

Challenges towards quality improvement in medical laboratory service in Nepal

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The quality of the laboratory services is essential in attaining the nationalized objective of improved primary health care principally at the peripheral level of the health care system. The health laboratories afford strategic support equally to clinical and public health services in providing quality services (1). In recent years, tremendous progress has been made in various fields of medicine and these developments have transformed health laboratory services (2,3). The quality of service remains an emerging concern nowadays as medical diagnostic laboratories are undergoing the process of accreditation for quality services in line with WHO standards. Unfortunately, the implementation of quality laboratory service in many developing countries has been unsystematic and is still questionable (4,5). The challenge lies in ensuring the quality of laboratory service through a well-trained manpower with appropriate and affordable technologies for low income countries like Nepal.

Public Health Laboratory Services are an integral part of the national health care system in Nepal. In the early 80th after the Alma Ata declaration, Nepal was among the first few countries that established laboratories at health centre level and instituted a system of health laboratory services in support of Primary Health (6). But, today, National Public Health Laboratory (NPHL) under the Ministry of Health and Population (MoHP), estimates that approximately 1,300 private health laboratories that include pathology laboratories, polyclinics, diagnostic centers and clinical laboratories are registered in the country where roughly 20,000 people get services every day (7). The National Public Health Laboratory in Teku, Kathmandu is the National Reference and Referral Laboratory. The NPHL has planning, organizational and administrative responsibilities for the Public Health Laboratory Network in Nepal (8).

All laboratories, whether in developed or less developed countries requires a quality assurance programme to make sure that test results are reliable and reproducible (6). Quality Assurance is mentioned as a continuous process which includes series of activities for improving and maintaining optimum level of quality of health care services that includes mainly; setting standards and protocols, communicating standards, developing indicators, monitoring compliance with standard and solving problems by team approach (9). WHO Model Quality Assurance System for procurement agencies advocate that Quality control is concerned with sampling, specifications and testing, and with the procurement agency's documentation and acceptance/rejection procedures which ensure that the necessary and relevant tests are actually carried out and that starting materials, intermediates and finished products are not accepted for use, sale or supply until their quality has been judged to be satisfactory (10).

A well-organized Quality Assurance Programme includes Internal Quality Control (IQC) procedures, External Quality Assessment (EQA) programmes and Quality Management (QM). Also, in Nepal, the Quality Assurance Programme includes Internal Quality Control (IQC) procedures, an External Quality Assessment (EQA) programme and Quality Management (QM).

IQC is a set of procedures that are used in daily routine work to control daily variance of test results, problems are identified immediately and the method is brought back on track. EQA programs are organized on a regional, national or international level concerned with the comparability of test results and considered as retrospective evaluation of quality. QM includes all other aspects of work organization that contribute to obtain reliable and reproducible test results (6).

In developing countries like Nepal, EQA programs take prominence over IQC procedures and QM. Quality Management includes all the support functions that are required to produce quality test results which include the support and supervision received from NPHL staff. QM includes training of laboratory staff, the use of standard operating procedures (SOP), standard supply management, standard equipment management and supervision of peripheral laboratories. The NPHL established an EQA programme several years ago. This programme was supported by a medical technologist from International Nepal Fellowship for a three-year period. However, after the departure of the international expert the programme slowed down. Limited documentation is available about programme activities and procedures. So far only district and higher level laboratories have been included in the EQA scheme (6,11).

The study conducted by the National Public Health Laboratory (NPHL) with support from the World Health Organization from November 2011 to January 2012 in over 200 laboratories in 15 major cities and concluded that apart from major nursing homes, a few hospital laboratories and private laboratories, the majority of labs surveyed were "not up to the standard" (12). Most of the labs were found paying no attention to safety measures that ensure the accuracy of results (12,13). In Nepal, specialized technocrats and professionals as MD, CMLT, BMLT, MMLT, lab assistants, technicians and post graduates in Biochemistry and Microbiology are involved in Clinical pathology and laboratory medicine service. Also, sadly unskilled manpower sully the laboratory ethics is also involved in practice having diminutive knowledge about laboratory science (14). Personality clash between pathologists and technicians regarding signing authority is also frequently observed (14). The pathologists are claiming to ensure full signing authority for all the tests performed in laboratory for their personal interest and overrule the technocrat system in laboratory having sole signing authority. This shows the diffidence of pathologists with other different laboratory technocrats. Often, it is exploitation towards laboratory professionals other than the pathologists working in Clinical Pathology Laboratory.

