EXECUTIVE SUMMARY

ASSESSMENT OF DIAGNOSTIC GAPS AND RELEVANT DIGITAL HEALTH SOLUTIONS IN INDIA

INTRODUCTION

This assessment identifies the priority diagnostic gaps in India and the relevant digital health solutions to address those gaps. The findings are based on interviews with 23 in-country experts that included government, implementing partners (IPs), patient advocates and digital health experts/vendors, a national-level mobile survey to 256 Indian patients[1] and desk research to validate key findings. Diagnostic gaps were identified within the context of disease burden and the diagnostic patient pathway, inclusive of pre-point of care (pre-POC) stages of health information seeking and early care-seeking, and point of care (POC) stages at the facility level, consisting of screening, diagnosis, linkage to treatment and treatment monitoring. Identified diagnostic gaps were prioritized based on their direct impact to patient health outcomes, stakeholder feedback, and the extent to which the gap affects multiple stages in the patient pathway. Relevant digital health solutions and enablers of their scale were identified based on a broad landscaping and stakeholder feedback.

COUNTRY CONTEXT AND DISEASE BURDEN

India is a lower-middle income country in South Asia, the second most populous nation in the world with 1.35 billion people, 70% of whom live in rural areas. A positive development trajectory has significantly reduced poverty and contributed to India's standing as the third largest economy globally, but the country is still home to 273 million people living in poverty.[2]

Recognizing widening gaps in healthcare access, India's government is making efforts to strengthen primary healthcare (PHC) and move towards universal health care. India's health system is underfunded, with government spending only 0.96% of its GDP on healthcare, lower than spend in other low- and middle-income countries (1.3%) and BRIC countries (3.0%).[1,3] This contributes to a lack of adequate public health services, especially in rural areas. As a result, India's population relies heavily on private health providers, with nearly 80% of care delivered through a vast private provider network.[4,5] Preference for private services, combined with a low national insurance coverage (20%), results in significantly high out-of-pocket expenditure that represents 65% of all health spend.[6,7]

Although the definition of essential diagnostic service delivery at PHC is well outlined, the highly fragmented and predominantly private provider network poses implementation challenges. The introduction of India's country-specific National Essential Diagnostics List in 2019 provides guidelines for an expanded basket of tests at different levels of the public health system[8] and efforts have been made by the government to strengthen national regulatory capacity for diagnostics. However, in practice, delivery of diagnostic services through both public and private providers operate with a wide and varying standard of quality.

DIAGNOSTIC GAPS IN THE CONTEXT OF DISEASE BURDEN

India's disease burden has shifted to one of rising non-communicable diseases (NCDs), and although communicable and maternal, newborn and child health conditions (MNCH) are declining, they still represent a significant need. Although neonatal disorders still are the leading cause of morbidity and mortality in India, communicable, MNCH and nutritional diseases dropped to 33% of the total disease burden in 2016 from 61% in 1990, while NCDs demonstrated the opposite trend, increasing to 55% of the disease burden in 2016, from 31% in 1990.[9] Urbanization, aging and rising air pollution have contributed to this growth of NCDs. The significant threat of antimicrobial resistance was also emphasized, driven by the high rate of inappropriate antibiotic use. Overall, the specific magnitude and pattern of disease burden varies greatly between different states.[10]

Insufficient government, donor and IP investment leaves an increasingly challenging and expensive need for expanded NCD diagnostics and care. Although NCDs have emerged as a strong priority for the government, the area is less established than other programme areas for communicable diseases and MNCH, which receive the most funding and implementation support. Although stakeholders concede that NCDs are the greatest current and future health need, this has not yet translated into a well-resourced and concerted effort to strengthen the related continuum of care, leaving a growing and unmet gap. To note, hypertension and diabetes are priority areas where strengthening of disease awareness, preventative measures and uptake of basic diagnostics are required. Cancers were also mentioned as an emerging priority, with substantial gaps in disease awareness and availability of appropriate diagnostic tools at all health levels.

