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Review Article

Increasing Trends in Unhealthy Practices of Clinical Laboratory Medicine Service in Nepal

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ABSTRACT

The medical laboratories are increasing significantly with striking challenges in ensuring praiseworthy public health service in Nepal. Quality medical laboratory service provision is important in order to enhance diagnostic value and save lives. Poverty, poor infrastructure, unskilled manpower and incompetency are major contributing factors leading to inefficient provision of health services in developing countries. Nepal has been increasing its network of clinical health laboratories in the Government and private sectors that are scattered in various geographical regions. The quality of service remains a growing concern even as medical diagnostic laboratories are undergoing the process of accreditation for quality services in line with WHO standards. But, still the status of clinical laboratory practice regarding quality assurance, skilled manpower, standard labs and cost effective quality service remains challenging due to different loopholes in policy making. The regulatory bodies and legal provisions seem to be in non-functional state. The malpractices in clinical laboratory medicine service are increasing exponentially. Therefore, this review draws attention towards unhealthy practices in clinical laboratory services and critically examines different factors affecting the healthy practice in medical laboratory science.

Key Words: Cuts and Commission, Nepal Public Health Laboratory, Nepal Health Professional Council, Quality Assurance, Substandard Chemical Reagents, Unskilled manpower

INTRODUCTION

Clinical Laboratory services are an essential part of all health systems. Medical Laboratories offer their services to many clients as patients, physicians or public health programmes for evidence based decisions. Many medical hospital, public health, and academic laboratories in both the public and private sector contribute through their diagnostic activities to health care and public health improvement. In addition, animal health, food safety, and environmental health laboratory services contribute to health care and public health security [1, 2].

Nearly 1,00,000 deaths annually are attributed to medical error [3,4]. Identification of errors and rectification strategies in laboratory medicine has received a great deal of attention [5]. Although medical laboratory service

provision is a well developed science, observations indicate that many laboratories turn out hazardously inferior work resulting in inaccurate determinations and failure to identify the causative agents in samples [2]. Globally, international differences exist in the guidelines on good quality laboratory services. The quality of service provision and the challenges laboratory practitioners face are different in developed and developing countries. Quality medical laboratory service provision is important in order to enhance diagnostic value and save lives [6].

Public Health Laboratory Services are an integral part of the national health care system. In the early 1980s 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 Care [7]. Pathology laboratories and medical diagnostic centers began mushrooming in major cities of Nepal especially in early 2000s [8] but are still in their infancy [9]. Government of Nepal has taken initiative to extend clinical laboratory service to the community level through improving the quality of the services and producing all level of workforce related to laboratory medicine [10].

The problems relating to wrong diagnoses and prognoses and substandard lab reports soared in later years which led the Ministry of Health and Population (MoHP) to devise Minimum Laboratory Standard (MLS) for non-government hospitals, nursing homes and private health laboratories in 2004 [11]. But, the laboratories are extending and running in haphazard way without having any standard guidelines throughout the country. The health scenario of the general public is at jeopardy due to malpractice carried out in different laboratories. Unhealthy labs and unhealthy practice are common. Therefore, this review briefly highlights the present scenario of laboratory science, the central reference laboratory, responsibility of licensing bodies, function of monitoring bodies, cuts and commission, personality conflicts and team management, competency, the role of different governing bodies and unhealthy practices in the present scenario of clinical laboratory service in Nepal.

National Reference laboratory and its network:

National Public health Laboratory (NPHL) is a government national reference laboratory under the Department of health services (DoHS) and Ministry of Health and Population (MoHP). It is directly linked to 277 government laboratories in the country. It was established in 1968 as Central Health Laboratory and the name was changed to National Public Health Laboratory in 1991 with the mandate for organizational and administration responsibilities for the health laboratory services in public health and clinical diagnostic in both public and private sectors throughout the country [12, 13]. NPHL under the Ministry of Health & 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 [11].

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. The laboratory network includes 6 central-level laboratories, 1 regional laboratory, 1 sub-regional laboratory, 9 zonal-level laboratories, 64 district-level laboratories, 132 primary health care centre laboratories and 24 health post laboratories. On the basis of five development regions, the largest numbers of laboratories are found in the Central Region with 73 laboratories followed by the Eastern Region with 63 and the Western Region with 53, the Mid-Western Region has 31 and the Far-Western Region has 18 [13].