However, it is troublesome to evaluate the level of quality of health care but the three basic elements of quality of care, namely; input, process and output are important. Mostly, it depends upon observation, interpretation and perception of individual evaluator or supervisor. The circumstances of hiring incompetent and untrained staffs are commonly pragmatic in laboratories of Nepal. The competency of all ancillary staff involved in the pre-analytic and post-analytic phases of testing are sparse. Neither competency assessment nor laboratory-related activity and staff evaluations are followed. Laboratory Standardization and Minimum Laboratory Standards are not maintained properly.

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Also, the unregistered laboratories are mushrooming gradually with certain loopholes in policy and subsequently unregistered manpower is habituated towards unhealthy practices in unhealthy labs (7,12-14). Unwanted charges for tests are frequently taken from consumers and no uniformity has been maintained throughout the country. Most small laboratories still perform manual assays, which are particularly prone to errors during sample collection, labeling and registration; and many laboratory staff at these level lack skills in recognizing pathology, and transcribing and delivering results. Lack of adequate resources to support these laboratory networks has resulted in equipment breakdowns, interruption of supplies and variable performance that can lead to considerable inconsistency in the accuracy of results, leading to incorrect diagnosis, inappropriate treatment or withholding of lifesaving therapy. Unmonitored Substandard chemical reagents, and medical kits and the essentials for quality lab test statements are frequently imported without any valid permission concerning quality assurance across the country (12,14). Also, no governing authorities are keenly enthusiastic to control such illicit practices.

In Nepal, with progress in growing medical sciences and its rapid privatization, the medical sector became more and more commercialized. Unfortunately, bribery and corruption has grown to newer heights in health sector and our doctors are also involved in questionable activities (14). Doctors have a self-interested motive behind sending patients for tests to the diagnostic facility that gives out maximum commissions, or the highest cuts, or maximum referral fees, or maximum percentage irrespective of the quality of these services (15). Our doctors are also no less prey to such moral decline and find it harder to survive without them. The health service has been transformed in commercial business and monetary deals. Instead of giving quality reports, diagnostic centers and laboratories are supposed to entertain and gratify the doctors merely as "Percentage" of doctor is fixed earlier but no existing data on commission practice is available. Even though, it is being practiced regularly, commonly observed and often shared by laboratory professionals. Cuts and commissions are silent killers of quality practice in medical laboratory and are vulnerable towards increment in malpractices day by day (14).

Even though, Government of Nepal (GoN) is committed to progress and develop overall health status of its people by providing preventive, curative and promotive health services through public sector health delivery system and by encouraging private sector to complement and supplement to GoN's efforts to meet the health need of the people (9). However, desired level of outcome of any health programme cannot be expected without assuring optimum quality of services it provides. Realizing this fact, due consideration have been given towards quality aspect of health care services while developing health plan and programmes. The second long Term Health Plan (SLTHP) has recognized the need for establishing Quality Assurance (QA) systems in public, NGO and private sector. It has also provided some strategic guidelines for developing QA system. The medium term strategic plan (MTSP) has suggested that the quality of health services in public, private and NGO sectors should be improved through total quality management of human, financial and physical resources (9). But, appropriate implementation has not been found in existence so far.

Unhealthy competition, weak monitoring system, turning service business into commercial business, use of low quality material, cuts and commission, unskilled manpower and loopholes in governing policy are factors affecting quality medical laboratory service in Nepal (14). Although, governing bodies have been trying to lash out ill practices and misconducts in laboratories. But, sometimes, often the Regional Health Directorate (RHD), NPHL, MQCD and District Public Health Office (DPHO) are also found bashful from their responsibility to conduct proper and periodic monitoring, having proper database and categorization of the laboratory as per their services and sealing the laboratory if it is found in violation of the minimum standard (7,12,13).

Still, lots of challenges and struggle remains to Nepal Public health Laboratory (NPHL), Nepal Health Professional Council (NHPC), Ministry of Health and Population (MoHP), Department of Drug Administration (DDA), Nepal Association of Medical Laboratory Sciences (NAMLS) and Nepal Medical Council (NMC) to wipe out the malpractices in health sector and enhance good quality laboratory service to nation (14). Regular QA researches, proper monitoring and scribed supervision, regular training towards quality assurance, and strict rules and regulations should be maintained abolishing cuts and commission practice system to enhance quality laboratory service. A fruitful public health trust on quality laboratory service will be in quandary until and unless the progress in the field of diagnostic medicine can benefit humanity and service seekers with trustworthy reliable, reproducible and rapid quality reports. Still, laboratory medicine practice and its worth service needs to be observed and are looked-for positive outcomes in Nepal.

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