"Health needs and donor funding are not completely aligned. Funding is directed more to communicable diseases and MNCH; now and in the next five-10 years the priority health needs are in NCDs, AMR and the infectious portfolio in the post-COVID world".

– Country Head, Implementing Partner, India

Dedicated government and partner support have contributed to declining tuberculosis (TB) prevalence, but gaps in timely case detection remain. Globally, India still contributes a quarter of TB cases and one in every four TB cases in 2018 were undetected.[11] Delayed care seeking, stigma that disproportionately affects women, a lack of access to accurate POC diagnostics and poor quality of services in the private sector were noted as key gaps to TB diagnosis. India is susceptible to rises in vector-borne diseases like malaria and dengue, due to the tropical climate, overcrowding and sanitation challenges, and lack of relevant diagnostics at lower levels of healthcare.

TB consultation at a chest clinic in New Delhi, India.

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India has made significant strides towards reducing its MNCH-related mortality rates over the past two decades, although maternal and neonatal mortality rates are still two times their respective Sustainable Development Goal targets. The greatest progress has been made in under-five mortality, which reduced 44% between 2009 and 2019 through vaccination, diarrhoea management and nutritional provision for children.[6,12] Highlighted gaps in maternal and neonatal-related diagnostics include a lack of early screening for pre eclampsia and postpartum haemorrhage, the need for early identification interventions for premature babies and/or those with low birth weight, and a lack of appropriate diagnosis of fever in young children.

DIAGNOSTIC GAPS IN THE PATIENT PATHWAY

Pre-point of care (pre-POC) stages were stated as fundamental and significant barriers to driving demand for diagnostic services. These barriers cause patients to delay engagement with the health system until they are seriously ill, as their efforts in seeking care are costly in time and money, and often unfruitful.

THE HIGH-PRIORITY PRE-POC GAPS ARE:

01 **Low awareness and health education on diseases and major symptoms.** Despite growing literacy rates, low disease awareness means that patients struggle to recognize symptoms and seek health information. This is particularly damaging for NCDs such as cardiovascular diseases and diabetes, which are often asymptomatic until late stages.

"The main problem is that people don't know what health issues they are having. They don't know about diseases and their symptoms and when disease reaches its last stage, then only people came to know about it".

– Patient survey response, India

02 **Lack of access to accurate, timely and trusted information.** Across urban and rural areas, 84% of patients surveyed most commonly seek health information from informal channels, such as the local chemist (45%), family and friends (32%) or a traditional healer or Ayurvedic doctor (7%). These sources are often not qualified and may contribute to misinformation. In line with this, better access to good quality information was the most popular answer from patients on what would most improve health services (37%), followed by better quality care (25%) and more convenient service (21%). Of those who desire better quality information the most, 61% of those who desire better quality information live in rural areas, indicating a greater need, as compared to urban areas (39%).

03 **Difficulty in navigating between care-seeking steps: when and where to seek initial care.** Patients often need to shop for providers before receiving health services, which delays diagnosis. A substantial proportion of patients surveyed (29%) indicated that knowing where to find good, reliable health advice or services would be the most helpful type of information to inform their care-seeking decision. Patients noted it would be useful to know what type of provider to approach for different health needs, their availability, and the service quality and cost.

04 **High out-of-pocket costs for health services and transport.** Lack of access to quality public services, private sector preference, the effort required to navigate different providers and low insurance coverage results in high out-of-pocket costs, which often exceeds the means of low-income populations and delays care-seeking. Patients frequently cited cost related barriers to seeking diagnosis, emphasizing the expense of private providers ordering repetitive rounds of testing, referrals and/or consultations and medicines, and the indirect costs of transport and lost work wages, heightened in rural areas with poor facility access.

Low perception of health service quality, leading to reduced patient trust. Overall, patients have little confidence in being able to obtain quality health services, with low expectations of public health services and disappointment in the lack of consistent quality from private services. Patient cited poor experiences in interacting with providers, which creates a cycle of avoidance in seeking diagnosis.