At the Central Level, Nepal has one national laboratory the National Public Health Laboratory at the Department of Health Services, Teku Kathmandu. Six central level hospital (250-350 beds) laboratories in Kathmandu, the Bir Hospital, the Kanti Children Hospital, the Mental Hospital in Patan, the Maternity Hospital, the National Tuberculosis Centre in Thimi and the Ayurvedic Hospital. There is one Regional Hospital (200beds) Laboratory in the Western Region in Pokhara and one Sub-Regional Hospital Laboratory in the Central Region in Birgunj. There are nine Zonal Hospital (50-200 beds) Laboratories: two in the Central Region, Janakpur and Bharatpur; three in the Eastern Region, Biratnagar, Chandraghadi and Rajbiraj; one in the Western Region, Butwal; one in the Mid-Western Region, Nepalgunj; and two in the Far-Western Region, Mahendranagar and Dhangadhi [13].

These laboratories network of NHPL along with private clinical laboratories are sustaining the pathology service in health sector of Nepal. Networking, licensing, monitoring, supervision, capacity strengthening and conducting research activities and National External Quality Assessment Scheme (NEQAS) of the laboratories are the major functions of NPHL [12].

A study was conducted from November 2011 to January 2012 by the National Public Health Laboratory (NPHL), with support from the World Health Organization 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” [8]. The study, which took into account the equipment and reagents used, safety measures, financial details and registration, raised serious questions over safety and sterility measures adopted during and after the tests. Most of the labs were found to disregard safety measures that ensure the accuracy of results [8, 14]. Also, the charges are much higher at some government hospitals than private laboratories at periphery.

Although, NPHL is with different important responsibilities of laboratories but they are in a weak condition having no right to punish such illegal entities as there is no laboratory policy in Nepal with proper guidelines, policies, accuracy detention and act to regulate laboratories. Due to impractical policy, illegal pathological laboratories exist and are growing dramatically without obeying the rules and enjoying the loopholes in the policy [11]. The government has no demarcation of certification to know the difference between registered and non-registered pathology laboratories. Monitoring mechanism is non functional and outcomes are very futile. The situation is burdensome for the consumers who are growing victims of

unhealthy practice within an undefined system [8, 11, 14].

Role of Nepal Health Professional Council (NHPC) and its challenges:

The laboratory science and its related occupation are managed by the Nepal Health Professional Council (NHPC). Its main duty is to supervise and check the regular registration of the laboratory personnel. Similarly, it also checks, promotes and manages the running medical laboratories regularly [9, 15]. According to the manual of Ministry of Health, each laboratory must have at least a Medical Laboratory Technologist. But, government has provided only 25-30 personnel for that post. According to data of NHPC, 37 Medical Laboratory Technologist (specialist), 725 Bachelor Medical Laboratory Technologist and 576 Laboratory Technician has been registered. But, this field cannot develop properly due to the lack of prerequisites, service motive encouragement and manpower centralization [9].

The NHPC Act 1996 stipulates that every health professional working in pathology labs and medical diagnostic centers is obliged to be registered with NHPC and is required to obtain a license to join any health related business and institution. The NHPC Act 2053 BS also provisions that the government appoints an Investigation Officer to investigate unethical acts performed by the health professionals and lodge the complaint against them in Court. The Act also entrusts the authority to NHPC to fine up to Rs 10,000 against those health professionals who perform the services without obtaining the license from the Council. However, a NHPC study assisted by World Health Organization (WHO) on the performance of health professionals from October 2010 to 2011 in 22 districts in Nepal, including Kathmandu, Bhaktapur and Lalitpur showed that approximately 90% of the technicians were unskilled [11].

The unregistered laboratories, untrained and unskilled manpower are growing in different regional centers due to the lack of sincerity and healthy advocacy of the NHPC. The consequences of the hiring of unqualified personnel are massive. This issue is about public safety, quality health care and increased health care cost. There is *no guarantee* that medical laboratory tests are being performed by qualified personnel. Unqualified personnel and unequipped laboratories are at an alarming stage these days with deteriorating laboratory service in different corners of Nepal. No legal action against illegal labs and personnel has been taken.

