Hannah E, Basheer N, Dumka N, Kotwal A. Understanding what really helps to ensure access to diagnostic services in the Indian Public Health System: a realist synthesis of the Common Review Mission reports (2007-2021). *Journal of Global Health Reports*. 2023;7:e2023035. doi:10.29392/001c.77888

Research Article

Understanding what really helps to ensure access to diagnostic services in the Indian Public Health System: a realist synthesis of the Common Review Mission reports (2007-2021)

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Keywords: Access to Diagnostic Services, Health Systems Strengthening, National Health Mission, India, LMIC

https://doi.org/10.29392/001c.77888

Journal of Global Health Reports

Vol. 7, 2023

Background

In India, the National Health Mission (NHM) has been supporting the states in building an integrated public healthcare network across the levels of care. This effort has improved access to, and utilization of, diagnostic services at public healthcare facilities. To continually enhance citizens' ability to seek and avail quality and affordable services, it is imperative to take stock of various components of the diagnostic ecosystem that may be common or unique to states and understand their influence on equipping the health system. The objective of the study was to understand key health system factors augmenting or limiting access to diagnostic services and outcomes.

Methods

Common Review Mission (CRM) reports between 2007 and 2021 were selected for the study. Data relevant to diagnostic services were retrieved using defined search terms. The data were segregated for each Indian state and categorized under the pre-determined themes: state-specific practices, key findings, and challenges. Analysis of the data was done iteratively to identify the themes emerging from the reports over the years. Each theme was analysed further to deduce context-specific enablers and barriers influencing access to diagnostic service delivery.

Results

The major themes that emerged include (i) the approach to health systems strengthening, (ii) efficiency of procurement and distribution systems, (iii) infrastructure, (iv) modes of service delivery, (v) implementation of Free Diagnostic Service Initiative, Comprehensive Primary Health Care and Biomedical Equipment Management and Maintenance Program, and (vi) quality of care , and (vii) diagnostic service outcomes.

Conclusions

In a complex adaptive system, access to diagnostic services depends on the concurrent strengthening of various health system components across the levels of care. The nation has strategized accessible, affordable and acceptable diagnostic services to achieve universal health coverage and care-continuum pathways. States need to leverage the existing mechanisms, assess their implementation, and arrive at feasible and sustainable solutions to strengthen access to diagnostic services.

Access to affordable and quality diagnostic services is crucial for population health, given their guiding role towards measures to improve health outcomes. While the availability of diagnostic services has been one of the key components under National Health Mission (NHM), several constraints in access have been identified as barriers to patient assessment and management[1] leading to empirical treatment, patients switching between providers or even opting out of care.[2] This reiterates the need for accessible, affordable and acceptable diagnostic services to achieve desired population health outcomes through universal health coverage (UHC) and care-continuum pathways.

In India, the NHM (erstwhile National Rural Health Mission), launched in 2005[3] is the prime vehicle for UHC, considering its role in shaping the public healthcare system. NHM has been instrumental in supporting the states in

building an integrated network of primary, secondary and a substantial part of tertiary care to provide care-continuum.[3,4] To review and track the progress under NHM, various monitoring mechanisms are put in place. One such activity is the 'Common Review Mission' (CRM), undertaken annually since 2007 for gauging states' experiences and challenges, for mid-course corrections and program strengthening. The CRM reports are important knowledge resources enabling status assessments of several health system domains within and across Indian districts and states.

Over the years, CRMs have highlighted the improved availability of diagnostic services and their role in enhanced public health service utilization. However, household expenditure in diagnostics[5] suggests extensive efforts and financial implications for users. A study analysing India's health consumption data estimated that diagnostic tests accounted for approximately 10% to 15% of Out of Pocket Expenditure (OOPE) on healthcare. The mean OOPE incurred by the patients on diagnostics was $74.7 ($68.0-$81.3) for inpatient services and $37.9 ($37.0-$38.8) for outpatient services. Whereas, at the public hospitals, it was $11.8 ($10.5-$13) and $22.4 ($17.6-$27.2) for inpatient and outpatient services, respectively.[6] To enhance citizens' ability to seek and avail quality and affordable services, it is important to take stock of various components of the diagnostic ecosystem that may be common or unique to states and understand their influence on equipping the health system. Hence, a realist synthesis of the CRM reports was done to understand the key health system factors augmenting or limiting access to diagnostic services, and service outcomes thereof.

