tests, techniques, equipment, and other required commodities at the different medical laboratories. The lack of central governance has resulted in a widely-diverse and non-standardised laboratory services that may eventually affect the quality of healthcare delivery to patients. To ensure a high-quality and standardised healthcare delivery across a state or a province, it is important that the relevant stakeholders outline and implement the necessary strategies to establish a streamlined medical laboratory network. In this article, we discuss the significance of laboratory procurement consolidation and centralisation in the steering of the standardisation of laboratory operations leading to a high-quality and efficient chemical pathology services in a defined region.
Malaysian Journal of Medicine and Health Sciences (2023) 19(1):280-285. doi:10.47836/mjmhs19.1.36

Keywords: Laboratory, Pathology, Procurement, Reagent rental, Standardisation

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INTRODUCTION

In recent years, there is a rapid expansion of pathology services to the district hospitals and remote health clinics, as part of the government's effort to provide accessible and comprehensive healthcare services to a wider population within a state. As the individual laboratories arranges and manages its diagnostic procurements autonomously with their own fund, the expansion has resulted in remarkable proliferation of various laboratory tests, techniques, equipment, and other relevant commodities across the different medical laboratory facilities (1). Consequently, the differences in the overall work procedures and quality assurance program contributes to the heterogeneity in the quality and efficiency of the chemical pathology laboratory service as well as issue of non-comparability of test results between individual laboratories within a state or province.

As a patient may be followed-up in different hospitals or health clinics within a region, incomparable and diverse quality of testing results between the laboratories may increase the risk of diagnostic errors and subsequently compromise the patient care and safety (2,3). Take serum creatinine, an important parameter in the diagnosis and classification of chronic kidney diseases (CKD) as an example. When serum creatinine is measured using the enzymatic method, the level can appear lower than the one measured using the Jaffe method, thus producing a lower eGFR that can lead to the misclassification of CKD and in turn, under-referral for further management (4). Apart from the incomparable results between different laboratories, the inconsistent turnaround time (TAT) of the laboratory report also creates unnecessary delay and disruption of patient management due to the need to trace the results from different laboratories.

In many other countries, laboratory standardisation is increasingly recognised as the pragmatic strategy to ensure efficiency and effectiveness of laboratory services (5). Therefore, the relevant stakeholders need to outline and implement the necessary strategies in establishing a streamlined and standardised medical laboratory

network. The implementation of metrologically-correct measurement systems has been internationally accepted strategy to reach laboratory standardisation. However, the cost of procurement is extremely high and could restrict the implementation especially in low financial setting institutions. In this article, we discuss the significance of laboratory procurement consolidation and centralisation as the cost-effective strategy in the establishment of not only laboratory standardisation, but also a high-quality and efficient chemical pathology services in a defined network.

CONSOLIDATION AND CENTRALISATION OF LABORATORY PROCUREMENT (CCLP)

The procurement and management of supply are defined as the systematic activity that ensures continuous maintenance of quality as well as the constant availability of commodities through optimal procurement planning, storage, and distribution from the vendors to the end-users. The product procurement by a laboratory must be in line with the intended use and obtained at the most cost-effective price to ensure that testing is accessible and affordable for all. Therefore, it is essential that a good procurement practice is implemented to ensure the suitability and sustainability of equipment and other supplies, and, ultimately safeguarding the overall efficiency of laboratory services (6).

Consolidation and centralisation of laboratory procurement, or refer to CCLP hereafter in this article, is a purchasing approach widely used in the many sectors to achieve a reduction in purchasing costs. CCLP is a new strategy that supports standardisation between laboratories with the aim of creating high quality and efficient pathology service for the population (5). In the context of pathology service, it is defined as an aggregation of the purchasing needs of all the laboratories in a defined network (7). The procurement procedure of the diagnostic supplies for all the hospital laboratories can be consolidated and centralised under a single procurement process such as at the state, district, provincial or national level.

Important steps for CCLP implementation

The implementation of CCLP require a sound and systematic planning to ensure its successfulness in achieving standardisation of laboratory services in a state or a specific region. Fig. 1 illustrates the steps involves in the implementation of CCLP.