Recognition of unqualified personnel and having legal action against them is itself an enormous challenge for NHPC as there are certain existing street labs who are proficiently engaged in managing market values, doctors and local political elites for safely carrying out unethical acts under non-registered labs rather concentrating on quality performance. Although, there is specific licensing system for laboratory professionals but chaotic situation of unhealthy practices and illegal laboratories is the outcome of negligence and improper monitoring of governing bodies.

Role of monitoring agencies towards quality assurance:

Quality assurance (QA) in health laboratories incorporates all the factors that may influence

the generation of reliable results which comprises two key components. Internal quality control (IQC) includes appropriate measures taken during day-to-day activities to control all possible variables that can influence the outcome of laboratory results. This is a continuous process that operates concurrently with analysis. External quality assessment scheme (EQAS) is the other component. This component is necessary to ensure comparability of results among laboratories. WHO has made considerable efforts during the 1990s to ensure the quality of results produced by laboratories through the application of quality assurance practices included as advocacy, capacity building and technical support [16, 17]. But, Nepalese laboratories were not able to embark upon it promptly.

The provisions of MLS 2004 for private, non-government hospital and nursing homes and private health laboratories require institutions, including laboratories, which provide health services to be registered under the Monitoring and Quality Control Division (MQCD) of the MoHP as per the recommendation of NPHL with the provision for periodic renewal. Similarly, it also directs all laboratories to compulsorily participate in the quality assurance programs of NPHL [11,13]. Monitoring includes pre-analytic, analytic, and post-analytic phases of testing which is not in the process of implementation. Though, MQCD and NPHL advocates about their efforts towards implementation of QA practices in health laboratories, their achievements have not been productive.

Continuous monitoring and evaluation of patient care activities within Quality management plan is also not applied within the Department of Pathology and Laboratory Medicine which hinders laboratories to achieve and maintain high levels of accuracy and proficiency. Also, it is fear-provoking that the law does not fully entrust any government body to monitor the quality of lab services [11]. The quality controlling and quality assurance in clinical laboratories is still improper and unguided. There is shifting and blaming pattern to one another regarding responsibility of registration and renewing of pathology labs and medical diagnostic centers.

Well-executed standardization programs greatly improve the quality of laboratory measurements that are used to detect signs of illnesses and to guide interventions to prevent or treat illnesses. The government has set minimum standard guidelines to be followed [11, 14]. But, unfortunately Laboratory Standardization and Minimum Laboratory Standards remain words often used in speech and debates by dignitaries and sometimes by professionals during seminar and conferences. They have neither been put it into practice nor are the authorities keenly interested towards its implementation for reduction of malpractice in Nepal. The Regional Health Directorate (RHD), NPHL, MQCD and District Public Health Office (DPHO) also shy away from their responsibility to conduct proper and periodic monitoring, having proper database, categorization of the laboratory as per their services and should seal the laboratory if it is found in violation of the minimum standard [11, 14]. As a result, web of malpractice in laboratories are expanding day by day.

With respect to periodic renewal and quality assurance, the Kathmandu centered supervision may be practicable at higher

centers but problem are apparent in regional laboratories. Other than registered clinical laboratories, a lot of unregistered laboratories with substandard policies and without any guidelines are providing laboratory service boldly as governing agencies do not have policies to crack down on existing illegal laboratories. The consumers are charged large amount of money in the name of sound pathological services at different regional centers while the samples are transported to top Reference/Referral laboratories of Kathmandu, Pokhara, Biratnagar, Delhi, Chandigarh, Patna, Mumbai, Lucknow and Darbhanga etc.

It's critical to know and often concealed whether the samples collected are transported to referral centers or not, and it is possible that copied or fake pathological reports are signed and given to the patients. The authenticity of reports is solely dependent on the moral caliber of laboratories and their professionals. There are no authorized supervising bodies in regional centers to monitor such type of illegal activities which are weakening the public trust in laboratories.

Although, the provisions in the Muluki Ain 2064 BS related to 'cheating' states that with/without carrying out any tests, if pathology laboratory provides wrong prognoses, both the pathology lab and person/s performing laboratory tests are made to compensate for the fees paid by the service seekers and are fined up to Rs 5,000 as well as sentenced to imprisonment for five years [11, 18]. Needful actions are not in observation regularly for such type of increased illegal efforts, misconduct and malpractices in this sector as government does not monitor the laboratories strictly that directly affect people's health.