METHODS

The key question of the review was: What factors influence access to diagnostic services in the Indian Public Health System? Specific questions were: What are the key health system factors that serve as enablers and barriers; and what are the resultant service delivery outcomes due to their interplay?

SOURCES

Common Review Mission (CRM) reports between 2007 and 2021 retrieved from the public domain were used.[7]

SELECTION

Data were retrieved using the search terms: *health system(s), infrastructure, procurement, logistics, human resources, services, diagnostics, laboratory, comprehensive primary healthcare, point of care testing, free diagnostic service initiative, biomedical equipment, user fees/charges, essential diagnostic list/EDL and quality of care*. All reported findings related to diagnostic service delivery were iteratively identified by the authors.

EXTRACTION

The data were segregated for each Indian state and were categorized under the pre-determined themes namely: *state-specific practices, key findings, and challenges*. The exercise was done for all reports during which the aptness and relevance of information under the categories were validated on the consensus of the authors.

ANALYSIS AND SYNTHESIS

Analysis of the data was done iteratively to identify the themes emerging from the state reports over the years. The major themes that evolved inductively were: the approach to health systems strengthening, efficiency of procurement and distribution systems, infrastructure, modes of service delivery, implementation of the Free Diagnostic Service Initiative, Comprehensive Primary Health Care & Biomedical Equipment Management and Maintenance Program, quality of care and diagnostic service outcomes. Each theme was further analysed to deduce contextualized enablers and barriers that influenced access to diagnostic service delivery. The findings were appraised for relevance and recent reports of the states were compared with the earlier ones to identify changes and their contextual underpinnings. Given the considerable heterogeneity in the field findings due to contextual and geographical variations across the states, a realist synthesis was done to summarise the results.

RESULTS

THE APPROACH TO HEALTH SYSTEMS STRENGTHENING (HSS)

Availability and access to diagnostic services are integral to an efficient health system. In the context of a complex adaptive system, it is plausible to posit that access to diagnostic services depends on the concurrent strengthening of various health system components spanning the supply chain, infrastructure, service delivery, and human resources across the levels of care.

In the initial years of NHM (2005-12), states adopted varied approaches for health systems strengthening focusing on levels of care, depending on the health systems maturity, and ability to absorb and utilize NHM funds in state and district planning processes. Piecing together HSS approaches and their resultant outcomes in service delivery, it could be inferred that states adopting strategies encompassing all levels of care simultaneously experienced expedited narrowing of service delivery gaps, including diagnostic services, which in turn incentivized service utilization and demand generation. Whereas, inadequately equipped primary or secondary-level facilities for service delivery overburdened the district hospitals, constraining access to diagnostic services across levels of care.

THE EFFICIENCY OF PROCUREMENT AND DISTRIBUTION SYSTEMS

Procurement and distribution systems occupy the centre stage in managing the supply chain as they determine the availability, cost, and quality of materials as well as the responsiveness and flexibility of healthcare organizations in meeting end-user needs and expectations.[8,9] In India, procurement of medicines and diagnostics is channelized through state-specific procurement and distribution systems, coordinated through autonomous bodies, state government-owned agencies, or state government procurement division/cell. Given the varying complexities of diagnostic technologies, the centralized procurement bodies or divisions are alone empowered to procure high-end equipment for States. However, there is near-universal flexibility for districts and facilities for emergency local purchasing of diagnostic paraphernalia using untied funds or rural/ urban local body grants.

States with a procurement policy, centralized and demand-based procurement system, computerized inventory management systems and decentralized distribution channels such as regional or district warehouses have reported better availability of diagnostic products and consumables. A well-defined procurement and distribution system with integrated quality assurance mechanisms improves the quality of products, decreases wastage, and improves governance and overall cost-effectiveness. Barriers to both availability and rational distribution of diagnostic products and technology for services in states, especially in the north-eastern region, are majorly attributable to the challenges pertaining to state-level contracts, district-level supply chain mechanisms and coordination with suppliers for equipment management.