1. Establishment of central governance team

The first important step for implementing CCLP is the establishment of a competent central governance team at the defined level, for example at the state or province. The team is responsible to compile and coordinate the various operational functions, including the planning of procurement, logistic issues, inter-laboratory communication, and standardisation process

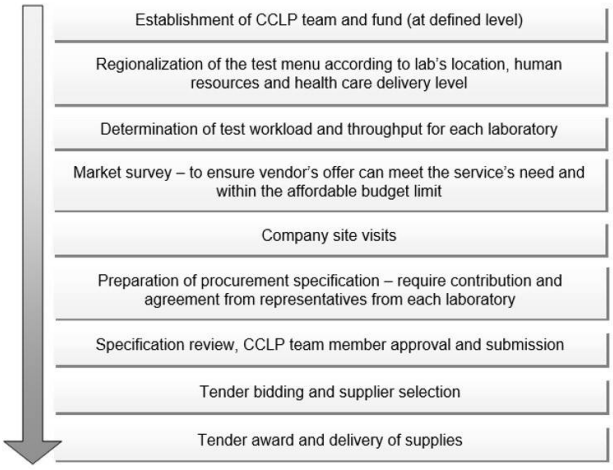

Figure 1: Steps involved in the implementation of CCLP

(5). In addition, the central governance is also plays an important role in the creation of policy and guideline, determination of the test menu and selection of analytical technology to ensure collective benefits in terms of service quality, speed, and cost-effectiveness for all the laboratories in the network (8). At the state level, CCLP governance team should consist of at least the director of the state health department, a state pathologist, state finance (or/and procurement) officers, a senior scientific officer as technical advisor, and laboratory managers from each laboratory.

2. Provision of adequate central funding

Provision of an adequate central fund is important to ensure the successfulness of CCLP implementation. Under the central governance team, the budget needed for the effort may be pooled from combining the allocated financial budget from each laboratory in a network. Pooling of budget is the best strategy especially in limited financial resources setting, where acquiring an extra budget allocation is a major problem. It is the responsibility of the central governance team to plan and ensure that the implementation cost of the CCLP is within the central funding capacity.

3. Determination of test menu within each laboratory

In general, laboratory services in public healthcare are stratified into a hierarchical tiered system (6). The system stratifies laboratories into national, provincial and district based upon agreed testing services, with each level offer increasing technical testing complexity and capacity. A hierarchical laboratory system is essential to strengthening public health laboratory services and informing effective CCLP policy (9). Determination of the common test menu within each laboratory level is an essential step toward establishing laboratory standardisation. The test menu should be harmonized between different level of laboratories and should consider several factors such as health care services offered, prevalent diseases, availability and capacity of laboratory infrastructure (equipment, space, water,

electricity and human resource), degree of remoteness, and the size of the population served by the health care centres (1,8). As a rule of thumb, a laboratory at the lower hierarchy conducts a lesser range of test with lower complexity on-site, and will refer the rest of the tests to the higher-level laboratory. Whereas, a laboratory at the higher hierarchy will offers the most comprehensive set of tests from basic routine investigations to highly complex laboratory tests. Nevertheless, since clinicians are the one that finally accountable for each patient in their care, it is crucial that the laboratories obtain their guidance on the test menus they prefer the laboratories to provide. Otherwise, it can result in laboratories providing tests that will not be utilized as well as failing to provide tests that are required (1).

4. Aggregation of test volume

Test volume for a specific analyte may vary in different laboratories depending on the laboratory's hierarchical level. In some laboratories, low test volume results in instrument underutilization and, thus higher cost-per-test (10,11). Discrepancy of test volume may also result in high variability of budget to workload ratio between laboratories. Therefore, it is important that the test volume from each laboratory is combined to produce a larger aggregated workload. Aggregation of workload or test volumes from multiple laboratories enable negotiation by central governance for a consistent and transparent pricing scheme from the vendors. This effort ensures that the laboratory services in the network are running at the most affordable cost to all stakeholders (12). Besides that, the standardised and uniform price offered may decrease the variability of test cost and budget to workload ratio in between the laboratories, allowing more objective budget allocation and expenditure monitoring by the central governance team.

5. Selection of analytical platform for all laboratories

One of the important fundamental measures to achieve standardisation of laboratory services in a state or region is the use of a common testing platform across multiple laboratories. The use of a common platform helps to reduce the equipment diversity and ensure that only supplies of the required standard or quality are used in each laboratory. This can avoid the use of products from different suppliers that may have differences in specifications and quality that could affect the test performance (8). Besides that, instrument diversity also has a great impact on laboratory commodity forecasting, supply chain systems, equipment maintenance, and the overall quality of laboratory service delivery (9). The selection of the common testing platform should be based on specific criteria agreeable by all participating laboratory in the network. Some criteria that need to be considered are analytical and/or clinical performance, technical requirements, and existing installed base. Other criteria such as test menu, actual test volume, human resource skills and degree for automation demand will determine the number and capacity of testing system that will be provided for each laboratory. All the criteria and preferences should be specified clearly in the tender document, and should be justified with sound standardisation policy by the central governance team.

Reagent rental and "all-inclusive pricing" approach procurement

In general, procurement process for diagnostic laboratories can be implemented in a few ways based on the regulation and policy of the respective region of the institution. Among high throughput and profit-oriented medical laboratories, the most popular method is the reagent rental approach. This approach has been proven as a profitable and cost-effective than purchasing method, especially when the laboratory workload is sufficient (10,13). It is also considered as the method of choice when the laboratory fund is insufficient for purchasing (13).