The law of consumer protection always focuses on the preservation and protection of life or liberty of the person. Philosophy of consumerism or consumer protection emphasizes on the protection, preservation and enhancement of human life. It refers to the measures adopted for the protection of consumers from dishonest and unethical malpractices by the business persons and to provide them speedy and effective redress of their grievances [19].

Also, the Consumers Protection Act 2054 BS, Section 18 (D) provisions fines up to Rs 5,00,000 and five years of imprisonment to violating individuals and institutions providing false services or counseling by taking fees/charges [11]. Not only that, consumer council and other authorities have been established by government for the settlement of consumer's disputes on better protection of the interest of consumers [19]. But, ignorance and illiteracy of consumers are the basic weaknesses of Nepalese consumers and majority of the consumers living in Nepal have low level of awareness and low extent of utilization of consumer rights.

No needful disciplinary action for abandonment of these malpractices has been taken yet. But, in spite of fulfilling these formalities consumer rights are limited only to paper. Enforcement of the legislation is in very poor condition. Moreover, there are many laws and institutional mechanism besides Consumer Protection Act to protect rights of the consumers [19] but they are found scattered and also inconsistent with each other and are acting as a safeguard

protecting body of malpractice in laboratory health services in Nepal.

Unskilled manpower, Illegal Labs and Malpractice:

Laboratory reports play a vital role in terms of determining the cause of a patient's ailment and severity of the disease. Ambiance, equipment selection, quality of reagent, temperature, lighting and human resource play equally important roles in maintaining the quality of any laboratory report. Unskilled manpower, use of low quality equipment and reagent and not maintaining the temperature are major reasons that lead to wrong reports [20]. Furthermore, haphazardly opened pathology laboratory, not following minimum standards, loopholes in policy, weak monitoring and enforcement and unhealthy competition among laboratories further encourage such foul play with public health.

The government has not defined specifications, specializations and the qualifications required to conduct a particular test. In polyclinics and labs, a lab assistant may be unqualified to handle all the tests. In Nepal, MBBS doctors and lab assistants trained for 15 months or so work on the same tests without any type of restriction [14]. Increasing cases of sufferers from substandard reports of the laboratories and monetary burden towards patients are seen. Not only does the patient suffer from substandard laboratory reports, it has also reduced public confidence in healthy competition among individuals and reduced the trust of the public.

At present, laboratories get registered at the Office of the Company Registrar (OCR) or the Small and Cottage Industries Development Centre (SCIDC) under the Ministry of Industry (MoI). Only a few pathology labs and medical diagnostic centers in Nepal have sought approval from MoHP as provisioned by MLS [11, 21]. According to National Public Health Laboratory (NPHL), there are altogether 1,500 registered laboratories across the country. However, NPHL, the authorized body to inspect quality of pathology laboratories is unaware about the number of unregistered illegal laboratories across the country [14]. In the name of quality and service in private laboratories, clients pay a large amount of money and the reports are again cross checked by other laboratories creating extra financial burden to service seekers. The Department of Quality Control, DPHO and NPHL should conduct regular market surveillance to abolish the system of unprofessional conduct in laboratory science and should also have strict rules to break the rapid pace of growth of private laboratories with standardization and consistency in charges for tests and quality given to consumers.

A previous study conducted by the Nepal Association of Medical Laboratory Sciences and the Medical and Chemical Supply Association Nepal (CHEMSAN) from August 2008 to January 2009 had shown that the condition of pathological labs were "very poor' [8, 10]. This study examined 373 Kathmandu-based private laboratories, including hospital laboratories, independent laboratories and medical centre laboratories and discovered that a majority were headed by lab technicians, health personnel with only a basic course in laboratory sciences, and only three percent of them had working clinical biochemists and clinical microbiologists, a prerequisite for laboratories and also discovered that 65

percent of the laboratories were being run illegally as they had not been registered with the government [8].

The MoHP formulated Minimum Laboratory Standard (MLS) to be followed in 2061. The MLS states that the minimum area for any laboratory to be set up should be 300 sq ft. There should be refrigeration facility to store reagent and other necessary medication, power back up system, allocated standard of incubator and reagent with minimum staff qualification to operate laboratories among others. However, NPHL said that 50 per cent of registered laboratories are operating below the standard and non registered laboratories are beyond the government's monitoring system [8, 11, 14]. In monitoring report of NPHL 2071/72 fiscal year, only 50 per cent laboratories are following the basic standards while 25 per cent needs to upgrade their standard whereas remaining 25 per cent has not been following any norm [14].