INFRASTRUCTURE

Infrastructural requirements for diagnostic services include functional healthcare facilities, functional spaces for lab and diagnostic services, adequate and appropriate technology, and digital infrastructure. The presence and ability to leverage infrastructure for diagnostic services will influence provider interactions, service delivery, users' treatment-seeking experiences, and outcomes.

HEALTHCARE FACILITIES

Service availability and utilization intrinsically depend on physical access to healthcare facilities. Key facilitating factors for states to establish adequate facilities within accessible limits are good baseline infrastructure, geographical accessibility, availability of land/spaces for the establishment, financial sufficiency, and a degree of administrative control over civil works.

FUNCTIONAL SPACES

Within healthcare facilities, the quality of diagnostic services is further enhanced when there are dedicated spaces for laboratories as per the Indian Public Health Standards (IPHS). Access to services is reported better when available spaces are rationally utilized by integrating diagnostic services under disease control programmes (e.g., Tuberculosis, Vector-Borne diseases, HIV/AIDS, disease surveillance, and Non-Communicable Diseases).

States with strengthened primary care with integrated services have relatively streamlined referral networks for care-escalation, as well as for public health surveillance. However, inter alia, delay in operationalization of functional spaces or service integration has been attributed to space-related constraints, shortfall in amenities (power/ water supply), first referral units at sub-district level (CHCs, SDHs), and delay in the rollout of sanctioned district public health labs.

DIAGNOSTIC TECHNOLOGIES

Infrastructural functionality needs appropriate diagnostic technologies, which requires states' awareness of their technological needs and availability. In addition to efficient procurement and distribution pathways, novel and cost-effective diagnostic technologies too drive programmatic changes. The introduction of Rapid Diagnostic Kits (RDK) at the primary level and CBNAAT machines for integrated vertical programmes are notable examples. With the roll out of comprehensive primary healthcare (CPHC), point of care testing has expanded, with their utility and service delivery being intricately linked with infrastructural, human resource, community level, and programmatic factors. For example, under-utilization of diagnostic technology has been reported due to reasons such as irrational procurement, space constraints, lack of power and water supply, lack of skilled manpower, high rate of equipment failure, challenges in acceptability and community interferences in the form of vandalism or theft. This underscores that technological availability is necessary but alone insufficient for the functionality and utilization of diagnostics services.

HUMAN RESOURCES FOR HEALTH (HRH)

While infrastructure is an essential requisite for diagnostic services, their optimal utilization to deliver quality services depends on a skilled workforce. Multifarious strategies have been rolled out across states for the positioning of skilled HRH to meet differential requirements at each level of care. While the states have indeed come a long way in narrowing down the requirement gaps, the rate of progress has been variable. Flexible staffing norms/ policies, good coordination between the Directorate of Health Services and NHM, and pragmatic mechanisms for selection, competency assessment, and deployment of skilled personnel have been found beneficial to address HRH concerns. Further, their retention relies on reasonable production capacity, conducive environment, job stability of contractually hired staffs, systematic-cum-responsive training systems and efficient financial disbursement practices.

Ad-hoc arrangements like irrational deployment and inter-district or inter-programme movement of trained HRH tend to offset sustainable positioning of skilled personnel. Experiences accrued over time suggest that sustainability

and progress depend on gradually transitioning from interim strategies to structured mechanisms supporting HRH. For instance, multi-skilling or task-sharing for diagnostic services needs to be supported with active recruitment and adequate supplies of diagnostic paraphernalia to aid the personnel for both conventional and up-skilled roles. Deployment, sanctioning or creation of new posts (lab technicians, staff nurses, specialists, radiographers) must be demand-responsive than normative placements. The state's domestic training capacity must complement existing capacity-building initiatives of the service providers to meet the training load with desired quality and outputs.

MODES OF SERVICE DELIVERY

Under NHM, diagnostic services across public health facilities are being provided through in-house and/or Public-Private Partnership (PPP) arrangements. States' ability to strengthen their in-house capacity stems from a combination of factors including strengthening of facilities, geographic accessibility, adequate manpower, financial adequacy, and provision of assured diagnostic service packages across the levels of care.

