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Can Cutting-edge Tech Reduce Rising CVD Burden?

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Each year World Heart Day is observed to increase awareness about cardiovascular diseases (CVDs), after all defeating them is something that matters to every beating heart. CVDs are disorders of the heart and blood vessels and are often referred to as “silent killers” because most of the patients with underlying heart ailments do not exhibit any obvious symptoms. Development and deployment of cutting-edge technologies backed by requisite government policy support and direction will help in bolstering the fight against CVDs and thus improving the quality of the individuals’ heart and also their lives. Let’s take a closer look.



India is rapidly becoming the global CVDs epicentre which is primarily attributed to a mix of genetics, poor cultural practices and lifestyle factors among Indians such as increased trans fatty acids content in foods due to repeated use of cooking oil, unique pattern of atherogenic dyslipidaemia, consumption of processed and ready-to eat foods, physical inactivity, obesity, high tobacco use, and increased stress levels that have contributed towards the increased prevalence of CVDs.

According to the Lancet's Global Burden of Disease study, India has an age-standardised CVD death rate of 282 per 100,000 population which is remarkably higher than the global average of 233 deaths per 100,000. The key to managing CVDs is early detection which can help identify the risk of cardiovascular diseases before it becomes too late. The industry is making tremendous efforts to reduce the disease burden, technology advancements in digital health and MedTech have enabled disease detection at an early stage, and also helped disease management of high-risk patients.

Technologies such as artificial intelligence (AI)-based medical imaging analysis and precise screening solutions, continuous monitoring wearables and digital therapeutics have emerged as key enablers for the prevention and management of CVD in India. These technologies can play a vital role in lowering CVD risk and reducing the associated mortality rate which is especially important for a country that accounts for 60 per cent of the world's disease burden. Some of these technologies to reduce cardiac disease burden are given below.

AI-based medical imaging analysis and screening solutions

AI-based medical imaging analysis solutions can precisely analyse and interpret cardiac-related abnormalities on medical imaging outputs including chest X-rays, computed tomography (CT) and ultrasounds. The AI algorithms in the solutions can quantify heart function, fluid buildup, valve anatomy, carotid artery stenosis grading, atherosclerotic plaque identification and characterisation which can help in the detection of CVDs such as heart failure, heart attack and stroke. These algorithms can rapidly process chest X-rays, CT and echocardiogram images within 60 seconds thus enabling early diagnosis of CVDs in the patients which can greatly enhance the chances of successful treatment in them. Furthermore, the AI algorithms can detect cardiac-related anomalies with high accuracy and are less prone to manual errors which can reduce misdiagnosis risk which is of paramount importance as delayed treatment can negatively affect health outcomes in the patients and also lead to potentially serious medico-legal consequences for the clinicians.

Startups, such as Mumbai-based Qure.ai, have successfully deployed solutions for early detection of heart failure, heart attack and stroke. Furthermore, companies such as Aarthi Scans and Labs are leveraging AI-Rad Companion, a state-of-the-art CT coronary calcium scanning technology developed by Siemens Healthineers to detect early signs of coronary artery disease in patients.

Besides CVDs detection, market participants have also developed AI-based screening solutions that leverage patients' historical lifestyle attributes including smoking and tobacco preferences, psychological stress, anxiety, diet, and physical activity to predict the risk of CVDs among them. Apollo Hospitals, among India's biggest hospital chains, has developed the Apollo AI-powered Cardiovascular Disease Risk tool that provides risk scores to the doctors based on all contributor factors allowing them to offer pre-emptive, proactive and preventive care for at-risk cardiac patients. Non-industry bodies such as the Cardiological Society of India, are focusing on developing preventive cardiology solutions that use deep neural networks which can accurately identify patients who can potentially develop heart disease in the future.

Wearable devices

Continuous Remote Cardiac Monitoring

Wearables including smartwatches have already gained popularity among individuals in India endeavouring to improve their physical fitness and overall well-being. However, the use of medical-grade wearables such as electrocardiogram (ECG) and cardiac patches and smart wearables including smart rings and smart bands for enabling 24x7 remote cardiac monitoring are also rapidly gaining traction in the country. These devices are equipped with an array of sensors including triaxial accelerometers, biomechanical, heart rate and rhythm sensors for monitoring physical activity, heart rate, electrocardiography, photoplethysmography, heart rate variability, cardiac output, blood pressure and heart rhythm measurement. The prominent advantage of these wearables is their ability to continuously track the above parameters, automatically detect cardiac anomalies using AI and share the data with the clinicians thus enabling them to detect underlying cardiac conditions and accordingly initiate early intervention and treatment. SmartCardia's 7L Patch launched in India in August 2022, is a 7-Lead ECG patch that continuously monitors P-wave, QRS beat morphology along with vitals such as pulse rate, oxygen saturation and heart rate of the patient. The data is analysed by AI algorithms to detect cardiac arrhythmia events and accordingly, the information is transmitted in real-time to the cloud allowing the clinicians to make well-informed decisions to prevent clinical deterioration in the patients.

Impacting Lifestyle Choices

Another benefit of the wearables is their ability to impact the individual's lifestyle choices and overall well-being by providing insights and healthy recommendations about daily habits. These devices can track the physical activity levels of the user and accordingly provide gentle nudges if prolonged periods of inactivity are detected to break the individual's sedentary habit. Furthermore, these devices also allow users to log in food intake and calorie consumption and subsequently provide insights about their dietary habits thus empowering them to make healthier choices and achieve their nutritional goals. India-based wearable companies such as boAt and Noise have launched smart rings that can monitor a range of health parameters of the user including heart rate, blood oxygen and physical activity levels and accordingly provide insights to the individual to help them live a healthier life. GOQii Technologies has launched GOQii Heart Care in India through which individuals using its GOQii tracker can share heart rate and other health data with cardiac specialists allowing them to provide specific nutrition advice and personalised coaching to the users to maintain good heart health.