The lab services operating illegally without prior registration for over a decade and without having even the basic minimum facilities are more common in Nepal. On the other hand, none of the concerned government bodies – MoHP, OCR, SCIDC, RHD or NPHL – have any rules and regulations that regulate health laboratories and effectively monitor their services. Also, there is no proper laboratory policy in the country and nor is there any law that outlines which institution is responsible for monitoring and ensuring the quality of laboratories and what sort of action is to be taken in case of any violation of MLS [8,11,14].

The government has no differentiation of official recognition to recognize the disparity between registered and non-registered pathology laboratories. Most labs never bother to register themselves because of the lack of clearly defined penalizing measures. Mostly, minimum criteria of laboratory establishment are also not included and laboratories are running successfully with incorrect reporting. The MLS clearly entrusts paramount authority to NPHL to take necessary legal actions if any health institutions ignore the directives. But both NPHL and the MoHP; the apex bodies to regulate the health sector have failed to curb illegal operations of health institutions [11, 21].

Game of Commission and its adverse effect:

Patient history along with physical signs and symptoms are vital, but most diagnoses need confirmation that only laboratory tests can provide [22]. The treatment of patients is directly related to the diagnostic reports carried out in pathological laboratories. The laboratory professionals also contribute to wellness testing, guiding treatment and monitoring patient progress. The quality reporting is the basis for proper and appropriate medication. The varied diagnosis reports may produce challenges to doctors while treating patients as they are confused as to what medication to prescribe or even to decide on further investigations [11].

It is often mentioned that the medical profession is noble and will remain noble. But, in Nepal with the advancement in growing medical sciences and its rapid privatization has led to unforeseen consequences. As the medical sector became more and more commercialized, doctors have a selfish reason behind sending patients for tests to the diagnostic facility that gives out

maximum commissions, or to the specialist who will give them the highest cuts, or to the hospital that will send them maximum referral fees, irrespective of the quality of these services [23]. Sadly, bribery and corruption has grown to newer heights in health sector in Nepal, and also our doctors are also involved in questionable activities. It is widely held that many doctors earn more from these bribes than from their transparent consultation fees [23]. Cash, cheques, expensive gifts, dinners, parties, free service to their relatives etc. are some of the common rewards of commission for greedy doctors paid by diagnostic laboratories and their professionals [23, 24].

Owners of diagnostic facilities today have little choice as all players give out commissions and local doctors refuse to send patients without cuts or commissions [23]. Unnecessary investigations are written by doctors and only a few of the tests are performed, and the extra blood collected is dumped in the sink. Fabricated results are given in the normal range for all tests that were not performed [8, 11, 14, 23, 24]. Also, the skilled manpower and well equipped laboratories give reports on the basis of their experience, by observing the sample and not performing the tests. Rather giving importance to quality reports, they are supposed to please the doctors only as "Percentage" of doctor is fixed earlier but no concrete data on commission practice is available. Even though, it is being practiced regularly and observed commonly. If diagnostic facilities didn't have to pay out these commissions, the tests would become cheaper and quality service will naturally enhance and service seekers will be benefited.

It is troublesome for the laboratory professionals to sustain their labs and impossible to survive without giving commissions in the market as it has become an industry norm, part of community culture and developed as standard practice [22, 23] and an established system. The situation is worsening day by day. It is a heavy burden to take care of laboratory, chemical reagents and kits, physical facilities, equipments and instruments, daily expenses and salaries of staffs with additional saddle of commission demanded by doctors. Thus, labs hire unqualified, unskilled manpower, use low quality chemical reagents and substandard equipments to reduce expenses of the clinical laboratory. Subsequently, they are forced towards unhealthy labs and unhealthy practices.

Commercial deals within medical sciences and health sector is rapidly increasing. Commissions and cut practice happen elsewhere in the world too [23, 24], but it is more worrisome here. In other countries, it seems to be confined to a few doctors; here it seems to have become a part of the system. Our doctors are also no less prey to such moral decline and find it harder to survive without them. The commission market works very efficiently and payments are made on time always with a lot of honesty in dishonesty. It is a form of corruption, and fairly widespread and an established system in itself.