Earlier the states facing constraints in delivering in-house services have forged PPP arrangements for laboratory and diagnostic services such as pathology, imaging services, etc. Now, it is being done irrespective of functional in-house laboratories. Reported challenges in PPP arrangements include poor contract management, the overlap between in-house and outsourced services; inadequate oversight and monitoring of service quality, compliance with terms, and financial flow. In hilly and north-eastern states, outsourcing diagnostics did little in improving access to care. Observations from states highlight that the shift towards PPP mode inadvertently hamper in-house service delivery, reflecting the need for strengthening in-house capacity.

For under-served areas, Mobile Medical Units (MMUs) have been operationalized to supplement the reach of specialists and diagnostic services. Challenges in diagnostics services through MMUs can be attributed to hindrances in overall service delivery. Factors such as vehicle type, irregular visits, HR shortage, limited utilization of high-end equipment, long down-time of equipment, abrupt service cessation due to non-renewal of contracts or legal proceedings with private partners, lack of microplanning, limited range of services, irrational distribution of vehicles, and inadequate referral linkages affect the MMUs functionality.

FREE DIAGNOSTIC SERVICE INITIATIVE AND COMPREHENSIVE PRIMARY HEALTH CARE

Until 2015, a few states and all union territories pioneered the provision of free diagnostic services. The rest levied user fees for generating funds, or cross-subsidizing free medicines. Targeted population sub-groups were provided free diagnostic services (e.g., BPL, Elderly, pregnant women, children, and financial support scheme beneficiaries). Regardless, the range of free or paid services was highly variable and often inadequate to needs. Variability in health system capacities and requirements thwarted states from committing to an assured package of diagnostic services at healthcare facilities.

Recognizing the need to strengthen mechanisms for universal access to quality diagnostic services in public health facilities, the Free Diagnostic Service Initiative (FDSI) was launched in 2015 to ensure a broader range of diagnostic and imaging services delivered free of cost.[10] NHM developed mechanisms to incentivize the states to adopt free diagnostic policy and formulate an assured minimum package of services at each level of care to ensure comprehensive healthcare. The programme leverages the existing institutional structures for its implementation, including the strengthening of in-house capacities for service delivery.[10] This was further strengthened through Comprehensive Primary Health Care (CPHC) rolled-out through Ayushman Bharat- Health and Wellness Centres (2018)[11] to provide an expanded range of free diagnostic services at primary healthcare facilities. This has enabled states to become better positioned to provide an assured package of free diagnostic services and point-of-care testing. Experiences from states pioneering in providing free diagnostic services suggest that states with a pre-existing policy and programme on free diagnostic services have a quicker adoption and customization of FDSI for robust implementation.

Although NHM has expanded the range of diagnostic services, long-standing systemic issues delay the translation of policies. Gaps in program implementation are found to affect population coverage, range of services, cost-efficiency, and quality of care.

BIOMEDICAL EQUIPMENT MANAGEMENT AND MAINTENANCE PROGRAM (BEMMP)

Maintenance and repair of diagnostic and laboratory equipment are essential for service continuity. BEMMP is an initiative to support state governments to outsource medical equipment maintenance comprehensively for all facilities and thereby improve the functionality and life of the equipment. States with purchase and equipment maintenance policies overseen by centralized procurement bodies widely practiced the incorporation of annual or comprehensive maintenance contracts (AMC/CMC) with the suppliers. Further, few states mapped equipment across facilities for maintenance, operationalized equipment management software (e.g., e-Upkaran) and took on technical experts (e.g., biomedical engineers) for in-house maintenance and repairs. These arrangements were identified to bolster inventory management, systematic calibration and equipment maintenance, reduce turnaround time for repairs, and allowed tracking of equipment downtime. In the absence of this, equipment upkeep with minimal downtime has been a challenge, rendering 30-60 percent of equipment non-functional especially in remote locations. To address these challenges, BEMMP was launched in 2015 to supplement FDSI, reduce the cost and improve the quality of care.[12]

Over the years, it has been noted that states with BEMMP or similar channels were able to institutionalize mechanisms to track non-functional equipment, undertake preventive and corrective maintenance, build capacity and

operationalize tollfree numbers for lodging complaints. These mechanisms have reportedly expedited the redressal of long pending maintenance and repair works.

