

Chapter-3

Diagnostics Services

3 Diagnostics Services

Laboratory diagnostic service is required to provide effective diagnosis of the disease suffered by the patient; measure the quantum of medicines to be provided; quantify the extent of cure effected; identify the medical sensitivities of the patient to avoid wrong medication resulting in adverse effects; and to extend the research and development capabilities of the medical process. The IPHS envisage that each district hospital laboratory should be able to perform all tests required to diagnose epidemics or important diseases from the viewpoint of public health.

The audit findings relating to diagnostic services are discussed in the succeeding paragraphs:

3.1 Radiology services

Adequate availability of functional radiology equipment, skilled human resources and consumables are the key requirements for the delivery of quality radiology services.

3.1.1 Availability of radiology services

IPHS 2012 prescribe radiology services for the district hospitals (X-ray, Ultrasonography and CT scan, etc.). Audit observed that the full range of prescribed radiology services was not available in the test checked hospitals. The details of availability of radiology services in the test checked hospitals are given in the **Table-16** given below:

Table-16: Availability of Radiology Services in test checked hospitals

Imaging Services		Availability of Radiology Services					
		DH		JH		DFH	
		Almora	Haridwar	Udham Singh Nagar	Chamoli	Almora	Haridwar
X-ray	500 MA ¹	No	No	No	No ²	No	No
	300 MA	No	No	Yes	Yes	No	No
	100 MA	Yes	Yes	No	No	No	No
	60 MA	No	No	No	No ³	No	No
Dental X-ray		Yes	Yes	Yes	No ⁴	No	No
Ultrasonography		Yes	Yes	Yes	Yes	No ⁵	No
CT scan		No	No	No	No	No	No
Mammography		No	No	No ⁶	No	No	No

Source: Information provided by test checked hospitals.

It can be seen that CT scan and Mammography services were not available in any of the test checked hospitals. Absence of radiology services in the above-mentioned hospitals

¹ Provided as per need.

² Machine (500 MA) not functional since 2015.

³ Machine (60 MA) not functional since 2015.

⁴ Non-functional since June 2013.

⁵ A Radiologist from DH Almora visited once a week.

⁶ Mammography machine was non-functional since April 2014.

was mainly due to non-availability of required radiology equipment and/or due to want of full time skilled human resources as detailed in the **Table-17** given below:

Table-17: Reasons for non-availability of radiology services

Name of radiology service	Category of hospital where service was not available	No. of hospitals	For want of Equipment	Post not sanctioned
X-ray	DFH	02	02	00
Ultrasonography	DFH	02	01	01
CT Scan	DH/JH	04	04	00
	DFH	02	02	00
Mammography	DH/JH	04	04	00
	DFH	02	02	00

Source: Information collected from test checked hospital.

For running Ultrasound Sonography machine in DFH Almora, a Radiologist from DH Almora was attached for operating this facility, once in a week. Details of Ultrasonography done in last five years in DFH, Almora are given in the **Table-18** below:

Table-18: Ultrasonography done in last five years in DFH Almora

Year	2014-15	2015-16	2016-17	2017-18	2018-19	Average Ultrasonography done per visit (day) ⁷
Ultrasound done	1,618	1,796	1,293	1,976	1,642	32

Source: Holistic Report, PNDT report and register maintained for weekly ultrasound at workplace.

Keeping in view the huge patient turnout for ultrasound, as detailed in the table above, no concrete initiative was taken by the DFH to get a radiologist post sanctioned and to provide regular facility, for which the patients had to be referred to DH Almora. Besides, Ultrasonography service was not available in DH Haridwar since March 2019 due to the machine becoming non-functional. It was also noticed that Annual Maintenance Contracts of the available radiology equipment were not done by any of the test checked hospitals⁸.

Further, IPHS prescribed three types of X-ray machines of varying penetration and radiation levels for different radiological investigations. It was observed that all the required X-ray machines for varying penetration and radiation levels were not installed in any of the test checked hospitals. Apart from DH Almora, the requirement was not even forwarded by other test checked hospitals to Director General, Medical Health and Family Welfare (DGMH & FW) despite instruction issued by the DGMH & FW (April 2018) to all hospitals to work out their requirements, as per IPHS, and forward the demand accordingly.

The absence of full range of radiology services, therefore, impacted the efficiency and appropriateness of the level of care to be offered in district hospitals as per IPHS.

In the Exit Conference, the Government assured that the district hospitals would be provided with radiology services as per IPHS.

