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National Essential Diagnostics List

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The Indian Council of Medical Research (ICMR) has finalised the country's first National Essential Diagnostics List (NEDL).

- India has become the **first country in the world 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.
- The **World Health Organisation (WHO)** released the first edition of essential diagnostics list (EDL) in May 2018. Even though WHO's EDL 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.
- In India, diagnostics are regulated under the regulatory provisions of the **Medical Device Rules, 2017**.
- 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**.

NEDL

- **Level of Healthcare:** NEDL has been developed for all levels of health care – village level, primary, secondary and tertiary care.
 - It builds upon the **Free Diagnostics Service Initiative (FDI)** and other diagnostics initiatives of the Health Ministry to provide an expanded basket of tests at different levels of the public health system.
 - FDI was launched in July 2015. Under this initiative, the **National Health Mission (NHM)** is supporting all states to provide essential diagnostics – laboratory and radiology at their public health facilities, free of cost.
- **Scope:** It includes a group of general laboratory tests for routine patient care and for diagnosis of communicable and non-communicable diseases.

- 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 with high disease burden of that disease.
 - It also encompasses tests relevant for new programmes such as Health and Wellness Centres (HWCs) under the **Pradhan Mantri Jan Arogya Yojana**.
 - In addition to tests, corresponding **In Vitro Diagnostics (IVD)** products have also been recommended. In vitro diagnostics are tests done on samples such as blood or tissue that have been taken from the human body
- A **guidance document on “Regulatory framework for diagnostics: National and International”** has been included.
- It also recommends **list of human resources** such as ASHA workers, lab technicians pathologists for different levels of health care as per the proposed list of diagnostics.

Importance

- Availability of quality assured diagnostics would be helpful in **optimal utilization of Essential Medicine List (EML)**.
- It will help India in achieving **Sustainable Development Goal (SDG) 3.8** i.e. Universal Health Coverage (UHC).
- Implementation of NEDL will enable **improved health care delivery** through evidence-based care, improved patient outcomes and **reduction in out-of-pocket expenditure; effective utilization of public health facilities**; effective assessment of disease burden, disease trends, surveillance, and outbreak identification; and address antimicrobial resistance crisis.
- It will also enable standardization of technology/diagnostic services and will aid in the **promotion of R&D for new appropriate and effective diagnostics** which in turn will lead to reduction in costs.

Indian Council of Medical Research

- The Indian Council of Medical Research (ICMR), New Delhi, is the **apex body** in the country for the formulation, coordination and promotion of **biomedical research**.
- It is one of the oldest medical research bodies in the world.
 - As early as in 1911, the then Government of India set up the Indian Research Fund Association (IRFA) with the specific objective of sponsoring and coordinating medical research in the country.
 - After independence, several important changes were made in the organisation and the activities of the IRFA. It was redesignated in 1949 as the Indian Council of Medical Research (ICMR) with considerably expanded scope of functions.

- The ICMR is **funded by the Government of India through the Ministry of Health & Family Welfare.**

Source: TH