India's novel AI MedTech against the 'Emperor of all Maladies'

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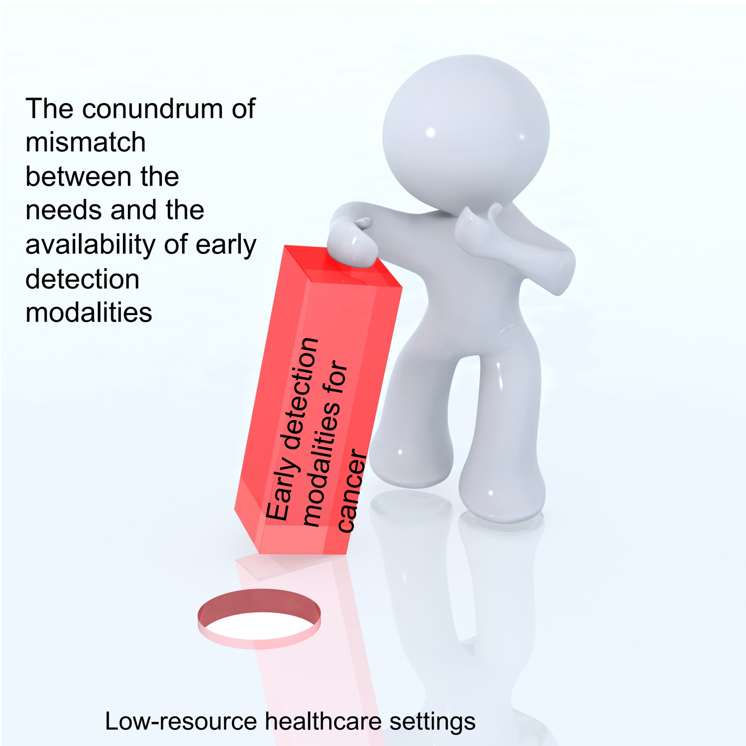
The challenge: Increasing cancer cases and deaths in India

- **Second-highest mortality due to cancer (851,678) and the third-highest estimated new cancer cases (1.32 million) in the world (IARC, 2022)**
- **Breast, Oral, and Cervical Cancer are leading causes of incidence and mortality,** with 60-70% of breast cancer cases and 60-80% of oral cancer cases reported at advanced stages
- **Significant barriers within the low-resource healthcare system hinder availability and access to early detection modalities** (Pramesh et al. 2014; Khanna et al. 2020; Shruti et al. 2023):
  - low public health spending and unaffordable private healthcare
  - lack of access to healthcare infrastructure
  - a shortage of human resources, including clinicians, radiologists, cytologists, pathologists, etc.

Historically, non-aligned health and industrial policies contributed to early detection modalities that are difficult to integrate into low-resource healthcare systems



Source: Image downloaded from Dreamstime.com

The Opportunity: AI-based Medtech for early cancer detection

Artificial Intelligence (AI), driving the scale and scope of problem-solving innovations in India (and globally) in the fourth industrial revolution

Surge in start-up firms, developing AI-based MedTech innovations addressing unmet needs of users (primary and end) and systemic challenges in low-resource healthcare settings by:

- Developing new methods
- Making existing modalities conducive for low-resource settings

Evolutionary approach to investigate what led to this new trajectory of innovations

Developed **a novel theoretical framework, the Inclusive Health Innovation (IHI) framework,** combining and extending two evolutionary approaches in innovation studies:

- Sectoral systems of innovation by Malerba and Mani (2009) to identify the role of key actors, knowledge and technologies; and
- Institutional triad of healthcare by Srinivas (2012) that connects co-evolutionary trajectories of industrial production, demand, and healthcare delivery

Primary assumption of IHI framework: Institutional bundles are the key explanatory variable to operationalise knowledge, distinct technological and problem-framing and solving capabilities to address unmet need

Empirically tested the IHI framework using a **multiple case study research design and online qualitative research methods,** mitigating COVID-19 disruptions to fieldwork