However, the effectiveness of this programme depends on the presence of a condemnation policy, Standard Operating Protocols (SOPs), consistency in digital and physical records of assets, as well as functional monitoring and feedback systems. Likewise, its role in ensuring continuity of diagnostic services primarily depends on their coverage to the peripheral level, timely registration of complaints, presence of responsive grievance redressal or tollfree helpline, and availability of in-house technical expertise (biomedical engineers/ managers).

QUALITY OF CARE

Quality of Care has been defined as "the degree to which health care services for individuals and populations increase the likelihood of desired health outcomes and are consistent with current professional knowledge."[13] Evidence and need-based services are essential for quality health services to be considered effective, safe and people-centred.[14] Essential testing is the first step towards ensuring the quality of care, which is integral to the goals of NHM and UHC. It helps reduce costs, unwarranted drug use or empirical patient care by facilitating thorough assessment, detection of asymptomatic and co-existing conditions, appropriate and timely treatment, referral, follow up and treatment adjustment as needed. It bears the potential to act as a driver of population health, catalyzed by increased health systems utilization in response to the growing burden of complex conditions.[1,15] Alternatively, compromised diagnostic services result in missed diagnoses and inappropriate and unsafe treatment often resulting in poor health outcomes, financial burden and loss of trust in the healthcare system.[13]

In view of major dimensions of care-quality such as patient safety, effectiveness, patient-centeredness, timeliness, efficiency and equity- a quality assurance system comprising all operations and service delivery at the facilities has been rolled out nationally.[16] It encompasses the constitution of state/district-quality assurance committees, implementation of internal and external quality assurance systems, laboratory accreditations, lab test validations, and compliance of radiology departments to Atomic Energy Regulatory Board (AERB) statutory requirements. Quality improvement initiatives subsume real-time tracking through laboratory information management system (LIMS), capacity building on Infection Management and Environment Planning (IMEP) and biomedical waste management (BMW) protocols, periodic documentation and analysis of key performance indicators and patient-satisfaction feedback.

States' engagement with quality systems has been variable, attributable to systemic inputs and health system maturity at the meso levels. At the field level, provider and community awareness are observed to have far-reaching roles in ensuring quality and accountable services. The shortfall in delivering quality diagnostic services is observed to be linked to delayed implementation and insufficient awareness of the updated essential diagnostic list (EDL), standard treatment guidelines, and programmatic requirements for quality assurance. Time differentials in the rollout of relevant programmes on diagnostic services and excessive prioritization of RCH services (e.g., JSY) also seem to affect awareness and service delivery. Though public healthcare facilities are supported for the comprehensive integration of quality assurance mechanisms, there is a pressing need for sustained attention.

DIAGNOSTIC SERVICE OUTCOMES

Utilization, financial implications and health outcomes are the conventional measures of diagnostic service outputs and outcomes. Utilization of diagnostic services is consequent upon various health system components discussed above. Additionally, service utilization also relies on provider and community awareness. Gaps in in-service orientation, skill development, change management, and IEC activities generating-community awareness of services and entitlements perpetuate under-utilization. With the reforms in service delivery like the introduction of point-of-care testing, integration of vertical programmes, and expanded coverage to peripheral facilities, service utilization has gained perceptible momentum. However, the demand generated has begun to outpace the expansion of infrastructure, human resources and supplies creating a situation of relative deprivation in some states.

While the health sector reforms intend to reduce the cost of care, financial risks follow when there is a lack of universality in the rollout and population coverage under FDSI or CPHC; limited-service delivery and diversion to private facilities co-exist; and when patients routinely have to incur out of pocket expenditure (e.g., user charges, informal fee, transport expenses) for availing services.

States when considering complete health systems strengthening than a piecemeal approach, have shown improved service outcomes such as improved case detection with satisfactory achievement of diagnostic and cure-rate targets under the programmes. Each systemic challenge, as presented above, has an overarching and negating effect on the range, affordability, quantity and quality of diagnostic services delivered through public health facilities within and across the states and facilities.

DISCUSSION

The CRM findings on laboratory and diagnostic services provide a knowledge base for comparison, cross learning and adaptation of efficient practices that are feasible within contextual boundaries. The analysis highlights both enablers and barriers (**Figure 1**) in augmenting access to diagnostic services. Redressal of barriers in different components requires focused and mutually complementing efforts.