Digital therapeutics

Digital therapeutics (DTx) uses evidence-based software that is clinically validated to prevent and manage chronic conditions including mental health, diabetes, and CVDs. In India, DTx are increasingly taking centre stage owing to their ability to improve patient-reported outcomes through monitoring, medication reminders, real-time customised health recommendations and personalised health coaching.

Enabling Behavioural Modifications

The DTx solutions use disease-specific programmes to encourage positive behaviour and lifestyle changes in individuals to mitigate heart ailments in them. The solutions offer disease-specific health education videos, recipes, and daily tasks to allow the individuals to respond better to symptoms, optimise their diet and adopt a positive physiological approach to improve sleep, reduce stress and enhance overall mental well-being. Through behavioural changes, the DTx solutions empower users to build positive daily habits which significantly improve their quality of life.

Bengaluru-based Credo Health's Cardiac Wellness and Rehabilitation programme enables the users to adopt heart-healthy behaviours including following a healthy diet, maintaining optimal weight, curbing habits such as smoking, and managing their stress levels to reduce the risk of heart disease. Mumbai-based Wellthy Therapeutics multi-lingual clinically validated DTx platform leverages behavioural science, and real-world clinical evidence to provide personalized recommendations and actionable information to the users to facilitate meaningful, sustainable behaviour change to better manage their conditions.

Improving Patient Engagement

One of the substantial advantages of DTx is its potential to improve patient engagement and compliance levels. Through multi-channel targeted outreach including reminders, motivational messages and rewards, DTx bolsters the patients' commitment towards their health goals. This approach to enabling structured lifestyle changes in patients is essential for the

prevention and management of CVDs.

Lyfe, launched by Mumbai-based Lupin Digital Health is an evidence-based, heart care DTx that offers medication reminders, exercise, and diet regimens, online and in-person modules and expert interventions through dedicated health coaches and care managers for cardiac patients. By leveraging guidelines and protocols designed by prestigious medical societies such as the American College of Cardiology, Lyfe provides holistic heart care programmes aimed at reducing heart attack risk and improving health vitals among cardiac patients. The efficacy of the heart care DTx has been clinically proven through an ongoing research study with more than 90% of subjects adhering to the recommended diet, medications, and exercise and 83.3 per cent patients maintaining their vitals in the normal range.

Challenges and Recommendations

Though AI-based medical imaging and screening solutions offer an invaluable diagnostic tool to healthcare professionals, they have their share of limitations. Difficulty faced by clinicians in interpreting the decision-making process of the AI algorithms coupled with the lack of access to a large number of curated datasets for the training of the models has hampered the wide-scale adoption of the tools in cardiac care. Through the implementation of explainable modelling or post-hoc explanations, the internal functioning of the algorithms can be provided to clinicians to improve their trust levels.

Market participants can partner with government agencies to get access to substantial curated imaging data sets that are technically and demographically diverse. Furthermore, there is a vast shortage of AI-trained professionals in India a country that otherwise produces thousands of IT professionals every year which is hampering the rapid development of medical imaging and screening algorithms. To mitigate this issue the companies can partner with universities in India to introduce AI-based offline and online courses that would allow upskilling workforces to address the talent crunch.

The use of wearables in India for health monitoring has grown significantly in recent years, however, they face challenges related to maintaining patient data privacy and data security. The lack of clear understanding among the patients regarding the privacy of their critical health information and what measures are adopted to protect their data stored on the cloud from unauthorised access due to security breaches can hamper the adoption of the wearables.

The enactment of the Digital Personal Data Protection (DPDP) Bill, 2023 successfully passed through the Indian parliament and received final assent from the President of India in August 2023 is a step in the right direction as obtaining explicit consent from the individuals before collecting or utilising their health data and display of notice regarding the purpose of the processing of the information is made mandatory for the wearable and digital health players which can address patients' data privacy concerns.

Going forward the government can also add additional sections to the current DPDP bill on similar lines to that of the US Health Insurance Portability and Accountability Act (HIPAA) which provides individuals the right to see their health data and request or change the information if it is incomplete or inaccurate. Additionally, the wearable and digital health players can also focus on the implementation of robust security measures such as consistently updating security protocols, encrypting patient data and deploying stringent controls to ensure patient health data is protected on the cloud from unauthorized access, theft or misuse.

Despite the innovations happening in the DTx space, the lack of a proper regulatory pathway for the approval of DTx is a prominent challenge faced by companies that have hampered the development of these products in India. To overcome this issue, the Central Drugs Standard Control Organisation (CDSCO) can develop alternative regulatory approaches wherein DTx products approved by CDSCO's reference regulatory agencies (US FDA, Health Canada, and EU Notified Bodies) should be provided abridged evaluation route or expedited review route which can help in facilitating accelerated regulatory approval for them.

Outlook

Considering the enormous patient population suffering from CVDs in India and the current gaps regarding the precise understanding of these conditions, the medical device industry in India needs to boost technology development to address these challenges. The industry can step up partnerships with leading local and foreign universities leveraging their research to improve the companies' expertise in cardiac care. Furthermore, the industry can also adopt breakthrough innovations used in developed countries including voice-based technologies and AI-based chatbots for detecting and predicting cardiovascular events in individuals. Finally, the companies should also work with the Government of India to identify any regulatory

roadblocks that hinder the ease of doing research and business related to cardiac care medical devices and subsequently address them to accelerate the development of these products. The development and deployment of these cutting-edge technologies, backed by requisite government policy support and direction, will help in bolstering the fight against CVDs and thus improving the quality of life.

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