

Establishing national centre for point-of-care technology for 'Swasth Bharat, Samridh Bharat'

In 2018, the Indian government recognized the gap in preventive, diagnostic, and treatment services for noncommunicable diseases at the primary and secondary health-care levels, resulting in the launch of the flagship program "Ayushman Bharat" (AB). The program has two components: first is the creation of 150,000 Health and Wellness Centres (HWC) across India at primary and secondary care levels, and second to start the Pradhan Mantri Jan Arogya Yojana (PM-JAY) health protection coverage for poor and vulnerable families.^[1]

Implementation of a program of such magnitude in India was not an easy task, necessitating the government to create an autonomous entity called the National Health Authority (NHA). The NHA will provide overall vision and stewardship for effective implementation of the PM-JAY in India and it will have the autonomy and direction to involve state governments, civil societies, insurance agencies, academia, and national and international organizations for furthering the goals of PM-JAY.^[1]

The exact burden of noncommunicable diseases in India is unknown, but we can draw rough estimates from the small population-based prevalence studies done in various parts of India. The Indian Council of Medical Research (ICMR) data have shown the prevalence of diabetes in the Indian adult population to be 7.1% (64 million).^[2] Further, the prevalence of hypertension has been estimated to be around 33.6% in the rural population of Karnataka, chronic kidney disease (CKD) stage 3 at 6.3% in Indian population (81 million), and the combination of diabetes and hypertension account for 60% of CKD cases.^[3] Among the 45+ aged population, 22% are at high risk for developing heart failure, 34% have asymptomatic heart failure, and 12% have symptomatic heart failure; thus in total, 68% (187 million) of this age group need surveillance for the development of potential symptomatic heart failure.^[4] With regard to coronary artery disease, 25% of the population (320 million) will have chest pain symptoms at least once during their lifetime that will require evaluation to rule out coronary artery disease.^[5] Finally, chronic obstructive pulmonary disease occurs in 4.2% (55.3 million cases in 2016) of the population.^[6]

Ultimately, the life expectancy for the Indian population is 68.8 years and increasing, which means more people will present with noncommunicable diseases.^[7] Unfortunately, the above figures are conservative estimates and the actual figures are likely to be higher. The existing health-care services in India will be challenged to cater to the diagnostic demand of this pathologic tsunami at primary or secondary care level. As a result, our tertiary care centers are overstressed and are finding it difficult to cope with the increasing patient burden.

In the existing Indian health-care setup, a high level of involvement and work from patients and their family is needed to get properly diagnosed. They have to continuously make sense of their illness, translate medical jargon, and produce and transport samples in a process that is costly and with transportation challenges. They then have to return the results to the treating provider on their own. Often, the quality and content of interaction of the patient with treatment providers are such that if the test-and-treat loop becomes overwhelming. This has the consequence that the patient may opt out or delay being tested, switch providers, resort to self-treatment, or seek unproven alternative medicine practices.^[7]

We believe that the excellent groundwork laid by the government will not bear the fruits unless the gaps in the test-and-treat loop are plugged at the level of HWC. The answer lies in the point-of-care tests (POCT). POCTs have rendered a very significant role in infectious diseases, especially in their early diagnosis and treatment. Few of the best examples are falciparum malaria, HIV, Kala-Azar, Dengue, etc. In the field of noninfectious diseases also, the POCTs can play a very important role. India needs to equip 150,000 HWCs with the POCT, both for communicable and noncommunicable diseases so that the patients are tested and treated during the same visit. Other nations have been using POCT to better the health delivery to their populations for many decades and have now moved toward the newer generation POCT and biomarkers using nanotechnology, microfluidics, integration with smartphones, connected instrumentation, self-running diagnostic machines, wearable sensor technology, data analytics, and artificial intelligence-based systems.^[8]

POC is defined as devices that can perform fast analysis and accurate diagnosis near the site of the patient-HWC interaction. Ideal POCT should be cost-effective, user-friendly, simple, and able to be performed by a user not having elaborate medical or laboratory knowledge.^[9] Examples of POCT already in use in India are the home-based glucose testing, urine pregnancy testing, and PHC-based malaria testing, all of which have provided ease of testing, cost-saving, analytic precision, all of which provide diagnostic certainty in the

test results such that many patients are currently using them for their own well-being.

