

“The primary obstacle in reducing cancer mortality has been the absence of effective screening programmes”

01 December 2023 | Views | By Bhagwati Prasad

Headquartered in California, USA, Harae Dx, a medical diagnostics company, is all set to introduce the next generation Artificial Intelligence (AI) enabled automated multi-cancer early detection system in India, China and the US in a three years-time period. The company holds strategic patents in its core technology platform, and the development and manufacturing of the entire diagnostics system will be executed through strategic partnerships using an outsourced model. In an exclusive interview with BioSpectrum, Dr Nitin Malekar, Director, Harae Dx Inc., shared while talking about the market, the untapped market potential and the unmet medical need for early detection of cancers with the commonest and amongst the most challenging one being the Breast Cancer in females.

What's the burden scale of cancer and cancer testing in India and globally?

Globally, cancer has surpassed its most formidable adversary cardiovascular diseases in killing more human beings as per a Lancet study. It surges ahead of the combined forces of AIDS, tuberculosis, and malaria, making it a critical global health concern. In cold, hard figures, cancer claims a staggering one in every six lives across the planet, as reported by the American Cancer Society.

The current landscape of cancer testing is at a crossroads, predominantly reliant on imaging technology and surgical tissue biopsies. While these methods are formidable, they are not without their limitations. Imaging technology's resolution is confined to detecting only larger tumours, often yielding inconclusive results. Surgical biopsies, while invaluable, are invasive and cannot be repeatedly administered throughout a patient's care journey. The key to positive health outcomes hinges on

timely and accurate diagnoses.

In the quest to reduce cancer mortality, the primary obstacle has been the absence of effective screening programmes, exacerbated by mounting cost pressures within the healthcare system.

The cancer biomarkers market, with a valuation of \$10.9 billion in 2019, is projected to soar to \$27 billion by 2027, boasting an impressive CAGR of 11.8 per cent from 2020 to 2027. These numbers paint a compelling picture of the rising demand for innovative diagnostic solutions that can transform healthcare.

In India, the cost of a Liquid Biopsy Test ranges from Rs 23,000 to Rs 30,000, depending on various factors, including the specific markers screened and the testing laboratory. It's a substantial investment for individuals and healthcare systems, and that's where Harae Dx enters the scene with a revolutionary approach.

Our Harae Dx system, 'Nidaan Biolab,' is a game-changer in itself. It minimises the need for extensive human intervention, as lab technologists simply need to introduce a small blood sample onto a specially designed disposable disc. This disc is then placed into the automated Nidaan Biolab, which orchestrates the entire diagnostic process, swiftly delivering accurate results. Gone are the days of cumbersome and time-consuming manual testing, thanks to this technological marvel.

We all understand the scourge of cancer, but as per your understanding how serious is the threat of cancer?

While unveiling the Alarming Realities of Cancer, numbers have an uncanny way of shedding light on the gravity of a situation. And when it comes to the battle against cancer, they tell a story that demands our immediate attention.

Delve deeper into the statistics, and the magnitude of the issue becomes even more apparent. Approximately 1,958,310 new cancer cases are anticipated worldwide, equating to a staggering 5,370 new cases each day. This is not a battle waged by a few; it's a global war that touches every corner of our world.

Closer home, it is essential that we grasp the urgency of this narrative. Let's focus our lens on India, where the cancer battlefield is becoming increasingly intense. Here, we anticipate a daunting 800,000 new cancer cases each year, which translates to a staggering 2,200 new cases every single day, according to the Indian Cancer Registry. The National Institutes of Health (NIH) data for 2022 reveals an estimated 1,461,427 new cancer cases, equivalent to 100.4 cases per 100,000 populations. Shockingly, one in nine people in India is destined to confront cancer in their lifetime.

However, it's crucial to emphasise the good news in this grim scenario. Many cancers are preventable if people make crucial lifestyle modifications and steer clear of habits that heighten their risk of this formidable disease. But cancer detection is done only in labs in hospitals and is available to less than 10 per cent of the world's population which is the economically affording.

The beacon of hope in this battle is to take screening/ detection up to the patient's doorstep. The key is 'Early & Easy Detection.' It's not just a matter of saving lives; it's about saving invaluable resources, sparing individuals from costly treatments, surgeries, and diagnostics.

The numbers may be staggering, but they also hold the key to a solution. We want to harness this knowledge to drive change, promote awareness, and save lives, by taking the lead in the fight against cancer, advocating for early detection, lifestyle modifications, and a brighter, healthier future for all.

Where does India stand in early detection of cancer?

The reality is stark and unsettling. A staggering 75 to 80 per cent of diagnosed patients confront advanced-stage disease upon diagnosis. It's a crisis that demands immediate, forceful action. Early cancer detection is the need of the hour.

India takes the lead in oral cavity cancer cases, with a shocking 119,992 reported cases, constituting 33.8 per cent of the global total (International Cancer Society). The nation also ranks second in breast cancer cases, with 162,468 (17.8 per cent), and cervix uteri cancers, with 96,922 cases (30.7 per cent) in the entire Asian subcontinent. In India, every four minutes, a woman faces a breast cancer diagnosis, making up a staggering 14 per cent of all tumours in Indian women.

In this pressing context, the need for well-organised Early Detection services at outpatient settings cannot be overstated. Every patient who walks into a hospital displaying early signs and symptoms should have seamless access to screening, diagnosis, and treatment. It's a mission that requires continuous research and practical strategies to ensure early screening and detection services remain available, effectively reducing mortality rates across the population.

COVID-19, while subsiding after two arduous years, has wreaked havoc on essential health services, not only in India but globally. Early cancer detection services have suffered significantly, with routine screenings plummeting in both developed and developing countries.

Take an example of the largest cancer killing women across the world, which is, Breast Cancer. The standard of care for detecting breast cancer is either a physical exam or mammogram, which is available only to less than 10 per cent of the world's population due to various reasons like cost, availability etc.

Based on mammography (which is only 60 million mammograms), currently only 2.3 million women are found to have breast cancer and half of these women succumb to the disease. As we understand, there are over 1.6 billion women over the age of 40 (age with the highest probability of getting breast cancer). If we extrapolate this figure, the results can be terrible. Statistics for men are also unknown.

The imperative of early cancer detection cannot be emphasised enough. It's the linchpin to improving survival rates, diminishing mortality and morbidity, and alleviating the societal disease burden. Our foremost goal in screening programmes is to identify cancer at its nascent stages, particularly when individuals are asymptomatic or have a family history of the disease. Early detection not only boosts cure rates but also makes treatment more accessible, thus guiding doctors and patients toward optimal outcomes.

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