Reagent rental defined an arrangement between a laboratory and an in-vitro diagnostic company in which one or more analysers are placed in the laboratory via an institution-appointed supplier. In exchange, the laboratory will make a guaranteed purchase of reagents and consumables over a certain period (14). The usual average contract period for a reagent rental is between 60 - 84 months (15). The cost payable for reagent rental can be in the form of monthly payment, buy out lease, fair market value lease, simple lease or cost per test (CPT). Nowadays, many laboratories opt for CPT of which the calculation is based on the laboratory's test volume (16). A CPT may include price of reagents, consumables and instrument rental with or without service maintenance. Another concept is "cost-per reportable" or CPR agreement. The pricing structure used in this concept is similar to reagent rental. The different is only that a CPR is defined as a price per patient's result obtained using the rented instrument (17).

There is no clear guidance on what components are included in a CPR. Based on mutual agreement between laboratories and the supplier, the CPR can be more complex covering all the additional components needed to report a patient's result such as chemicals, quality controls, calibrators, service maintenance, supply deliveries, printers, instrument interface work, data management systems, waste disposal, software upgrades, inventory and manufacturer test failures. This means that the pricing format denotes inclusion of all test components in a single price per test, therefore termed as "all-inclusive pricing" reagent rental (18).

For an individual laboratory, "all-inclusive pricing" reagent rental may potentially raise the overall procurement cost due to the additional components. However, under larger scale combined procurements such as CCLP, the revenue and reimbursement earned may exceed the total cost invested. In view of this, several large organizations such as United Nations Children's

Fund, Innovation for Global Health and The U.S. President's Emergency Plan for AIDS Relief are currently supporting the use of bundled or "all-inclusive pricing" approach as the most preferred procurement method for HIV viral load testing nation-wide (18). Nonetheless, the evidence-based information on the collective benefits of this procurement approach to the laboratory services is still scarce. Therefore, it is important for laboratories to conduct scientific studies to substantiate more accurate findings particularly regarding the effectiveness of the "all-inclusive pricing" concept with respect to the centralised and consolidated procurement.

Standardisation of laboratory services through CCLP

The CCLP is considered as one of the appropriate strategies to obtain a standardised testing platform for all laboratories in a network. Standardisation of testing platform is an important fundamental element in the establishment of laboratory services standardisation in a state or province (19,20). There are several ways how the laboratory services standardisation can be accomplished through this effort (Fig. 2).

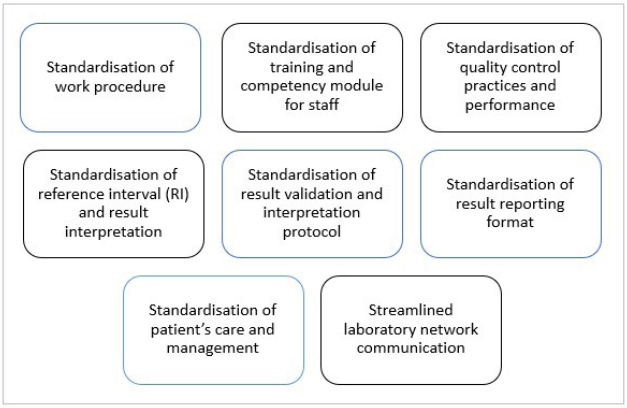

Figure 2: Standardization of laboratory services

1. Standardisation of work procedure

The application of standardized analytical instrument can reduce the diversity of technology and testing methodologies, thus enabling the establishment of uniform work procedure and technical troubleshooting protocol across all the laboratories in the network. Furthermore, standard operating procedures and document transfer were also made possible, therefore facilitating document preparation process for quality accreditation in some laboratories.

2. Standardisation of training and competency module for staff

The use of a uniform analytical equipment and testing protocol enable creation of a standardised training and technical competency assessment module for laboratory technicians thus allowing more objective comparison of the staff's work performance. In the long term, this can minimise operator-dependent result variation in between laboratories. In addition, the movement of staff within the laboratory network is feasible without posing major issue. As they were trained with a standard training module, they will be readily familiar with the analytical system and be able to work efficiently even they are stationed in different laboratories in the network (1).

3. Standardisation of quality control practices and performance

According to Centres for Disease Control and Prevention, laboratory standardisation is achieved when test results have the same analytical accuracy and precision across measurement systems, laboratories, and over time (21). As different laboratories use of different testing platforms, reagents and consumables, monitoring and ensuring quality of results produced by the various laboratories are more complex (1), intricating the process of standardisation. When all laboratories use similar testing platform and methodology, they are able to share the same quality control protocol and best troubleshooting practices. In addition, participation of all laboratories into a similar proficiency testing programme permit more effective and meaningful quality performance monitoring and comparison as all the laboratories are belong to the same peer group. Consequently, the quality of results from each laboratory are equal and standardised in terms of accuracy and reliability.

