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TAXONOMY OF CHALLENGES IN MEDICAL LABORATORY DIAGNOSTIC SERVICES

Abstract:

The Sustainable development goals 2030 has focused on human health and is dependent on a nation's healthcare system. Medical diagnostic laboratory services (MDLS) plays an important role in the modern healthcare system as it significantly helps in evidence-based decision-making. The MDLS suffers from many issues identified both globally as well as nationally with steps taken to address those challenges. However, constrained understanding of challenges affecting MDLS made it difficult to design interventions which can cater to laboratory systems in more holistic and standardised manner. Accordingly, it is required to categorize and develop the taxonomy of the various challenges existing in MDLS that will help in defining the scope of challenges and will provide an overview of the various challenges to which a laboratory can get exposed to. This study develops the taxonomy of challenges that can be encountered in MDLS using systematic review.

Further, the existence of those challenges in the Indian context is determined that will potentially validate theoretically identified challenges. In the study, the analysis for Indian context is performed using content analysis over the content collected by interacting with various health experts like doctors, lab managers and lab technicians coming from different type of laboratories. The study identified 30 challenges which are categorized in the three-layer hierarchy. The first layer consisted of two challenges followed by eight challenges in the second layer and 20 challenges in the third layer. Out of the 20 challenges in the last layer, 16 challenges could be identified in the Indian context based on the content analysis of the experts interactions. The study concludes that the challenges exist for the MDLS which could be categorized into three layers.

Keywords:

Medical Laboratory,
laboratory services,
laboratory challenges,
Indian laboratory

1.0 Introduction

Globally, human health is used as an important development indicator and has been incorporated into the Sustainable Development Goals 2030 (United Nations 2012). Any nation's health sector plays a critical role in its population health development and it requires an effective health system. Medical diagnostic laboratory services (MDLS) plays an important role in making informed decision making in any modern health sector (Kanashiro-cussiol et al. 2010) and poor focus has corresponded in inadequate success of many health programmes (Berkelman et al. 2006). Economically, diagnostic laboratories sector have a formidable market presence with global and Indian market size of 23,000 Billion rupees (2012) (Health Research International 2012) and 117 Billion rupees (2013) (RNCOS Industry Research Solutions 2013) respectively. Further, in India, Ranson *et al* (2012) found that MDLS could account to upto 21% of the total out of pocket (OOP) health expenditure (Ranson et al. 2012) that could be a critical expenditure for any household considering government to OOP health expenditure ratio being 1:2 (World Health Organization 2015).

Nevertheless, MDLS have been associated with issues. Firstly, they are reported to cause medical errors and delays owing to faults at different diagnostic steps from pre-analytical to post-analytical stage affecting medical decision making (Plebani 2009). Secondly, the cost of ensuring the quality of lab test results has been reported to be very high especially for developing countries (Kapil 2013), but still lab results quality risks may remain (Gulletta et al. 2010). Thirdly, the availability of the complete battery of the tests in all the regions of the nation is not feasible especially in developing countries (Suhanic et al. 2009). Various strategies like national laboratory systems establishment (Nkengasong et al. 2009), workforce trainings (Abimiku 2009), Failure Mode and Effect Analysis (FMEA) model adaptation (Chiozza & Ponzetti 2009) and tele-informatics (Suhanic et al. 2009) have been suggested to improve the diagnostic laboratories. However, lack of comprehensive understanding of challenges made it difficult to design interventions which can address MDLS issues in more holistic and standardised manner (Abimiku 2009).

This study focussed on identifying the challenges prevalent for MDLS and develop a taxonomy of those challenges. The study will contribute theoretically in domain of MDLS research by identifying the challenges for MDLS. Practically, the study on development of challenges taxonomy will enable the programme managers to develop more holistic and robust interventions for improving MDLS. Finally, the designing of an approach for identification and validation of challenges is the methodological contribution of the study that could be considered for other sectors.