⁷ Total ultrasound/ {52 (weeks) x 5 (years)}.

⁸ Except DH Almora.

3.1.2 Operation of X-ray machines without license

As per Section (3) of Atomic Energy (Radiation Protection) Rules 2004, license from Atomic Energy Regulatory Board (AERB) is necessary for establishing X-ray and CT Scan units.

Audit observed that none of the test checked hospitals, where X-ray services were provided, had obtained requisite license during the period 2014-19 from the AERB. No initiative was taken by the district hospitals to obtain AERB certificate. It was only after the instructions issued (June 2018) by the DGMH & FW that the district hospitals applied for obtaining the AERB certificate. The registration was awarded after March 2019 to three⁹ out of four hospitals where this service was available. In the absence of AERB certificate, the test checked hospitals not only violated the prescribed regulatory requirements but also compromised the safety of patients and staff in the Radiology departments of these hospitals.

3.1.3 Thermoluminescent dosimeters (TLD) for Radiation Protection

TLD badges¹⁰ are used to detect radiation at levels that can be harmful to humans. All the staff working in the X-ray room have to wear monitoring equipment such as TLD badges and pocket dosimeters. As per Atomic Energy (Radiation Protection) Rules, 2004 and AERB Safety Codes, monitoring equipment shall be provided to radiation workers and dose records shall be maintained. In case of any institution violating the prescribed regulatory requirements, AERB is empowered to suspend/modify/withdraw the licence/registration issued to the X-ray installation or seal the X-ray installation(s) in accordance with Rule 10 and 31 of the Atomic Energy (Radiation Protection) Rules, 2004 respectively.

It was observed that the monitoring equipment were not provided to the technicians of the X-ray room during the period 2014-19 in three¹¹ out of four test checked hospitals where X-ray services were available. The safety of these technicians was therefore, compromised.

In the Exit Conference, the Government stated that instructions would be issued to all district hospitals to provide TLD monitoring equipment to the technicians.

3.2 Pathology services

Pathology services are the backbone of any hospital for extending evidence based health care to the public. As in the case of radiology services, availability of essential equipment, reagents and human resources are the main drivers for the delivery of quality

⁹ DH Almora, DH Haridwar and JH Udham Singh Nagar.

¹⁰ Thermoluminescent dosimeters or TLDs are made from materials that measure cumulative exposure to ionizing radiation. They are worn for periods of approximately three months and are then processed to determine the dosage of radiation detected. TLD badges are logged to maintain cumulative records of an individual's exposure to radiation over an extended period of time. TLD badges include several types of Thermoluminescent dosimeters, devices that can measure doses as low as millirem.

¹¹ DH Haridwar, JH Chamoli and JH Udham Singh Nagar.

pathology services through in-house laboratories. The audit observations related to these services have been discussed in the succeeding paragraphs:

3.2.1 Availability of pathology services

IPHS prescribe 70 types of pathological investigations in the categories of clinical, microbiology, serology and biochemistry to be carried out in the district hospitals.

Audit observed that the pathology services in the test checked hospitals were provided through in-house laboratories. However, full range of desired pathological investigations was not available in any of the test checked hospitals. The summarised position in terms of percentage of services provided under each category of pathology services is given in the **Table-19** below:

Table-19: Pathology services offered by test checked hospitals (in per cent)

Types of pathology services (no. of tests prescribed)	Hospitals with per cent shortfall				
	1 to 25 per cent	26 to 50 per cent	51 to 75 per cent	76 to 99 per cent	100 per cent
	DH/JH				
Clinical pathology (29)	02	02	00	00	00
Pathology (08)	00	00	00	02	02
Microbiology (07)	01	00	00	00	03
Serology (07)	00	03	01	00	00
Biochemistry (19)	00	02	02	00	00
	DFH				
Clinical pathology (29)	00	00	00	01	01
Pathology (08)	00	00	00	00	02
Microbiology (07)	00	00	00	00	02
Serology (07)	00	00	01	00	01
Biochemistry (19)	00	00	00	00	02

Source: Information provided by test checked hospital.

None of the desired investigations under the categories microbiology and pathology was carried out in five¹² and four¹³ test checked hospitals respectively.

