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Standardisation of pathology laboratories in Pakistan: Where we stand today

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1. Introduction

Competent and proficient laboratory facilities are essential for optimal health care provision and disease prevention. This article is a follow up of an earlier article “Standardisation of Pathology Laboratories in Pakistan” published in March 2009 [1]. The article focuses on the progress made over the past seven years along with the upcoming challenges and future recommendations.

With the accreditation of Armed Forces Institute of Pathology (AFIP), Rawalpindi in 2012, Pakistan started its journey in the field of standardisation of Pathology laboratories. AFIP is a premier reference laboratory which was able to meet the requirements of the comprehensive ISO 15189:2007 standard for medical laboratories and since then, slow but steady progress has been made in this sphere. To this date, 8 laboratories have been awarded ISO 15189:2012 accreditation for limited scope of tests [2].

2. Last seven years on standardisation of Laboratories in Pakistan

2.1. Continuing medical education (CME) for physicians

The importance of continuing education is highlighted in the previous article for the progression of standardised practices. With this aim, a system of CME based on awarding credit points was devised by Pakistan Medical and Dental Council (the regulatory authority for medical and dental practitioners in Pakistan) and various medical organisations have been registered and accredited to impart education for this purpose. However, this system has been temporarily suspended as physicians found the procedure cumbersome because of lack of easy access to CME programs in many remote regions. The system is expected to be implemented at a later date after simplification and ensuring ease of accessibility for the doctors [3]. The College of

Pathologists Pakistan (CPP) has promulgated the Code of Ethics for Pathologists in the year 2010. The Code of Ethics lays emphasis on patient privacy and confidentiality, informed consent and respect of patient specimens and tissue samples. Personnel and organizational accountability is highlighted in the code as a quality assurance tool. The code sets high standards for moral and ethical values of pathologists in Pakistan. Pathology, Pathologist and Clinical Laboratory have also been defined for the first time. An essential goal of CPP is educating and raising awareness among the general public, patients, physicians and pathologists regarding disease processes.

2.2. Education of technologists and technicians

In the last seven years, some progress has been made to increase the number of qualified medical laboratory technologists (MLTs). According to an estimate, there are 7000 practicing MLTs in Pakistan [4]. The void is filled by the laboratory technicians who receive less than two years of technical education and have limited training experience compared to the technologists [4]. In Pakistan, approximately 30 institutions are offering Bachelor's degree program in Medical Laboratory Technology and Clinical Laboratory Sciences [4]. Pakistan Association of Medical Laboratory Sciences (PAMLS) and Medical Laboratory Technologist Association of Pakistan (MLTAP) are two parallel bodies promoting education and continual professional development of MLTs.

2.3. Current accreditation status

Pakistan National Accreditation Council (PNAC) awarded accreditation to the first medical laboratory in 2012. Besides 8 medical laboratories, so far PNAC has accredited 4 testing and calibration laboratories for health care sector. The council itself has achieved several

Abbreviations: Armed Forces Institute of Pathology, AFIP; Continuing medical education, CME; College of Pathologists Pakistan, CPP; Medical laboratory technologists, MLTs; Pakistan Association of Medical Laboratory Sciences, PAMLS; Medical Laboratory Technologist Association of Pakistan, MLTAP; Pakistan National Accreditation Council, PNAC; Asia Pacific Lab Accreditation Cooperation, APLAC; National External Quality Assurance Program Pakistan, NEQAPP; Health Care Commissions, HCC; Healthcare establishments, HCE; The Punjab Health Care Commission, PHCC; Minimum Service Delivery Standards, MSDS; Disability adjusted life years, DALYs; Basic Health Units, BHU; Rural Health Centres, RHC; Khyber Pakhtunkhwa, KPK; Proficiency Testing, PT

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mile stones over the years by signing Mutual Recognition Arrangement with International Laboratory Accreditation Corporation and Asia Pacific Laboratory Accreditation Cooperation (APLAC) in 2009 [2].

Pakistan Accreditation Council Bill was enacted in March 2017 whereby the council was designated as the national body authorized to coordinate with other regional organisations for implementation of accreditation standards. Furthermore, the council is given the authority to device strategies and guidelines to extend accreditation services throughout the country. Training of individuals and conformance assessment bodies on standards and the accreditation of the later is also within the jurisdiction of the council [5].

PNAC is a member of the Multilateral Recognition Arrangement for Quality Management System of the Pacific Accreditation Cooperation and the International Accreditation Forum, allowing recognition of its accreditation by the member countries. PNAC is periodically assessed by APLAC for conformance to international standards. The council carries out educational and training courses on regular basis. Multiple seminars and workshops with national and international speakers are held for capacity building in this field. So far, more than fifty technical experts and assessors have been trained for inspections and assessments.