2.0 Conceptual Framework

A conceptual framework of the taxonomy of the challenges is developed using meta-analysis approach whose methodology is shown in Figure 1. A systematic review of the past peer-reviewed journal literature published in various journals from 2009-2013 is

performed. Peer-reviewed literature as it is a common way to get access to the researchers' viewpoint whose selection is done using keywords based search. "Google Scholar" search engine is used for peer-reviewed papers as it is considered good and easy to operate source for public health related studies (Shariff et al. 2013; Gehanno et al. 2013; Shultz 2007) but, some cautions have been raised (Bramer et al. 2013; Shultz 2007). The total of four levels of filtering mechanism is applied to shortlist journal papers for this study that lead to selection of 213 papers.

The data analysis is an iterative process with repeated reading of papers to understand the various challenges reported without a priori themes or categories for classifying data into different challenges. Each paper is reviewed line by line and repeatedly to develop distinct themes and categories of challenges. Consequently, the three level taxonomy is developed by pooling and analysing all the challenges related to medical diagnostic laboratory services raised in various peer-reviewed journal (Figure 2). The study identified that MDLS are exposed to two kinds of level one challenges namely external and internal challenges.

2.1 External Challenges

The study defines challenges which affect the laboratory but cannot be controlled by the laboratory as external challenges. These challenges are mainly based on those factors that either provide input or generate output from the laboratory and could be further classified on the basis of the external decision-making stakeholders into level two challenges as Sectoral Commitment, Research and Development, Lab activities performed outside lab and Users.