Overcrowding of the emergency department (ED) is rapidly becoming a global challenge and a major source of concern for emergency physicians. The evaluation of cardiac biomarkers is critical for confirming diagnoses and expediting treatment decisions to reduce overcrowding; however, physicians currently face the dilemma of choosing between slow and accurate central-based laboratory tests or faster but imprecise assays. With improvements in technology, POCT systems facilitate the efficient and high-throughput evaluation of biomarkers, such as troponin, brain natriuretic peptides (BNP or NT-proBNP), procalcitonin, bio-adrenomedullin, or proenkephalin. In this context, POCT may help ED physicians to confirm a diagnosis of conditions, such as acute coronary syndrome, heart failure, or kidney damage. Compared with classic laboratory methods, the use of POCT devices has shown comparable sensitivity, specificity, and failure rate, but with the potential to provide a prompt and accurate diagnosis, shorten hospital stay, and alleviate the burden on the ED. Despite this potential, the full advantages of rapid delivery results will only be reached if POCT is implemented within hospital-standardized procedures and ED staff receives appropriate training.^[10]

India, with its 150,000 HWCs, is going to the world's largest provider of health care at the doorsteps of their people. It is impossible to provide a conventional laboratory at every HWC due to insufficient human resource, space, and budgetary requirements. In the absence of short test-and-treat loops for noncommunicable diseases, doctors and patients feel handicapped and it leads to high referral rates to more expensive tertiary care setups for minor diagnostic issues.

AB is indeed a major step toward universal health coverage and the Government's vision of "Swasth Bharat, Samridh Bharat." Unfortunately, this goal cannot be achieved unless we make HWC capable enough to diagnose diabetes, myocardial infarction, acute kidney injury, CKD, dyslipidemia, and heart failure. All these are achievable now if we make POCT available in HWC. It is not the noncommunicable diseases alone. We also need to equip HWC with POCT to diagnose dengue, malaria, chikungunya, Japanese encephalitis, scrub typhus, urinary tract infections, and many other common infectious illnesses.

ICMR, All India Institute of Medical Sciences (AIIMS), Department of Biotechnology (DBT), Department of Science and Technology (DST), Defence Research and Development Organization (DRDO), and the National Health Mission (NHM) are various stakeholders in the

effective delivery of medical care. We stand to make a call that they should be working jointly for the development of cheap-, accurate-, and need-based POCT for the Indian Population. Unfortunately, despite the demonstrably large burden of noncommunicable diseases in front of us, India is still lacking the implementation of nationwide POCT for the early and accurate diagnosis of myocardial infarction, heart failure, diabetic kidney disease, etc.

Analogous to the above example of NHA for PM-JAY, we therefore propose a National Centre for Point-of-care Technology (NCPT) that should act to coordinate, collaborate, and create systems for the innovation of POCT. NCPT should work on a mission mode in collaboration with NHA and bring AIIMS, ICMR, DBT, DST, DRDO, and NHM together on a platform dedicated for the development of POCT for the proposed 150,000 HWC in India.

The focus of NCPT should be to create and evaluate systems for conducting laboratory-based tests and population-based studies, to collaborate with international innovators within India, to streamline technology transfers, aid in industry collaborations, improve physician awareness, and work with governments to implement the existing and upcoming technologies of POCT. The technology is already available for the diagnosis of many noncommunicable diseases using POCT mentioned above. It is currently used mainly in the EDs for quick diagnosis and treatment of emergency patients. Unfortunately, the costs of these tests are significant and need to be brought down by the proposed NCPT so that the last person sitting in the villages can get tested and treated by the HWC.

Some POCTs that are already available in the market include troponins, BNP, NT-proBNP, HbA1c, urine microalbumins, beta-human gonadotropin, lipid profiles, D-dimer, arterial blood gas analysis, lactate, hemoglobin, liver functions, kidney functions, urinalysis, malaria, and the infectious diseases of dengue, leptospirosis, and typhoid. Availability of these tests at the HWC along with the treatment algorithms will bring a paradigm shift from tertiary hospital-centered care to a HWC-centered care in India. NCPT and its products can thus become a GameChanger for Indian health-care system. Newer technologies in the field of POCT also need to be adopted in a time-tested manner.^[8] NCPT will need to adopt research and technology transfers in these newer technologies as a part of a futuristic goal.

To summarize, an HWC with the help of the POCT technology can complete the test-and-treat loop at a single patient visit and enable the government to deliver its promised health care to the Indian population. The use of cheap and accurate POCT under the flagship of NCPT

will be the GameChanger for the Indian health-care system and it will create an AB in its true sense.

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