At the POC level, India suffers from an under-resourced and unregulated health system, with significant shortages of skilled healthcare workers (HCWs), adequate supplies, quality-assured diagnostic services at PHC level and disparate data management systems. These gaps are amplified in rural areas and drive a poorer patient experience. This was evidenced by over half (60%) of surveyed patients living in rural settings expressing that they were unsatisfied or only somewhat satisfied with their last health care experience, compared to those living in peri-urban or urban settings (45% and 43%, respectively).

THE HIGH-PRIORITY POC GAPS ARE:

01 Difficulty in navigating between care-seeking steps. This gap persists across the continuum of care, with a considerable proportion of surveyed patients (21%) indicating that more convenient service is most important to them in improving health services. Accessing diagnostic testing requires an intense level of involvement from the patient. In trying to access services quickly in a fragmented and disease-siloed service network, patients zigzag between multiple providers and levels of care, both across public and private sectors. This results in delays in diagnosis, follow-up testing and ongoing treatment monitoring, and also leads to inflated costs. Out of frustration, patients are likely to opt-out, delay getting tested and/or revert to self-testing or self-treatment practices.

02 Inadequate availability and capacity of HCWs, especially in rural areas. India experiences understaffed, overburdened and under-trained community health workers (CHWs) and HCWs at PHC. Nationally, India has 21 HCWs (doctors, nurses, midwives) per 10000 people, less than half of the 44.5 per 10000 minimum recommended by the World Health Organization.[13] Rural areas suffer from a more acute HCW shortage, as only 40% of the health workforce serves 70% of the population in rural areas.[14] Additionally, a lack of standard of care, especially within the private sector, results in highly variable service quality and poor patient experience.

03 Insufficient availability of diagnostic tests and equipment, especially in rural areas. Challenges in supply chain management, especially in last mile distribution and tracking, lead to shortages of diagnostic equipment, regular stock-outs, and wastage of diagnostic health commodities in public health facilities. For example, a facility survey conducted at districts in Uttar Pradesh, Maharashtra and Karnataka found major gaps in the availability of essential tests and large variations across districts.[15]

04 Poor quality diagnostic tests and equipment. A recent study of India's laboratory diagnostics industry reported that of the nearly 110 000 medical laboratories in the country, just under 1% are accredited.[16] Limited enforcement of accreditation and undefined standards create a low barrier to market entry for laboratories, resulting in a diagnostic market dominated by unorganized standalone centres, with varying quality and clinical standard compliance.

05 Lack of a comprehensive disease surveillance system. Several stakeholders emphasized that robust disease surveillance is not conducted on a continuous basis, across diseases or from multiple health system levels, limiting targeted programme intervention.

06 Lack of interoperability between information management systems and/or applications. A lack of common interoperability standards that govern the use of digital health systems in India is a key bottleneck to integration of systems between programmes and providers, as well as the bundling of diagnostic capabilities across disease areas. As the health system is siloed by programmatic areas, separate information management systems and applications continue to be developed in parallel. A lack of interoperability was noted as a barrier to greater patient benefit in the past implementation of digital diagnostics, such as digital X-rays and computerized tomography scans, often deployed to date in a transactional and/or disease-focused manner. There is positive momentum from the government and partners on this topic, but significant focus, buy-in and investment across the federal government, the existing private sector ecosystem and appropriate regulatory bodies is needed for practical progress.