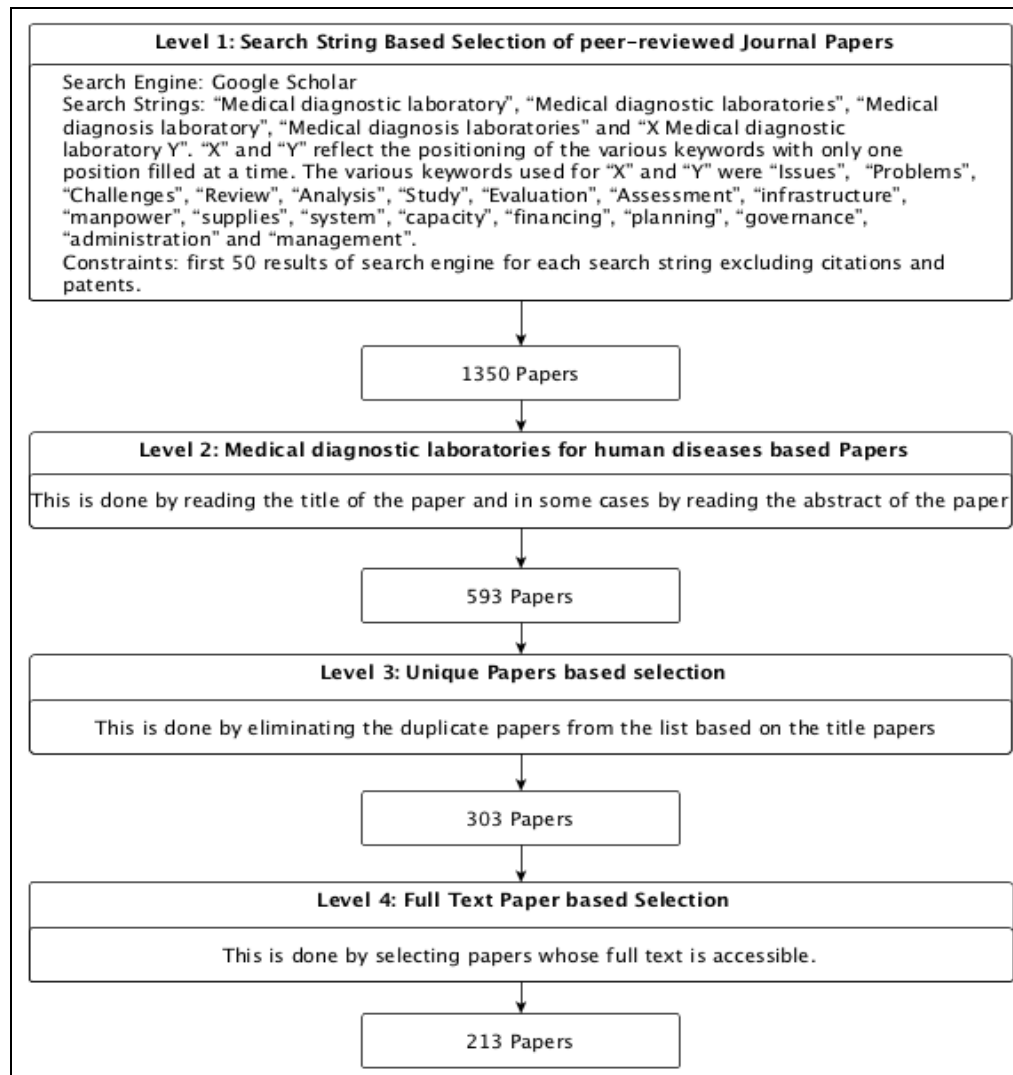
2.1.1 Sectoral Commitment

Any service provider including MDLS providers requires the support from the decision makers of its sector to ensure the functioning of the individual service provider. The various decision makers in case of MDLS could be international organizations like World Health Organization (WHO), government authorities, institutional authorities, manufacturers and suppliers. In such a scenario, poor or inappropriate decision-making by higher authorities and other influential stakeholders can effect individual laboratory by affecting the whole sector. This decision-making can affect either the governance of the sector in general or the desirable resources accessibility to the sector. Accordingly, level three challenges are categorized into governance and resources.

Governance related challenges are commonly related to the regulation and monitoring, financing and planning. Kapil (2013) discussed that weak regulation and monitoring will reduce the reliability and trust of microbiology laboratory results among the users in India. However, too strict regulation and monitoring could increase the requirement for documentation and manpower that could alter business cost and could affect MDLS accessibility to people and business sustainability in short term (Kapil 2013). Abimiku *et al* (2009) raised the issue that in many resource limited countries like Nigeria, MDLS is

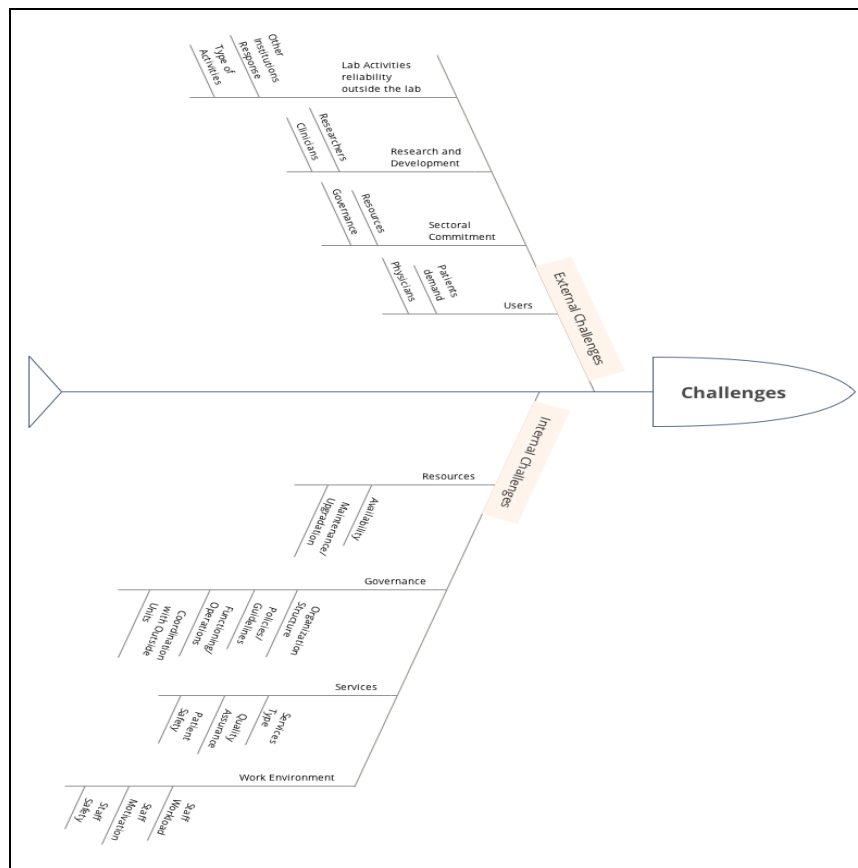
suffering from inadequate financial support and lack of government laboratory policy resulting in unreliable laboratory results (Abimiku 2009).