But, some honest doctors and laboratories are sufferers who are neither recognized nor rewarded. Eventually, some honest doctors and laboratories also get sucked into this corrupted game of commission due to loopholes in health policy. Cuts and commissions are silent killers of quality

practice and promoting malpractices in clinical laboratory service gradually more and more. The patient pays a large sum of money which increases the cost of health care and seriously undermines patient confidence and trust in our health care standards.

Cuts or commissions have toxic effects on healthy laboratory practice and raise questions on morals and ethics of doctors in clinical practice. Although, the Medical Code of Ethics (2.7) passed by Nepal Medical Council (NMC) which has all doctors registered under the NMC Act 1964, says under its title 'Commission' that it is unethical to receive or offer any gifts, gratuity, commission, or bonus in consideration of or in return for referring, recommending, or procuring of patients for prescribing medical and surgical treatment, investigation and consultation [11, 25]. Even though the act has been formulated [25], the NMC is not serious about ensuring the medical doctors, hospitals and private medical colleges and hospitals [11] where such types of malpractices are habitually being carried out.

The NMC Act 1964 stipulates that NMC can invalidate the registration of the doctors performing such unethical acts, as per the recommendation of the probe committee formed to conduct the study, as well as on the complaints lodged against the violation of the code of ethics [11]. To some extent, the rules and regulations are maintained but never followed strictly to eliminate the unethical acts. The politicalization of health sector and different associations of medical doctors has limited themselves to votes and power politics only. Sometimes, an optimistic debate and healthy discussion among higher dignitaries in electronic and printed media are observed to stop these illegal activities but has never been implemented. Abolishment of cuts and commission is an emerging challenge to NMC as this has become an established system and is acutely expanding day by day.

Also, the MLS for private, non-government hospital and nursing homes and private health laboratories 2061 BS provisions that NPHL shall take action as per the existing laws against those pathological laboratories providing services without registration under MoHP and not participating in the quality assurance program carried out by the NPHL [11, 14]. Corruption, commissions, unhealthy labs and malpractices in health sector is absolutely scandalous in a country where Nepalese peoples are pushed into poverty each year simply as a result of expenditure on health care. But, the shocking fact and appalling situation is that the NMC, NHPC, NPHL, MoHP, which are meant to regulate health institutions, health professionals, doctors and pathology labs have failed to execute the responsibilities outlined by the law properly [11].

Law against Black Marketing and Social Act 2032 BS, Competition Management and Market Protection Act 2063 BS and Consumers Protection Act 2054 BS mention that if a service provider is found guilty of false services s/he can be penalized with fine and lifelong imprisonment [27, 28]. There is no firm legislation and the charges are being taken haphazardly for different tests. Unhealthy competition, weak monitoring system, turning service business into commercial business, use of low quality material , commission, unskilled manpower are major reasons behind the increase in black marketing and malpractice in pathology laboratories in Nepal.

Competency, Conflict and Team work within laboratory:

Laboratories by definition are composed of a diverse set of individuals with different experiences, backgrounds, perspectives, and personalities. Resources, responsibilities, intellectual ownership, and personality conflicts are a few common sources of laboratory tension [26, 29]. Competent individuals work together through effective teamwork in all phases of the testing process to ensure that the most accurate test results are provided in a timely manner. Teamwork can be categorized as internal, i.e., within the laboratory; and external or ancillary, as relating to other departments or systems within the greater organization [30].

Laboratory testing encompasses such disciplines as clinical chemistry, hematology, immunology, microbiology and molecular biology and immunehematology. Medical laboratory science professionals generate accurate laboratory data that are needed to aid in detecting cancer, heart attacks, diabetes, infectious mononucleosis, and identification of bacteria or viruses that cause infections, as well as in detecting drugs of abuse. In addition, testing quality and other special services are conducted with other members of the healthcare team. Medical laboratory technicians are competent in the collection, processing and analysis of biological specimens, the performance of lab procedures, the maintenance of instruments, and relating lab findings to common diseases/conditions.