07 Health data not used for clinical or programmatic decision-making. Within India's fragmented provider network, patients are responsible for carrying their diagnostic samples, test results and records between service providers, resulting in misplaced or unused records that lower the quality of clinical services. As mentioned above, there are a lack of interoperable platforms that facilitate information exchange across different providers or health system levels. At the facility level and especially for national programmes, paper-based data collection is prioritized for reporting and rarely used by frontline HCWs for decision-making to better inform diagnostic needs or leverage previously collected information.
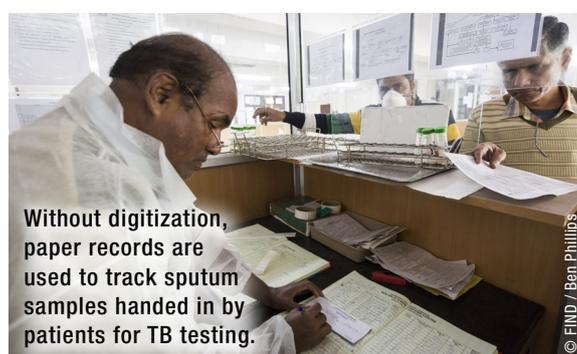
Without digitization, paper records are used to track sputum samples handed in by patients for TB testing.

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RELEVANT DIGITAL HEALTH SOLUTIONS

Digital health solutions can help address several high-priority gaps identified, summarized below. Although India has high digital maturity overall, digital health maturity lags behind other sectors and is considered moderate.[17,18] However, India's digital health landscape is rapidly evolving.

ENABLERS OF SCALE

India has an increasingly low-cost and fast digital infrastructure, with high mobile phone penetration and growing smartphone penetration.[16] Importantly, India's government has established a very positive and enabling environment for ICT intervention in health, pushing further ahead in August 2020 with the launch of the National Digital Health Mission, in which every Indian will receive an electronic health account in the form of a mobile application. Although India's Ministry of Health and Family Welfare (MOH&FW) continues to demonstrate an exciting vision in advocating for the use of technology in health[19], there is opportunity to further investigate how to support them in effectively defining a regulatory framework and stage gates for the implementation of digital diagnostic health solutions. Digital solutions selected for government and partner investment should prioritize those that ensure interoperability with other systems and integration with existing workflows, connect to a unique patient identifier, are built with simple, configurable and modular design that demonstrates scalability in low-resource environments, illustrates a roadmap to sustainable financing and generates value for its end-users by addressing their key pain-points. (To note, if these factors are not well-considered and executed, they act as barriers to scale.)

"Many digital solutions are targeted, but it's important to look at the impact on the whole pathway - the cascade of health care from diagnostic to treatment to follow up. Any solution must be viewed not as a standalone but using a connective design across the pathway".

– Digital Solution Vendor, India

It is with this context that these recommendations are made.

DISEASE FOCUS

Based on the diagnostic gaps observed from a disease-specific lens, digital health solutions can help bring focus to NCDs and antimicrobial resistance, by building awareness, routine screening and diagnosis. Digital solutions that can contribute to integration of testing at PHC, especially for diseases with high co-morbidity (e.g. TB and diabetes) could leverage existing national health programme infrastructure. It will also be important to ensure continuing focus on improving the quality of other significant areas such as antenatal care and newborn screening, malnutrition, anaemia, and HPV screening in females, as well as diagnosis of vector-borne diseases such as dengue.

PATIENT PATHWAY:

01 Pre-POC: improving access to accurate, timely and trusted information to increase efficient care-seeking.

Solutions that address pre-POC diagnostic gaps by targeting patients with accurate and relevant health information via basic mobile phone features via short message service (SMS) messaging, unstructured supplementary service data (USSD) codes, WhatsApp and social media like Facebook would help address the considerable need for health education and drive demand for diagnostic services. These solutions should be championed by trusted patient influencers, such as local private providers, CHWs and community leaders and could be valuable to improve patients' knowledge of early symptoms of diseases with high prevalence (e.g. TB) or to increase awareness of NCDs, thereby promoting early care-seeking for diagnosis. Digital tools such as mobile marketplace apps that combine tailored messaging with a basic symptom tracker/self-screening module and geo-mapping to provide guidance on what action to take next would improve the efficiency of care-seeking and help address the challenges of navigating the fragmented provider landscape.

02 POC: improving existing capacity of frontline CHWs and HCWs at PHC and local private providers to increase the quality of screening and diagnosis and strengthen referral, especially in rural areas.