2.4. Quality assurance programs and calibrations

In the absence of ISO 17043 accredited body in Pakistan, the laboratories which are accredited or striving for accreditation rely on overseas External Quality Assurance schemes and PT Providers. Often the overseas schemes are costly and unaffordable and hence the laboratories have to rely on local non accredited schemes. One such scheme is the National External Quality Assurance Program Pakistan (NEQAPP) run by AFIP [6]. On the other hand, the situation is marginally better for calibration laboratories as presently four institutions are accredited against ISO 17025 International Standard, the standard for calibration laboratories. In Pakistan, National Physical and Standards Laboratory is one of the four institutes extending calibration services.

2.5. Registration and licensing of laboratories

The two tier plan was proposed in the earlier article to bring laboratories in line with the international standards [1]. According to this plan, in the first step, the laboratories fulfilling predefined minimum criteria are to be registered by a regulatory body. At this stage, greater emphasis is to be laid on education, training and proficiency testing while keeping the paper work to the minimum. With grounds prepared, in the second step the laboratories are to be encouraged to further enhance their quality level by adopting international accreditation standards on voluntary basis.

Registration and licensing of laboratories, similar to the proposal in the two tier plan has been introduced at the provincial level with the establishment of 4 Health Care Commissions (HCCs). Their objective is to license and register physicians, healthcare establishments (HCEs) and medical laboratories. Until October 2016, collectively 31,000 registrations were recorded with the Punjab Health Care Commission (PHCC) and 16,000 licenses were issued. However, a separate figure for the registered and licensed laboratories is not available. The Minimum Service Delivery Standards (MSDS) formulated by PHCC mention the number of technical staff and pathologists required to be present in the three levelled health care system [7]. The test range for these levels is specified in keeping with the disability adjusted life years (DALYs) of the diseases [8,9].

At primary health care level, there are 2456 Basic Health Units (BHU) and 298 Rural Health Centres (RHC) in Punjab [7,8]. The approved tests at this level are routine blood and urine examination and detection of malarial parasites in the blood film. While there are no technicians or technologists in BHU, one or two technicians are usually

appointed at RHCs [8].

The pathologists and technologists are recruited at secondary health care level. The hospitals at this level are categorised depending upon the bed strength. A maximum of three pathologists are appointed in category 'A' hospital whereas the number may be less in categories 'B' and 'C' hospitals. Moreover, the diagnostic tests other than those performed at the primary care laboratories are all grouped as advance services and are only available at secondary or higher level laboratories. At this level, Tehsil Head quarter Hospitals provide services to half to 1 million population with 40 to 60 beds whereas District Head Quarter Hospitals cater for a population of 1 to 3 million, indicating huge demand and supply discrepancy, specifically for diagnostic services [8].

The tertiary care level comprises teaching hospitals in major cities with more specialists including pathologists and wider testing range, grouped under specialist services. Notably, sub specialities of pathology and hence pathologists have not been separately addressed for any level of health care [8].

The Minimum Health Service Delivery Package of Khyber Pakhtunkhwa (KPK) demarcates the range of diagnostic services available at the secondary care level. Moreover, essential infrastructure, minimum basic list of equipment, infection control strategy, waste disposal procedures and colour coded delineation of drains and water pipe lines are identified as minimum prerequisites [10].

The provincial HCCs are responsible for provision of minimum guidelines to the HCEs and laboratories, carry out inspections, inform the HCEs and laboratories of the discrepancies, conduct follow ups, grant license and regularly monitor them for continued compliance [11].

3. Problems, prospects and recommendations

3.1. Broader picture

The need for standardisation of medical laboratories for optimal healthcare delivery is of paramount importance. For a developing country like Pakistan, accreditation of the first laboratory was a mile stone as it removed reservations regarding the achievability of international accreditation and has encouraged other laboratories to follow suit. However, only 8 laboratories are accredited under ISO 15189 standards so far and 4 are in the pipe line. Furthermore, there is an expanding pool of laboratories which lie at various stages of compliance [2]. However, the situation for the majority of laboratories at the opposite end of the spectrum has only marginally improved. This state is comparable to South Asian Association for Regional Cooperation countries. In Sri Lanka, 17 clinical laboratories are accredited and for a population of over 1.25 billion in India, 576 laboratories are accredited by the National Accreditation Board for Testing and Calibration Laboratories [12,13].

It is to be noted that the 8 accredited laboratories are not uniformly distributed in Pakistan. With 3 accredited laboratories in federal capital, 4 in the province of Punjab and 1 in Sindh, the other two provinces, KPK and Balochistan, are still lagging as accreditation has not been achieved for any laboratory in these provinces so far. Moreover, these two provinces lack any calibration facility. That is to say, not only laboratories in these provinces struggle to get scheduled calibrations for their equipments but also in-house calibrations of instruments like weighing machines and emergency calibrations in case of instrument repair are not always possible. The problem is further compounded if back up instruments are not available which is quite common in resource poor settings. In the context of medical laboratories, the importance of calibration for determining the measurement accuracy of various testing devices and instruments and hence validating the test results produced by those instruments cannot be emphasized more. Therefore urgent, meticulous, persistent and collaborative efforts dedicated to the improvement of laboratories in low resource areas are

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