Figure 1: Four level criteria for selection of journal paper for systematic review (Source: Own)



(Source: Own)

Resource related challenges are commonly associated to inputs consumables, manpower, physical infrastructure and public infrastructure needed by any MDLS for its functioning. Petti *et al* (2006) discussed the issue of lack of availability of adequate number of skilled workforce and consumables to perform tests in sub-Saharan Africa that lead to unreliable and reduced number of cases for diagnosis. Further, in remote areas, the MDLS also suffers from the lack of adequate public infrastructure as water and electricity (Petti et al. 2006).

Figure 2: Lab Challenges Taxonomy Fish-Bone Diagram

(Source: Own)

2.1.2 Research and Development

Research and Development is needed to develop better and newer solutions for the existing and future challenges of the MDLS. It has two steps of solution development and solution dissemination that are dependent upon researchers and clinicians. Accordingly, the level three challenges are related to either researchers or clinicians.

Researcher related challenges are commonly associated with the researcher's intent and output. Wallis *et al* (2010) discussed for tuberculosis (Tb) tests that lack of interest of industrial research in developing tests for low profit market affect the accessibility of reliable tests in resource-limited countries. Further, the developed tests could suffer from certain practical issues like cost, resource and/or skill intensiveness and inadequate reliability (Wallis et al. 2010).

Clinicians groups/ societies based challenges are commonly associated with standards and guidelines for developed tests quality assurance and diagnosis reliability. Wallis *et al* (2010) discussed that many non-commercial tests developed for detection of Tb can provide commercial level tests accuracy at cheaper level but they cannot be used for clinical purposes owing to lack of standardization and optimization to achieve quality

assurance (Wallis et al. 2010). Harton *et al* (2011) discussed that lack of guidelines for Pre-implantation genetic diagnosis (PGD) testing at the European level has created variability in the practice across Europe (Harton et al. 2011)

2.1.3 Lab activities reliability outside lab

A diagnostic test involves number of steps (Jain & Rao 2015) but laboratories may not be able to perform in-house all the steps of a diagnostic test requiring support from other units like hospital wards, field sample collectors and other laboratories in performing one or more steps. In such cases also lab has the responsibility for quality assurance of test results.

Accordingly, the level three challenges are related to the lab activities which are performed outside the laboratory boundaries and response of other units. Plebani (2009) discussed that laboratory results are more error prone in cases of performing pre-analytical and/or post-analytical steps outside the laboratory control than in cases they are performed under the laboratory control. This is owing to the difficulty in evaluation and monitoring of the steps performed outside laboratory control (Plebani 2009).

The response of the other units based challenges are associated with the ease of involvement of laboratories with these units. Brady *et al* (2011) showed that Irish hospitalwards have no involvement of the laboratory staff in many diagnostic test suitability and procurement related decision making activities. This resulted in inadequate monitoring and evaluation of the tests practices and results quality owing to compromised audit trails (Brady et al. 2011).

2.1.4 Users

Users are the stakeholders that actually consume the services and their satisfaction criteria significantly affect the laboratory decision making. Patients are direct users who directly use the laboratory services and doctors are the indirect users who decide the services which a patient needs to use (Jain & Rao 2015). Accordingly, the level three challenges for the users is classified on the basis of type of consumer into patients' demands and doctors/physicians perception.

The patients demands based challenges are associated with the patient's knowledge and its application. The frequency of patients visiting the laboratory could depend on their awareness and association of health benefits with the information received from laboratory evaluation (Afolabi 2009). Physicians/doctors based challenges are associated with physician's trust on the laboratory results as well as their knowledge level. Petti *et al* (2006) discussed the issue of underutilization of MDLS in Sub-Saharan Africa owing to physicians inadequate trust on laboratory results (Petti et al. 2006). Charron *et al* (2010) stressed upon the importance of cardiologist's laboratory tests knowledge upgrade for better selection of laboratory tests (Charron et al. 2010).