4. Standardisation of reference interval (RI) and result interpretation

Reference interval (RI) is an essential component in any laboratory report, and represents the basis of result interpretation (22). Clinical and Laboratory Standards Institute recommends each laboratory establish its own RIs based on the methods used and population served (11,23). Consequently, RIs are vary between laboratories depending on the equipment and testing methodologies used. As a clinician needs to review analysed results from multiple laboratories in the state, the use of common RI is essential because it provide a similar clinical information for a particular test result regardless where the result produced, thus avoiding unnecessary confusion to the clinician. In general, the establishment of a common RI for a population require reference measurement systems, traceability of field methods and high-quality RI studies (24). In the setting where all the laboratories in a network are analysing the same biological sample from populations with similar socio-demographic and ethnic characteristics, the establishment of the common RI is easier in case where all the laboratories are using similar analytical measurement system traceable to the same measuring system (3). It is required that only the central laboratory perform the RI studies, whereas the other laboratory in the network verify the RI through method comparison.

5. Standardisation of result validation and interpretation protocol

Different analytical systems utilise different testing methodologies, thus they are potentially affected by different pre-analytical and analytical variables. These variations should be addressed appropriately during

the result validation process so that the clinicians can correctly interpret the results before deciding on the patient's diagnosis and management. The application of a similar analytical measurement platform across laboratory network facilitates the establishment of a standardised result validation and interpretation protocol, hence ensuring standardised patient management and treatment across the state. This ensures a standardised result interpretation, therefore reduced possibility of diagnostic error related to the variability of result interpretation (25).

6. Standardisation of result reporting format

When a reports of laboratory results are presented in different formats, there is a high chance of misreading and misinterpreting the information, albeit when read by the same doctor (25). Therefore, the standardisation of laboratory reports is essential, especially in a region where patients are moving freely between different hospitals to have their samples collected and analysed. A standardised reporting format would enable more accurate result interpretation to guide patient's diagnosis and management across different hospitals. Through CCLP, the use of a common analytical measurement system and LIS in all the laboratories enable harmonisation of the result reporting format. Test name's abbreviations, reporting units, result value decimal points, report attributes, remarks and interpretive comment can be standardised according to the laboratory and clinician's preference. Furthermore, as many laboratories are now seeking conformation from accreditation bodies such as ISO 15189, the reporting format can be revised based on the standard requirements.

7. Standardisation of patient's care and management

The use of different analytical methods can give rise to result variability that increases the potential of confusion and misinterpretation among the clinicians. To illustrate, the method of 99th percentile Troponin for the diagnosis of acute myocardial infarction is dependent on the cut-off level. As a result, different laboratory methodologies to measure Troponin may produce different cut-off values, thus resulting in a different diagnosis for the same patient whose blood sample is sent to different laboratories (26). In a standardised system, test results can be interpreted and compared against results from different laboratories in the network. This allows a consistent definition of cases, and standardisation of the case diagnosis and management. Besides that, duplication of test can also be avoided, thus facilitating case referral and transfer. In addition, the patients can attend any nearby health facility, and be offered the same range of services. This help to maximise the use of health services offered at close-to-patient settings and increase the patient's compliance to follow-up better (1).

8. Streamlined laboratory network communication

In some regions, peripheral laboratories are widely separated from the central laboratory, creating logistic issue and preventing effective communication in between laboratories. The integration of a common LIS into the testing platforms of all laboratories able to creates a streamlined inter-laboratory communication. The ordering of tests outsourced to the central laboratory could be performed electronically by the peripheral laboratories, thus reducing the busy workload in the central laboratory. On the other hand, all the laboratories are able to gain access to a particular result in real-time, irrespective of where the tests were conducted. In other words, the results for patients whose tests were performed in one hospital laboratory were also available for viewing at the other hospitals in the network. Consequently, this reduced the duplication order of tests and shortened the result turnaround time (TAT), thus increasing the service efficiency and enabling prompt treatment delivery to all patients.

CONCLUSION

CCLP is considered an appropriate and potential strategy that can be implemented to steer the standardisation of medical laboratory services across a state or province. Efficient capital investment planning and management by central governance team, and good collaboration with ministry of health, suppliers, and diagnostic manufacturers are apparently crucial to achieve a cost-effective diagnostic procurement that results in a highly standardized laboratory services and patient's care across a network. In addition, the centrally-coordinated diagnostic procurement enables the regionalisation of test menu that was appropriate for each level of healthcare delivery, therefore providing a wider access to essential diagnostics and monitoring tests to all people in the population. We strongly recommend CCLP as the best strategy to reform the pathology services or other relevant healthcare delivery across a state or a region, especially in limited financial settings.

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