Solutions that address POC diagnostic gaps related to quality of care are best targeted to CHWs and HCWs at PHC and local private providers. Digital health solutions including job aids, provider-to-provider telemedicine, automated screening tools with capabilities to stratify patient risk or artificial intelligence-led diagnostic applications connected to smart devices can provide guidance to HCWs, help them work more efficiently and improve the quality of care. India has seen several scaled examples of solutions that directly support CHWs and lower level HCWs with mobile applications, with opportunity to leverage local lessons to integrate these solutions at PHC level. However, significant time and investment is required to ensure operational and technical functionality, political buy-in, HCW training and interoperability with other existing systems.

"The key here is how do you make the interaction between the healthcare provider and patient more accurate – whether in the field, home or facility".

– Healthcare Provider and Digital Solution Vendor, India

03 POC: bringing focus to disease prevention and screening to identify health risks, diagnose disease and target intervention earlier

Mobile digital solutions that leverage geo-localization to facilitate individual case identification, contact tracing, and targeted alerts to individuals and the government enables real-time surveillance of on-going disease burden and speeds up the response and management of unanticipated outbreaks. Additionally, digital solutions that are tailored to support the integration and/or bundling of basic tests, provide an opportunity for the early identification of at-risk patients and faster intervention.

04 POC: developing a national laboratory information management architecture, to accelerate progress towards an integrated diagnostics network.

Solutions that contribute towards the development of a national laboratory information management architecture, designed to be basic, modular and appropriate for use by laboratories in lower tier cities, would accelerate progress towards an integrated laboratory network, which could also be leveraged for disease surveillance.

05 POC: supporting central, state-level and frontline HCWs to utilize data more effectively for decision-making.

Connectivity solutions that enable the transmission of data between different laboratory, logistics and/or electronic medical record information management systems will help improve national-level disease surveillance, utilization of data for targeted health interventions, individual patient care and supply chain logistics. Importantly, interoperability between the major systems capturing diagnostic data across both the private and public sector is critical to ensuring a more streamlined continuum of care for patients.

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Data obtained at a central laboratory should be easily accessible and shared with the relevant stakeholders for effective disease surveillance and decision-making.

As mobile penetration and ICT literacy in India continues to rapidly grow, scale-up of digital health tools will be necessary to optimize the nation's limited resources, bridge inequity in healthcare access and strengthen the availability of quality diagnostics. Looking forward, India's active digital health ecosystem and the spotlight on diagnostics from COVID-19 positions the nation well to accelerate digital intervention in diagnostics where it is needed most - at the frontlines of service delivery.

"Integration of service delivery – a screening and diagnostic layer - with digital systems is a huge gap and should be the next big revolution in public health".

– Country Head, Implementing Partner, India

ACRONYMS, ABBREVIATIONS AND DEFINITIONS

CHW:	Community health worker	**MNCH:**	Maternal, newborn and child health
HCW:	Healthcare worker	**NCD:**	Non-communicable disease
ICDS-CAS:	Integrated Child Development Services – Common Application Software	**PHC:**	Primary health care
IP:	Implementing partners	**POC:**	Point of care
MOH&FW:	Ministry of health and family welfare	**TB:**	Tuberculosis

1 This survey was conducted via mobile phone and on an opt-in basis. The resulting participant demographics reflected those that have likely have higher mobile phone ownership and usage in India. There was a higher proportion of male respondents (82% vs. 52% in population), less representation from those aged under 14 years old (6% vs. 26% in population) and greater representation from those aged 15 to 25 years old (42% vs. 18% in population), general alignment of rural to urban dwellers (78% living in rural areas vs. 70% in population) and respondents with no formal education were under represented (15% vs. 46% in population). Overall, there was consensus across the different research methodologies (patient survey, expert interviews and desk research) of the major assessment conclusions.

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For more information and examples of specific digital health solutions that address diagnostic gaps, please contact FIND at digitalhealth@finddx.org