2.2 Internal Challenges

The study defines challenges on which the laboratory has direct control and happens within the walls of the laboratory. These internal challenges could be further classified on the basis of the activities performed by the laboratory as Governance, Resources, Services and Work Environment.

2.2.1 Services

Laboratory primary output is the test services to its users and faces challenges based on certain characteristics of services. Accordingly, the level three challenges for the services is classified as type of services, quality assurance and patient safety. Type of services based challenges is associated with the types of tests that are performed by the laboratory along with the ambience in which these tests are provided to the users. Elbireer *et al* (2011) discussed the issue of limited tests menu in public laboratories affecting the disease control strategies in Uganda. Further, geographical positioning of certain laboratories make them inaccessible to many Tb patients for the sputum test (Elbireer *et al.* 2011).

Quality assurance related challenges are associated with reliability of the services given to the users including both the results and its delivery reliability. In India, Kapil (2013) raised the issue of implementation of many quality assurance guidelines by the MDLS owing to challenges related to time, complexity and cost (Kapil 2013). In use of RNA testing of dried blood spots for HIV detection, laboratories were unable to communicate consistently and quickly the outcome of the tests to the initial collection points (Schito *et al.* 2010). Patient safety related challenges are associated with the potential side-effect of the use of laboratory services. Elbireer *et al* (2011) discussed patient safety risks in laboratories of Uganda as patient's blood or sputum from is collected within the laboratories with poor ventilation system that increases the risk of noso-comical infections (Elbireer *et al.* 2011).

2.2.2 Work Environment

The work environment is the laboratory responsibility to provide quality working ambience for its staff. Accordingly, the level three challenges for the work environment is classified as staff motivation, staff workload and staff safety. In Africa, Petti *et al* (2006) indicated that staff workload owing to shortage of staff has reduced their inclination towards maintaining quality control (Petti *et al.* 2006). Further, Cuevas *et al* (2011) indicated that poor staff motivation and higher workload lead to the skipping of many slides for sputum examination for tuberculosis in Ethiopia, Nepal, Nigeria and Yemen (Cuevas *et al.* 2011). Elbireer *et al* (2011) raised the issue of staff safety in the laboratories of Uganda where patient's sample is collected within the laboratory with poor ventilation system that increase the risk of noso-comical infections (Elbireer *et al.* 2011).

2.2.3 Resources

A laboratory has finite availability of resources as consumables, infrastructure, finance and staff for utilization. Accordingly, the level three challenge in resources exists in availability of desirable resources and maintenance/up-gradation of resources. In Africa, Petti *et al* (2006) discussed that laboratories can have issues in retaining the staff as they move to laboratories or areas with better choices. Further, the laboratory may suffer the issue of getting inadequate number of skilled technicians (Petti et al. 2006).

2.2.4 Governance

A laboratory needs to have good governance to ensure proper functioning and management. Accordingly, the level three consists of challenges which could be categorized into laboratory policies/guidelines, laboratory organization structure, laboratory functioning/operations and coordination with other institutions or units or departments like clinics.

Laboratory policies/guidelines related challenges are associated with implementation and designing of the laboratory policies. In case of Irish Hospitals, Brady *et al* (2011) showed that the change in Irish government policy to promote Point of Care Tests (POCT) resulted in creating new oversight and governance responsibility for the laboratories. However, the laboratories were not completely successful in designing and implementing their modified policies to achieve desirable service outputs (Brady et al. 2011).

Laboratory Organization structure related challenges are associated with having a proper staff hierarchy to avoid inter-professional conflicts. In Nigerian healthcare system, Afolabi (2009) indicated conflict risk because lab technicians and assistants with special training can compete with pathologists/physicians in analysing and presenting test results in clinical manner (Afolabi 2009).

Laboratory functioning/operations related challenges are associated with ensuring smooth day to day laboratory functioning in a given ambience to ensure quality services. Plebani (2009) raise the issue of laboratories suffering from performance errors owing to poor laboratory practices (Plebani 2009). Brady *et al* (2011) showed that Irish laboratory functioning like level of resource support varied differently for different tests affecting the quality assurance of those tests services (Brady et al. 2011).