The need for lab tests to be handled by professionals with well defined strict guideline is the basic necessity to promote quality service in laboratory. In Nepal, there are different manpower as MD, CMLT, BMLT, MMLT, lab assistants, technicians and also specialized post graduates in Biochemistry and microbiology who are actively involved in practicing clinical laboratory medicine with their skills and experiences for the betterment of public health Service. Besides that, unskilled manpower are also involved in conducting tests in clinical microbiology, biochemistry, histo-cytopathology, hematology, genetics and molecular biology having little knowledge about laboratory science. Every trainee and every situation is different here. A competent team increases level of interaction that provides pathways for building trust and a sense of community between professionals within the laboratory. But, this is in sparse condition in Nepal.

Clinical laboratory test results are a key factor in 70% or more of all medical decisions [26, 30]. Here, the fact is that there has always been a power clash between the pathologists and technologists although the job description has been pre-defined. Sometimes, the signing and department authority has also been challenged within the laboratory professionals themselves. Although the act has been formulated but not practiced regularly. The questions are often raised that every individuals involved in laboratory tests should get the signing authority which provokes the fiction and diffidence of professionals. The indeterminate job responsibilities, under-disciplinary act, conflicts and clashes over authorities and premature decisions cause serious problems in working environment which affects the laboratory practice directly and indirectly. Laboratory experts should focus on quality reporting issues not on personalities showing good professionalism that can decrease the

malpractice and increase the working stamina within the working individuals.

All front office personnel, including receptionists, medical assistants, secretaries, phlebotomists, couriers, technologists, pathologists and even the office manager should be properly trained for anything they do that affects any aspect of the laboratory operation [30]. But, the scenario of hiring incompetent and untrained staffs is frequently observed in laboratories of Nepal. The competency of all ancillary staff involved in the pre-analytic and post-analytic phases of testing are not examined properly here. Neither the training has been found documented to competency assessment nor has incorporation of competency assessments of laboratory-related activity into staff evaluations has been followed yet.

Conflict over science and issues can be beneficial to productivity and development but conflict over working styles and personalities can be destructive [30, 31, 32]. Previously, some disputes have also been raised among lab professionals regarding the guidelines of NHPC and discriminatory decisions about the lab practice, registration and authority of health professionals in laboratory medicine practice. Some issues have been resolved and few are in puzzled position. Most of the specialized postgraduates in the midst of frustration migrated outside Nepal as registration issues have not been addressed hale and hearty by NHPC till now. Still, they are found struggling towards the decision of regulating bodies and waiting for healthy decision. Specialized post graduate professionals should be motivated and promoted rather than a bachelor graduate for the better quality care in laboratory service. Sometimes, the fake signature of the pathologists/technologists is also done, and fake reports are issued when they are not available in labs. Pathological reports signed by assistants are also frequently observed who had only taken basic trainings and attended seminars. During inspection by government officials, majority of pathology labs and medical diagnostic centers display rented equipments of other equipped labs, scanned certificates with fake documentary paper work. In case a supervisor visits the labs, they are bribed to silence [11]. MoHP, NHPC and NPHL lacks in the supervision and monitoring team for such type of illegal behaviours and ill practices [11] which are increasing in Nepalese health sector nowadays.

Use of Substandard low quality Chemical reagent and kits:

National Drug Policy (NDP) 1995 includes reagents and medical kits under the definition of drugs. National Medicines Laboratory and Drug Inspectors are responsible for supervising and monitoring the drugs, including chemical reagents and medical kits. The Department of Drug Administration (DDA) under the MoHP is the national authority for regulating medicines, including chemical reagents and medical kits [11]. Pharmacies which obtain license merely for selling medicines also provide pathology lab services without adequate equipments. Many such shops act as collection centers, which are unethical and unlawful [11, 14].

But, there is no authority to control such illicit practices. Unmonitored Substandard chemical reagents, and medical kits and the essentials for quality lab test statements are frequently imported without any authentic permission regarding quality assurance

across the country. Therefore, the frequent use of low quality reagents are witnessed all over throughout the country.

The quality of reagent determines the quality of the tests. Quality reagent is important for a reliable test. Reagents or kits require a cold chain in order to maintain their stability and remain as effective diagnostic tools. It has to be stored in between the temperature of two to eight degree Celsius constantly. Substandard chemical reagents and medical kits can result in wrong prognoses. Large consignments of such sensitive reagents are transported by road in vehicles that are not properly equipped [8, 14, 17].