To ensure access to diagnostic services, their availability needs to be improved through infrastructural development as well as mapping and gap-analysis across the levels of care, especially in states with a higher proportion of facil-

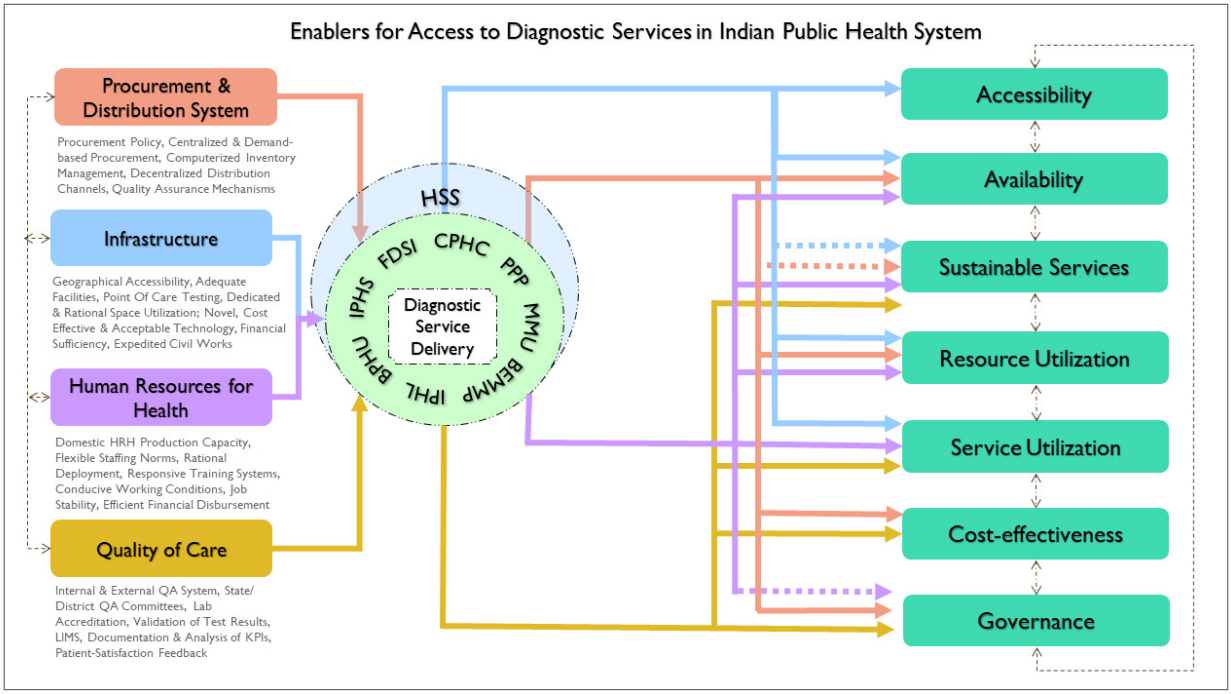

Figure 1. Enablers for access to diagnostic services in Indian Public Health System

Source. Original. **Description**. Linkages of health system factors with various components of access have been illustrated. Bold arrows indicate direct linkages and dashed lines indicate indirect linkages. Various inputs contribute to Health Systems Strengthening (HSS) efforts, including current programmes, strategies, and initiatives toward diagnostic service delivery.

Abbreviations. BEMMP- Biomedical Equipment Management and Maintenance Program, BPHU- Block Public Health Units, CPHC- Comprehensive Primary Health Care, FDSI- Free Diagnostics Service Initiative, HSS- Health Systems Strengthening, IPHL- Integrated Public Health Laboratory, IPHS- Indian Public Health Standards, MMU- Mobile Medical Unit, PPP- Public-Private Partnership

ity-shortages. Addressing the shortfall in primary-level facilities and community-health centers will ensure population coverage and service delivery through their in-house labs.