Coordination with other health units challenge is associated with adequate involvement with other health units to ensure proper functioning and output of the lab results. Brady *et al* (2011) showed that Irish laboratory were unable to completely coordinate with other departments or units due to lack of adequate manpower affecting the quality assurance of those tests services in which outside units support is required (Brady et al. 2011).

3.0 Field Study

The exploratory field study has involved interacting with doctors and lab staffs to determine the challenges that are faced by them. These interviews are done using open-ended questionnaire with verbal consent of the respondents. The declaration of the use of information for academic research and publication was made orally to the respondents. A purposively 18 different institutions associated respondents (Table 1) are interviewed to cover different types of Indian laboratory as mentioned in Jain *et al* (2015) (Jain & Rao 2015). Such a sampling approach is chosen to quickly capture the challenges in smaller sample size owing to the exploratory nature of the field study.

The directed unconstrained content analysis is performed using the basic process of analysis as explained by Thomas (Thomas 2006) for this study. In brief, the information collected during field visits (respondent's responses and personnel observations) is repeatedly read to understand the content in the context of the laboratory challenges. Concepts in the content is segregated and coded into different level three challenges identified in the conceptual framework (Figure 1). Same sentence could be coded multiple times under different themes, while many sentences are not coded at all. These codes are used to build taxonomy of the laboratory challenges by categorization and sub-categorization as per the challenges conceptual framework hierarchy.

Table 1: Institutions Profile as of 2015

Institution	Categorization		Location	
	Public/ Private*	Type*	State	City
1	Public	Tertiary	1	1
2			2	2
3			3	3
4		Secondary	1	1
5				3
6			3	4
7				5
8			2	6
9		Primary	1	1
10				
11				
12		Stand Alone (SA)	3	3
13				7
14			4	8
15	Tertiary			9
16	Private	Secondary	3	10
17		SA		3
18		SA	1	1

(Source: Own)

4.0 Results

The analysis of the field study information has resulted in the identification of all the level one and level two challenges identified in conceptual framework (Figure 1). Further, in total 16 of 20 level three challenges are identified and are explained below. The identification of 80% of level three challenges and 100% of level two and level one challenges using a purposive sampling approach and small sample size indicates approach feasibility and usefulness.

4.1 Sectoral Commitment

The study has identified the challenges related to sectoral commitment which can be categorized into level three challenges 'external governance' and 'external resources'. The 'external governance' challenge has been associated with inadequate political will to push for MDLS that seems affect the MDLS. Globally, studies have raised the issue related to politics in healthcare sector like policy making (Gómez & Ruger 2015), governance system (Ramesh et al. 2015) and funding (Olsen 2015).

Firstly, the concerns of poor planning has been raised as the current health system capacity is believed to be inadequate to handle greater demand of other services with increase in laboratory diagnostic services. Secondly, the current health system is found to be bureaucratic and poorly regulated. Thirdly, the policies related to laboratory funding are not considered very conducive, especially for public laboratories that could lead to limit tests, workload inequality and results quality concerns. Fourthly, the information dissemination is unequal like awareness of IPHS standards that could be beneficial for better coordination among laboratories as well as could act as a roadmap for laboratories. In another case, in absence of adequate awareness mechanism, public health institution established in an existing government institution premises, is considered as the institution only for the government employees in the premises. In another case, the laboratories' location in the hospital institutions has not been found to be user-friendly. Finally, poor staff hiring support is raised for public laboratories.

The decision-makers, other than government, namely industries and international organization have been reported to have an impact on the laboratory functioning. Industries planning and decisions have impact on the laboratories functioning as they determine the available options for the laboratories for procuring raw materials. Many times labs prefer international companies' products either due to complete solutions provision by these companies or due to no comparable alternative in national companies. International organizations determines the global roadmap which is used commonly by the national governments. World Health Organizations (WHO) test recommendations for banning serological test for Tuberculosis (Tb) has left labs to costly nested-PCR test alternative.