Various important pathology and clinical pathology investigations were not available in test checked hospitals such as Cytology to examine the behaviour of cells under microscope; Bone marrow aspiration to check the levels of White Blood Cell/Red Blood Cell (WBC/RBC) platelets; Immuno haematology to detect antigen in blood; Coagulation disorders to check the blood clotting disorders; Thalassemia to check the inherited blood disorders; Leptospirosis to detect zoonosis, Brucellosis to detect the Brucellosis bacteria in blood; and ELISA test for HB to measure Hemoglobin/Hepatitis C Virus (HB/HCV) infection in blood. Besides, investigations in the categories of serology and biochemistry were also partially carried out by all test checked hospitals. Various important tests under Biochemistry which were not carried out by test checked hospitals were serum phosphorous to know the level of phosphorous in blood; serum magnesium to know the level of magnesium in blood; and Thyroid to check the working of Thyroid gland, *etc.* As such, the provision of evidence-based treatment remained largely unachieved.

¹² DH Haridwar, JH Udham Singh Nagar, JH Chamoli, DFH Almora and DFH Haridwar.

¹³ DH Almora, JH Chamoli, DFH Almora and DFH Haridwar.

In the Exit Conference, the Government assured that availability of full range of desired pathological investigations would be taken care of, as per IPHS, in due course of time.

3.2.2 *Essential resources*

Equipment: IPHS prescribe 60 essential pathology equipment for the district hospitals depending upon their bed capacity.

Audit observed that all the essential equipment was not available in the test checked hospitals and the shortage ranged from 48 to 78 *per cent*. Various critical equipment such as Chemical balance; Glycosylated Haemoglobin meter; Hot plates; Paediatric Glucometer/Bilirubino meter; Blood gas analyser; Floatation bath; and Cyto spin were not available in any of the test checked hospitals.

Human resources: Pathologist and Laboratory Technicians (LTs) are the key personnel for in-house laboratories and are responsible for taking samples and carrying out all prescribed pathological investigations and validation of test reports. As per IPHS, district hospitals should have one to four Pathologists and six to 18 LTs depending upon their bed capacity.

Audit observed that pathology service was not available in DFH Almora. In other five test checked hospitals limited pathology services were available. However, the post of pathologist was not sanctioned in DFH Haridwar and in three¹⁴ other hospitals, the pathologist post was kept vacant for a period ranging between one and three years. It was also observed that the availability of manpower in the test checked hospitals was not in consonance with IPHS. Even the existing vacancies of LTs against the sanctioned strength were not filled in JH Udham Singh Nagar and JH Chamoli where there was a shortfall of 40 *per cent* and 80 *per cent* respectively.

The Department, therefore, failed to augment the strength as required in accordance with the IPHS. It did not even fill the existing vacancies against the sanctioned strength.

In the Exit Conference, the Government assured that shortage of equipment and manpower in the pathology laboratory would be taken care of, as per IPHS.

3.2.3 *Quality Assurance of pathology services*

IPHS provide that pathological tests performed by hospitals shall be validated by External Quality Agency on a regular basis.

It was noticed that none of the test checked hospitals carried out the validation of pathological tests performed by them during 2014-19. The hospitals, therefore, failed to ensure quality assurance of the pathological services provided by them.

In the Exit Conference, the Government assured that validation of pathology test from External Quality Agency would be taken care of, as per IPHS.

¹⁴ DH Almora, DH Haridwar and JH Chamoli.

3.2.4 *Waiting Time and Turn-around Time*

Time taken in receiving samples from the patients for investigations *i.e.* Waiting Time (WT) and time taken in getting the investigation done and reporting the results to the patients *i.e.* Turn-around Time (TAT), reflects the overall efficiency of the diagnostic services, in terms of patient satisfaction.

Audit observed that the doctors prescribed the tests/investigations over the patients' prescription slip. The patients were registered in the pathology departments for the procedures, based on the recommendations given by the doctors.

Scrutiny of the records of the pathology department revealed that none of the test checked hospitals maintained the records related to number of pathological investigations suggested by the doctor to the patient. Besides, in the registration registers, the date of recommendation by the doctors was not mentioned. In the absence of this vital information, the time lag (WT) between the date of recommendation for investigations by the doctors and actual registration in the radiology and pathology departments was not ascertainable. Further, in the absence of the test indent forms in pathology department of the test checked hospitals, it was also not ascertainable whether all tests/investigations were performed by the hospitals. Besides, no records were maintained in any of the test checked hospitals regarding the TAT in respect of pathological investigations performed during 2014-19.

To sum up, the provisioning of diagnostic services in the test checked hospitals was sub-optimal, marred by inadequacy of prescribed equipment and shortage of human resources, thus depriving patients of evidence-based treatment procedures.