Case studies: Linking unmet needs in the AI MedTech innovations

Framing unmet needs and challenges in existing early detection modality in India	**Incorporation of unmet needs in AI-based MedTech innovations**
• Low sensitivity of mammography for women under 45 and with dense breast tissue • Radiation and pain • Shortage of qualified human resources, and inadequate infrastructure to have mammography and ultrasound in population-based screening • Cultural issues with touch-based screening	**Thermalytix (2017) by Niramai Analytix Private Limited, Bengaluru, India** • Developed by a team led by Dr Geetha Manjunath, an experienced computer scientist and industry leader, motivated by lived experience and pain of late diagnosis of breast cancer in the family • Active collaborations of radiologists, thermographers, and clinical researchers in the design process, and with hospitals for structured datasets to develop ML innovation • Radiation-free breast screening innovation using ML to interpret thermal images offering a non-invasive, point-of-care, portable design, screening for women of all ages • Tailored for low-resource healthcare settings with basic training • Delivery models based on different business models focussed on lowering capital expenditure
• Shortage of dentists and skilled workforce to conduct visual inspection • Lack of objective detection of precancerous oral lesions using visual inspection of the oral cavity • High cost of adjunct technologies	**OralScan (2020) by Sascan Meditech Pvt Limited, Kerala, India** • Developed after 30 years of interdisciplinary research and collaborations of Dr Subash Narayanan, a physicist specialising in optics, and later its application for cancer diagnostics • Motivated by the lived experience and pain of a wrongful diagnosis of cancer in a family member, Dr Narayanan collaborated with dentists, engineers, and clinical researchers for biomedical instrumentation • Point-of-care, non-invasive imaging of the oral cavity, using a multispectral imaging technology-based hand-held • device and tablet that facilitates tissue analysis via customised software based on ML algorithms for real-time feedback on tissue status • Tailored for low-resource healthcare settings with basic training • Delivery models based on different business models focussed on lowering cost of screening
• Lengthy process and costly cervical cytology by pap smear • Lack of uptake of visual inspection with acetic acid • Shortage of labs and pathologists	**CervAstra (2020-21) by Aindra Systems, Bengaluru, India** • Developed by a team led by Adarsh Natarajan, an electronic engineer with experience in the IT sector and a management degree motivated to leverage technology to solve complex problems. • Collaborated with pathologists, oncologists, and experts from the Indian Institute of Technology (Chennai and Mandi) to develop design and algorithm. • Expedite analyses of pap smear samples using an AI-based computational pathology platform to examine and detect normal or abnormal cells within a few hours with minimal human intervention • Advances in optics, electronics, and mechanical systems for edge compact design and portability, increasing reach beyond the diagnostic centre • Easy to use with basic training for frontline health workers. • Delivery models based on different business models

Insights using IHI framework

Signs of increasing policy linkages in science technology and innovation, health and industrial policies since 2012 to develop a MedTech ecosystem supporting capacity to frame unmet needs and innovate for low-resource healthcare settings driven by advanced computing technologies.

- Space for non-domain start-up founders, specialising in AI and its subsets, and physical sciences, to collaborate with users like clinicians, radiologists, and oncologists to develop screening solutions for the Indian context
- Policies enabling funding and incubation to support early-stage developments and manufacturing to innovators, and bringing together actors like universities, research institutes, hospital networks for clinical studies, private funders, accelerators, NGOs

Policy recognition to the innovations, e.g. National Strategy for Artificial Intelligence, India (NITI Aayog 2018; p 28) stresses,

> 'The increased advances in technology, and interest and activity from innovators, provides an opportunity for India to solve some of its long-existing challenges in providing appropriate healthcare to a large section of its population.' 'Cancer screening and treatment is an area where AI provides tremendous scope for targeted large-scale interventions.'

Pocket wins against cancer as demand-generating policies evolve slower in complex health systems like India.

User data informing ML algorithms provide an **increased focus on incorporating the ethical use of AI, data governance and privacy in regulations**

Next steps in research – utilisation and adoption of these innovations in Indian healthcare.

Reflections for transdisciplinary engineering

Policies to translate unmet needs into demand for innovation: Policy bundles supporting contextual and institutionally aware engineering, providing platforms to incubate health innovations that are necessary and desired, rather than being externally imposed.

Using AI to scale solutions in low-resource healthcare settings: AI and its subsets are used to develop novel methods and augment existing methods for early cancer detection in low-resource healthcare settings**.** E.g. focus of design on prioritising and meeting the needs of users and healthcare delivery mechanisms

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