External resources related challenges has been associated with many issues which affect the number of test types which can be ordered by the laboratory. Firstly, non-staff

resources like electricity, cold chain, instruments are not sufficient to meet the MDLS needs. Indian healthcare market has been reported to have the challenge of missing cold chain facilities for transportation and storage (Finpro 2008). Secondly, the health sector seems to suffer from the shortage of all kinds of laboratory staff with desirable skills among doctors, lab technicians, data analyst. Garg *et al* (2012) have reported the consistent shortfall of doctors, lab technicians and other health workers in rural public health institutions (Garg et al. 2012). Further, Rao *et al* (2013) has reported poor skills of doctors at PHC level in disease management as well as diagnosis (Rao et al. 2013).

4.2 Research and Development

The study has identified the challenges related to research and development which can be categorized into level three challenges 'clinicians' or 'researchers'. Clinicians related challenges have been associated with issues regarding lack of the availability of Indian compatible test guidelines and standards. It has been reported that Indian specific normal value reference range is not available like bone density tests standards.

Researchers related challenges have been associated with the issue related to the desirable tests characteristics. Firstly, the laboratories have to use time consuming tests owing to lack of availability of low cost and high reliability test alternatives suitable for Indian scenario. Secondly, laboratories have felt that the researchers do not seem to be interested in doing research related to laboratory practical needs. Arunachalam (1998) has reported that Indian researchers focus is less towards the health areas more important for India (Arunachalam 1998).

4.3 Laboratories activities reliability outside laboratory

The study has identified the challenges related to 'Laboratories activities reliability outside laboratory' which can be categorized into level three challenge of 'response of other institutions'. This has been associated with issues related to the poor response of other units in coordinating pre-analytical steps activities. The MDLS have felt that approach of other health units regarding sample collection and transportation activities is less than desirable.

4.4 Users

The study has identified the challenges related to users which can be categorized into level three challenge of patient's demands and doctors/physicians perception. Patient demand related challenges are associated with issues of MDLS access by the patients and patient's perception. Firstly, while, the patients prefer laboratories which are easily accessible (geographically, communication and financially) and meet all their test requirements, their demand is not constant and costs of providing services is not always cheap. MDLS could make up a significant proportion of the OOP expenditure (Ranson et al. 2012). Further, it has been shown that physical distance can be an important barrier in accessing the health services owing to increased cost, time and support (Balarajan et al.

2011). In such cases, patients may require external help like physician recommendations, reimbursement policies, and insurance policies to access the services.

Secondly, the patients' perception towards the laboratory significantly drives their decision making. They may not come to a public laboratory facility because it is perceived to be catering to needs of only particular group of individuals. Awareness also plays an important role in building perception among the people and make people more cooperative with laboratory like responsibly providing samples for testing. Balarajan *et al* (2011) has also raised the issue of the behavioural factors like knowledge, awareness and perception which affect the health services utilization among the patients (Balarajan *et al.* 2011).

Physicians/Doctors demand related challenges are associated with issues of doctor's behaviour and knowledge. At one end of the spectrum, doctors are possible to have limited knowledge about various aspect of MDLS like laboratory mandates. It has been reported that public healthcare may lack awareness of newer methods of diagnosis (Finpro 2008). On the other end of the spectrum, doctors could take the benefit of organisation hierarchy and awareness of laboratory mandates could cause unintended influence on MDLS functioning. Physicians absenteeism had been reported in literature as one of the issues affecting Indian Health system (Balarajan *et al.* 2011). Finally, the communication gap between physicians and laboratories personnel can also be prevalent.

4.5 Services

The study has identified the challenges related to laboratory services which can be categorized into level three challenges of 'Services Type' or 'Quality Assurance'. 'Services type' related challenges are associated with issues of ability of the laboratory to provide maximum number of services and improve the accessibility of the laboratory. Firstly, laboratories could fail to meet their mandate regarding the number of test types that need to be provided at the facility. Secondly, they could struggle in conducting adequate awareness activities (sign boards, dress codes for the staff, awareness campaigns) to make patients aware of their presence and services provided at the facility.