But, many laboratories neglect the handling of reagent and use low quality product leading to incorrect results. The authorities of DDA are silent and unwilling to carry out their duties strictly for supervising and monitoring chemical reagents and medical kits which signifies that there is no standardization and uniformity of chemicals used in labs. Negligence towards quality control and the government's lack of activity to monitor the laboratories are directly affecting people's health care. Consequently, pathology laboratories and diagnostic centers in the country are sucking money out of patients in the lack of stringent legislation and weak health advocacy.

Nepal Association for Medical Laboratory Science (NAMLS):

Beside the governmental organization, for the same purpose with regard to improvement in laboratory health services, a group of laboratory medicine professional of Institute of Medicine, Tribhuvan University Teaching Hospital (IOM, TUTH), Maharajgunj, Kathmandu made a non-political and non-profit, non-governmental organization named "Nepal Association for Medical Laboratory Science" (NAMLS) with the mission of continuous improvement in laboratory medicine profession. It was established and registered in Chief District Office (CDO), Ministry of Home affairs, Govt. of Nepal, May 1998 which is now full member of International Federation of Clinical Chemistry and Laboratory Medicine (IFCC) and Asia Pacific Federation for Clinical Biochemistry and Laboratory Medicine (APFCB) since 2010. Since its establishment, NAMLS is working for the betterment of medical laboratory service and is mostly involved in all of the committee of ministry of health & population related to medical laboratory services like laboratory policy and planning and creating awareness about quality control management system [33].

NAMLS conducted a study from August 2008 to January 2009, on Status of Private Clinical Laboratory Medicine Service showed that 84% of the pathology labs in and around Kathmandu Valley did not meet core government standards [10, 11, 33]. Although the policy has been formulated by the NAMLS, but the implementation still remain problematic in scattered laboratories in different regions of Nepal. There is vast difference in charges of different tests in different labs. Some of the tests are being carried manually in the advanced technological era and results of that test also vary from one lab to other.

No uniformity and transparency regarding instruments, equipments, charges for tests, quality assurance and quality controlling has been formulated and executed for the practice of private laboratories. Even, no

authorities from NAMLS have been found full of zip and passionate towards scrutinizing such illegal activities and malpractices. Quality improvement and quality promoting is not under appropriate supervision of NAMLS. Therefore, the tendency towards malpractice in laboratories still exists and is increasing.

CONCLUSION

Despite poverty and conflict in past few decades, Nepal has attained considerable achievement and remarkable success in clinical laboratory medicine service, but still there are many problems and challenges. The challenges lies in ensuring the quality of laboratory service through a well trained manpower with appropriate and affordable technologies with reduction in malpractice of illegal provisions as medical diagnostic laboratories are undergoing the process of accreditation for quality services in line with WHO standards.

In Nepal, health laboratories have not been able to contribute optimally because of various reasons as lack of clearly defined national policies for laboratory services, shortage of trained manpower, poor linkages and communication, shortage and inappropriate laboratory equipment, non-availability of public health trust. Hence, non-utilization of standard operating procedure manuals in laboratory techniques, poor development of internal quality control methods, inadequate number of laboratories participating in external quality assessment schemes, lack and negligence of scrutinizing body, lack of judiciary actions against illegal and illegal practice of clinical laboratory medicine service are contributing factors. Still, there are lots of challenges and struggle to NMC, NPHL, NHPC, MoHP, DDA and NAMLS to exterminate the malpractices in health sector although they have been trying to kick out ill practices and misconducts which have increased nowadays.

The progress in the field of diagnostic medicine can only benefit humanity, if the laboratory services are accessible to users and the results produced by the laboratories are reliable, reproducible and rapid enough to be useful. Moral ethics as well as medical ethics of health personnel is important to enhance good quality laboratory health service in the country. Regular QA researches on laboratory science should be conducted. Proper monitoring and supervision should be followed. Regular training should be conducted in different regions of country towards motivation, quality controlling and healthy practice of laboratory service and transparent data should be released well-timed to formulate public trust on quality healthy service. Rules and regulations should be strictly maintained abolishing cuts and commission practice system to enhance quality laboratory service.

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AUTHOR'S CONTRIBUTION

SP- himself was involved in reading different research articles and reviewed different articles and scripted the full manuscript with his critical intellectual content.

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