Recently, a financial impetus was provided by the 'India COVID-19 Emergency Response and Health System Preparedness Package' (ECRP I & II)[17,18] to support states in expanding their network of diagnostic laboratories and testing capacity. Additional resources through the fifteenth finance commission health sector grant and health infrastructure mission (PM-ABHIM) target to fill critical gaps in public health infrastructure in the country. The targets also include the establishment and strengthening of block public health units (BPHU), integrated public health labs (IPHL) and diagnostic infrastructure.[19,20]

The implementation status of FDSI has been illustrated in **Table 1**. The option to forge PPP should be exercised with discretion and not at the opportunity cost of strengthening the in-house facilities. As per the revised National Essential Diagnostic List, 7 tests are listed at the village level, 14 at the SHC-HWCs, 64 at the PHC-HWCs, 72 at the CHCs, 81 at the SDHs and 159 at the DHs. The NEDL recommends a substantial proportion of the listed tests be undertaken at the facility.[21] Further, the overall experience from PPP arrangements reinforces the rationale that at least high-volume low-cost services must be provided through in-house facilities.

Across public health facilities, the presence of amenities and supply chain of diagnostic products must be robust, adequate and timely for the continuity of services. The agencies supporting the procurement of diagnostic equipment and technology should provide training for the operators at the health facility to ensure maximum utilization of the resources. It is also essential to incorporate redressal mechanisms for reducing equipment downtime through BEMMP implementation. In parallel, their rational use needs to be promoted through the dissemination and implementation of process standards.

In addition to state-specific strategies to ensure HRH availability, it is imperative to have a gradual shift towards definitive institutionalization of human resources to sustain their availability in the health system. HR availability in gross numbers must proportionately reflect in terms of skilled personnel for diagnostic services, as shortfall in skill

Table 1. Implementation status of free diagnostic service initiative (FDSI)

FDSI	States/UT	In-house	PPP
Free laboratory services	36	25	11
Free CT scan	27	10	17
Free radiology services	10	10	0
Teleradiology	13	0	13

Source: e-Samiksha Report (https://esamiksha.gov.in/); as of January 1st, 2023

sets for diagnostic services would underscore the need for capacity-building measures and supportive supervision.

With newer reforms under NHM, public health facilities are now better endowed with a clear direction for providing an assured package of diagnostic services along with guidance on quality improvement and patient safety measures. As the reforms intend to build on and refine the existing programme structures, there is a need for scrutinizing programme implementation against defined processes, and identifying shortfalls and solutions that are both feasible and sustainable for the health system.

Additionally, states' change management mechanisms should be strengthened to ensure both provider and community sensitization of the services and entitlements to foster increased accountability and demand for free diagnostic services by the users.

LIMITATIONS

The Common Review Mission (CRM) undertakes rapid assessments to understand the functional status, key drivers, and challenges in the implementation of various health programs. Given the spectrum of programmes assessed within a stipulated time duration, the scope for a thorough evaluation of each program is limited. Since the CRM is a planned and recurring exercise, the state and the districts are aware of the assessment beforehand. This has often led to focused improvement of the assessment sites, which invariably influences the field reports. The scope for social desirability bias, response bias, and observer bias is a known limitation of such assessments. The review mission focuses on the supply-side factors, which predominate the results of the paper. Also, the current review may have oversimplified and subsumed some of the factors in the process of linking them to the diagnostic ecosystem.

CONCLUSIONS

The review focuses on key health system factors influencing access to diagnostic services in the Indian public health system. By placing diagnostic services within the context of a complex adaptive system, it can be appreciated that access to diagnostic services depends on the concurrent strengthening of health systems components such as procurement and distribution systems, infrastructure, service delivery and human resources across the levels of care. Each health system component has an overarching and complementing effect on enabling access to services. The nation has strategized accessible, affordable and acceptable diagnostic services to achieve UHC and care-continuum pathways. States need to leverage the existing mechanisms, assess the implementation status and arrive at feasible and sustainable solutions to strengthen access to diagnostic services.

FUNDING

This research received no specific grant from any funding agency in the public, commercial, or not-for-profit sectors.

AUTHORSHIP CONTRIBUTIONS

ND and EH conceptualized, designed and defined the intellectual content of the study. NB contributed to literature search and data acquisition. EH, NB and ND contributed to manuscript preparation, editing and review. ND and AK critically reviewed and finalized the paper. The manuscript has been read and approved by all authors.

DISCLOSURE OF INTEREST

The authors completed the ICMJE Disclosure of Interest Form (available upon request from the corresponding author) and disclose no relevant interests.

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Submitted: May 02, 2023 GMT, Accepted: June 01, 2023 GMT

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