'Quality Assurance' related challenges are associated with issues of inability of the laboratories to maintain the quality of facility and its output. Laboratories quality assurance mechanism could lack periodical quality checks, poor records documentation (like Standard Operating Protocols, Specimen rejection documentation), in-house produced non-standard chemicals and unsigned reports disbursement in absence of signing authority. Balarajan *et al* (2011) had also raised similar issues in Indian health sector namely high physicians absenteeism and limited working hours (Balarajan *et al.* 2011).

4.6 Work Environment

The study has identified the challenges related to work environment which can be categorized into level three challenges of 'Staff Motivation' and 'Staff Workload'. Staff motivation related challenges are associated with issues of financial compensation un satisfaction, staff shortage and laboratory funding un satisfaction. Further, in case of public laboratories, the laboratories cannot retain all the funds generated from customer services. Shewade et al (2012) have also identified the need for the institutions to be permitted retain user fees for better functioning of user fee based financing reform (Shewade & Aggarwal 2012).

Staff workload related challenges are associated with issues related to laboratory automation. Many laboratories feel the workload owing to inadequate automation or too much patient inflow. Sometimes this workload is seasonal or variable and happens in situations like mass casualty. Further, studies have reported that secondary and tertiary level hospitals have been reported to be overburdened due to poor primary healthcare facilities in urban areas (Gangolli 2005; Ministry of Health and Family Welfare 2010).

4.7 Resources

The study has identified the challenges related to resources which can be categorized into level three challenges of 'Availability of desirable resources' and 'Maintenance or Up-gradation of resources'. 'Availability of desirable resources' related challenges are associated with issues regarding the inability to develop or procure resources (working area, instruments, consumables) owing to funds constraint. Further, certain issues are associated with accessibility of the available resources like lesser working hours of the available doctors. A similar issue of limited working hours of physicians for curative services was also raised in literature (Balarajan et al. 2011).

'Maintenance or Up-gradation of resources' related challenges are associated with issues regarding instrument maintenance and consumables procurement that can be deemed as tedious process owing to bureaucracy or nature of the resource like maintaining glass based products. Indian planning commission working group (1999) has also reported that around 50% medical equipment are non-operational due to inadequate maintenance (Government of India 1999).

4.8 Governance

The study has identified the challenges related to governance which can be categorized into level three challenges of 'Functioning/operations of the Laboratory', 'Coordination with Different Institutions' and 'Organization Structure'. 'Functioning/operation of the laboratory' related challenges are associated with issues regarding poor resource management (overburdened machines), administrative activities and general operations (delayed power backup). In certain cases, no special effort is done to exclude unauthorized people from getting free of cost tests. Shewade *et al* (2012) have also

reported the weak administrative mechanism for user fee management (Shewade & Aggarwal 2012).

'Coordination with Different Institutions' related challenges are associated with several issues. Firstly, the lack of interest to interact and work with other institutions like academic institutions could result in lack of awareness of various standards like IPHS by the laboratory staff. Secondly, communication gaps could arise between laboratory and other institutions (like sample collecting and transporting institutions) or groups (like doctors). Thirdly, laboratory could create negative perceptions towards other institutions (like other laboratories) that could affect long term collaborative functioning of the laboratories. Finally, laboratory may fail to identify importance of lab activities which are not part of the pre-analytical, analytical and post-analytical steps.

Organization structure related challenges are associated with issues regarding inter-professional conflicts that could lead to blaming each other for wrong results. Further, staff at higher position could demand activities which are not the responsibility of the lab. It had been shown by Nichter (1986) that Primary Healthcare Centres in South India had instances of professional and organization role conflicts due to perceived risk of losing social status and future pay scale (Nichter 1986).

5.0 Conclusion

The assessment done in the study identified a comprehensive list of challenges known in the MDLS and taxonomy of these challenges is prepared. The study further validated these identified challenges using the exploratory field survey in various cities and states of India. The study main limitation is the inadequate sampling criteria, but, it is not considered to have very strong influence on the study output. Since, the main objective from field study is to check the possibility of existence of all the identified challenges in India. The bigger sample size can potentially help in identifying the remaining challenges. This study output creates an inclination towards the concerns of implementing existing technology and solutions in different systems without adequate understanding.

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