

Role of Diagnostic Laboratories in Healthcare – Dr. Th. Dhabali Singh

"From tasting urine to microscopy to molecular testing, the sophistication of diagnostic techniques has come a long way and continues to develop at breakneck speed. The history of the laboratory is the story of medicine's evolution from empirical to experimental techniques and proves that the clinical lab is the true source of medical authority." (Darlene Berger: A brief history of medical diagnosis and the birth of clinical laboratory. MLO; 1990)

The emergence of medical diagnostics as a practice in Manipur coincides roughly with the establishment of the Regional Institute of Medical Sciences (formerly Regional Medical College) in the year 1972. Till then, Manipur remained mostly insulated from the advances in medicine and the rapid strides in modern day diagnostic techniques elsewhere. The concept of medical diagnostics was almost non-existent then. Till as late as the fifties, disease was largely believed to be either the punishment of sins or the result of witchcraft or possession where "therapy" included prayers, penitence, ritual sacrifices and invocation of spirits.

Manipur in the health news

Manipur has always been in the news for the wrong reasons except for the achievement by its sportspersons in the national and international arena. With all its problems and odds, it seems an aberration that within such a short span of time, the state is already on the health map of India. Manipur bagged the first place for its performance in healthcare sector among small states in 2012. Another indicator of Manipur's development in health sector is the latest Sample Registration Survey (SRS) data where Manipur has the lowest infant mortality rate. This all sounds good but with a doctor-patient ratio of 1:1660, Manipur cannot be the best place to be born in unlike all the media hype. Healthcare facilities in the hills are pathetic. We have miles to go.

The rationale for quality diagnostic testing

Today laboratory is an important component in healthcare and is widely acknowledged as the seat of medicine. Most critical treatment decisions are based on laboratory results and with the advent of Information Technology and computers, people are becoming more and more health conscious. The International Diabetes Federation estimates that the number of diabetic patients in India has more than doubled from 19 million in 1995 to over 41 million in 2012. Other "lifestyle diseases" which require diagnostic and therapy interventions are also on the rise. This, against the backdrop of top killers like coronary heart diseases, lungs diseases, stroke, tuberculosis, liver diseases and cancer does not paint an encouraging picture at all.

In the developing world where infectious diseases are the major causes of death and which account for more than half of all deaths in children, an important contributing factor to the enormous burden of ill health is the lack of access to good quality diagnostic testing. If we take a closer look we will notice that in a year more than 95% of all deaths due to malaria, acute respiratory illnesses, enteric infections, HIV and tuberculosis occur in developing countries.

Early diagnosis and treatment not only reduces the risk of the patient developing long-term complications but for diseases such as tuberculosis, sexually transmitted diseases (STDs), Hepatitis and HIV, prompt treatment reduces the chances of transmission of the disease to other members of the community. Accurate diagnosis usually requires a specific diagnostic test, often involving access to a diagnostic laboratory. In settings where access to diagnostic laboratory services is limited, WHO recommends the use of a syndromic approach to clinical management, where patients presenting with a particular syndrome are treated for all of the major causes of the syndrome. A major

disadvantage of this approach is the risk of giving inappropriate treatment and the accompanying potential for inducing antibiotic resistance.

Role of diagnostic laboratories in disease control

Good quality diagnostic tests are of prime importance in effective disease control and reducing the burden of infectious diseases. The choice of which diagnostic test to use will mostly depend upon the treating clinician's judgement about its appropriateness and on the availability of approved tests in laboratories nearby.

It is a fact that all patient samples start deteriorating from the moment samples are drawn, hence, it is always advisable to process these samples for testing in a nearby laboratory within the shortest possible time. If this is not possible, then the samples need to be preserved under strict optimum conditions before testing.

Diagnostic tests have crucial role in supporting clinical decisions and in patient management where they are used to confirm or rule out a diagnosis in symptomatic patients. For asymptomatic cases or non-specific symptoms, diagnostic tests are used to screen individuals to prevent the spread of a disease in the community. Diagnostic tests are also often used in epidemiological studies and drug resistance surveillance.

The medical diagnostics sector – regulations and accreditation

In the recent times, the absence of strict regulatory environment has led to the mushrooming of large number of small laboratories with limited facilities. The diagnostics market in India is largely unorganised and this unorganised sector constitutes a major portion of the industry. At present, there are no well-defined established set of criteria in terms of qualification, infrastructure or equipment for setting up a laboratory. Of the almost 60,000 diagnostic laboratories in the country, only about 200 of them are accredited. The **National Accreditation Board for Testing and Calibration Laboratories (NABL)** is the sole accreditation body with the criteria assuring accuracy, reliability and conformity of the tests results. The diagnostics landscape is expected to change in the coming years with registration and quality compliance mandatory for laboratories and diagnostic centres under the National Clinical Establishment Act, 2010. At present, the absence of strict regulations for setting up diagnostic laboratories is a major area of concern which has the potential to further accentuate the problem of the chaotic and largely unorganised health sector.

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