

National essential diagnostic list (NEDL)

August 20, 2019

Source: *The Hindu*

Manifest pedagogy:

Reforms in health is a topic which needs continuous updating. Students need to have a holistic idea to write good answers. It is desirable to read all health articles at once by students which are posted on Manifest-11 since beginning

In news:

- India has got its first National Essential Diagnostics List (NEDL) finalised by the Indian Council of Medical Research (ICMR)

Placing it in syllabus:

Paper-1 Society

Current dimensions:

- Problems faced by India in diagnostics
- What is National essential diagnostics list?
- How will it solve problems in diagnostics?

Content:

NEDL aims to bridge the current regulatory system's gap that do not cover all the medical devices and in-vitro diagnostic device (IVD)

Problems faced by India in diagnostics:

In India, diagnostics (medical devices and in vitro diagnostics) follow a regulatory framework based on the drug

regulations under the Drugs and Cosmetics Act, 1940 and Drugs and Cosmetics Rules 1945. Diagnostics are regulated under the regulatory provisions of the Medical Device Rules, 2017. The diagnostic laboratories sector is highly fragmented with standalone centres accounting for 45-50% of the market and organized ones having a 25-30% shares. Hospital-based diagnostic centres account for the rest. Their core problems are:

1. *Monopoly* – Most pathology labs have monopolies in their geographic locations.

There is no stratification of labs and there is a lack of awareness among the people.

2. *High competition* because of low entry barriers amid lack of regulations continues to be a challenge for large diagnostic chains such as Dr Lal Pathlabs Ltd, Thyrocare Technologies Ltd, Metropolis Healthcare Ltd etc.. who have voluntarily got their laboratories accredited by NABL
3. *No Rate transparency* – Since there are no published rates for most path labs, the test rates could vary from 50%-200% of the actual test cost without an assurance of quality
4. Most laboratories do not offer sample collection facilities which is a pretty basic facility
5. Parliament enacted the Clinical Establishments Act, 2010, which prescribes minimum standards for facilities and services for clinical establishments, but this has to be adopted by states as health is a state subject.

So far only 10 states—Uttar Pradesh, Uttarakhand, Rajasthan, Bihar, Jharkhand, Sikkim, Mizoram, Arunachal Pradesh, Himachal Pradesh, and Assam—have implemented it, leaving a large number of laboratories unregulated.

6. National Accreditation Board for Testing and Calibration

Laboratories (NABL) is the nodal agency for accreditation of laboratories but accreditation is a voluntary process. According to details on the NABL website, 783 medical laboratories have been accredited as of 31 January, 2019. This shows less than 1% of the total laboratories are accredited.

7. NABL standards are very high and it is expensive for many labs to build and sustain the infrastructure that is required for accreditation.
8. The current regulatory systems do not cover all the medical devices and In-vitro diagnostic device (IVD)

National essential diagnostics list (NEDL):

- India has become the first country to compile such a list that would provide guidance to the government for deciding the kind of diagnostic tests that different healthcare facilities in villages and remote areas require.
- EDL has been developed for all levels of health care – village level, primary, secondary and tertiary care (from village to district level).
- Tests for each level of care have been proposed based on the utility and requirement of test at that level, infrastructure, training available or proposed to be made available through other initiatives.
- Even though WHO's EDL (first edition released in May, 2018) acts as a reference point for development of national EDL, India's diagnostics list has been customised and prepared as per landscape of India's health care priorities.
- The list also encompasses tests relevant for new programmes such as Health and Wellness Centres (HWCs) under the Pradhan Mantri Jan Arogya Yojana

Scope of NEDL:

- Both in vitro diagnostics and other diagnostic tests

- like radiology have been included.
- Test category includes a group of general laboratory tests for routine patient care and for diagnosis of communicable and non-communicable diseases.
 - These tests are grouped in categories (like Haematology; Clinical pathology; Biochemistry; Microbiology and Serology).
 - Inclusion of the diagnostic test on specific diseases selected on the basis of disease burden: Vector borne diseases (Malaria, Dengue, Filariasis, Chikungunya, Japanese encephalitis); Leptospirosis, Brucellosis, Tuberculosis, Hepatitis A, B C and E, HIV, Syphilis.
 - Certain tests have been put as desirable tests and should be included in regions or states (endemic areas) with high disease burden of that disease.
 - A guidance document on “Regulatory framework for diagnostics: National and International” has been included.
 - Information on Human Resources has been included.
 - Information on equipment required for delivery of diagnostic services has been included

How will it solve problems in diagnostics industry?

ICMR has noted the key challenges in diagnostics sector and has finalised the implementation of the NEDL:

- Adoption by States and harmonisation with local standard diagnostic protocols and treatment guidelines.
- Provision of requisite infrastructure, processes and Human Resources.
- Ensuring quality of tests including EQAS and quality control and adequate utilisation of EDL tests for making informed decisions for treatment protocols

The implementation of NEDL which has included remedies for all the challenges would enable improved health care services delivery through

- evidence-based care,
- improved patient outcomes;
- reduction in out-of-pocket expenditure;
- effective utilisation of public health facilities;
- effective assessment of disease burden, disease trends;
- surveillance and outbreak identification;
- address antimicrobial resistance crisis.