

Saving Newborns On Priority

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With a high number of neonates dying every year in the country, there is a need for quality medical devices to save the little ones. Having a majority of global players catering to the demand for this sector, Indian companies are slowly entering this space to provide the much-needed relief.



The demand for neonatal monitoring and care equipment is seeing an upward trend in India. India, with its huge population base, has the most neonatal deaths, 75 per cent, occurring during the first week of life. Preterm birth, childbirth-related complications, infections, and birth defects cause most of these deaths.

In 2021 India had an infant mortality rate of 28 deaths per 1000 live births, representing sustained progress over the past couple of decades. The United Nations International Children's Emergency Fund (UNICEF)'s report states that "80 per cent of all newborn deaths result from three preventable and treatable conditions: complications due to prematurity, intrapartum related deaths (including birth asphyxia) and neonatal infections.

The report also suggests that Australia, Japan, Singapore, Korea, and China have reported around 2 deaths per 1,000 live births. Although the death rate in the US is less than that in developing economies, it is still significant, with 47 per cent of 2.4 million newborn deaths (112,800) in 2019 recorded during the neonatal period. This is where the role of the medical devices for neonates comes to the fore.

The neonatal critical care market

According to ResearchAndMarkets.com, the global neonatal critical care equipment market size is expected to reach \$1.36 billion in 2030, expanding at a CAGR of 8.7 per cent. The rising number of preterm births, increasing incidence of newborn jaundice, and launch of new products are some of the factors responsible for market growth.

Another report published by Allied Market Research mentions that the global newborn screening market was estimated at \$1.1 billion in 2021 and is expected to hit \$2.0 billion by 2031, registering a CAGR of 6.8 per cent from 2022 to 2031.

Some of the equipment used as medical devices to cure neonates heart or cardiorespiratory monitor, blood pressure monitor, pulse oximeter, X-Ray, CT scan, MRI nasogastric tube etc.

Indian context

In a developing country like India, where there is a high number of newborn deaths, both the domestic and the global neonatal medical devices industry, has seen a huge demand for their products. The rising birth rate in the nation is additionally contributing to the growth of the neonatal medical devices sector.

Key factors driving the neonatal critical care equipment market growth include growth in the incidence of neonatal jaundice, an increasing number of preterm births, and the introduction of innovative equipment for use in the neonatal intensive care units (NICU).

As per a report in Technavio, the neonatal and prenatal devices market size in India is to grow by \$4 billion. The report "Neonatal and Prenatal Devices Market in India by Product and End-user - Forecast and Analysis 2022-2026" suggests that the market will witness a YOY growth of 4.01 per cent in 2022 and a CAGR of 5.21 per cent during the forecast period.

The neonatal devices market in India is fragmented, and the vendors are deploying growth strategies such as offering innovations and high-quality products to compete in the market.

According to the Technavio report, the rising incidence of preterm births is driving the neonatal and prenatal devices market growth in India. Premature babies are often associated with high neonatal mortality, short- or long-term morbidity, and disabilities such as cerebral palsy, sensory impairments, and others. According to the National Neonatology Forum (NNF), 13 per cent of births in India are premature births.

Nitesh Kumar Jangir, Co-founder, InnAccel and Director, Critical Care opines, "Private companies are contributing to this sector by specialising in child and maternal care and paving a path for the localisation of medical devices for the Indian market. New-age startups with innovative technologies are entering the pregnancy and labour monitoring space with highly differentiated products. Remote monitoring and cloud-enabled solutions from companies are helping universalise ICU-grade physiological monitoring. Finally, new technologies in the respiratory support space have already saved over 10,000 babies in India alone, babies that would have had very poor outcomes if such technologies had not been developed and deployed in India."

Abbott, the global healthcare company, has launched its Amplatzer Piccolo Occluder in India, the world's first medical device that can be implanted in the tiniest babies (weighing as little as 700 gms) using a minimally invasive procedure to treat patent ductus arteriosus or PDA. The Amplatzer Piccolo, a device even smaller than a small pea, now offers hope to premature infants and newborns who need corrective treatment, and who may be non-responsive to medicine and are at high risk to undergo corrective surgery.

Says **Payal Agrawal, GM, Abbott's Structural Heart Business in India and the Subcontinent**, "We are passionate about developing life-changing technologies to help people, including vulnerable infants, live better lives. It is gratifying to know that through our devices, these children have a chance at a normal life and can live their fullest lives."

Researchers from the Indian Institute of Technology (IIT) Jodhpur and Western Michigan University, USA, have identified significant neonatal and infant mortality predictors using multiple machine learning (ML) techniques. The study uses nationwide household survey data from India. The primary objective of this research was to identify early warning signs of child mortality that community health workers can use.

Bengaluru-based Centre for Cellular and Molecular Platforms (C-CAMP) has joined hands with SELCO Foundation, a sustainable technology foundation, to launch the pilot deployment of a long-supported portfolio technology in maternal and neonatal health monitoring. The technology's USP is non-invasive diagnosis and management of neonatal sepsis. The deployment of this technology developed by C-CAMP startup and former incubator Spotsense in the tribal majority Sargur, Mysore district, Karnataka is expected to significantly improve these numbers and make quality healthcare accessible to socially and economically vulnerable communities.

Coeo Labs, an Indian medtech startup, designed a neonatal CPAP system that can help reduce deaths due to Respiratory Distress Syndrome (RDS) during neonatal transportation. Moreover, financial assistance is being provided to local manufacturers in India as part of the government's 'Make in India' programme.

Chennai-based Phoenix Medical Systems is a manufacturer of infant and maternal care products and assistive devices. The Phoenix range of maternal and infant care products includes warming systems, jaundice management units, respiratory care equipment and obstetric and gynaecological tables. Phoenix also makes Smartcane, an electronic travel aid, refreshable Braille readers and standing wheelchairs. The company has a presence across 32 countries in Africa, Europe, the Asia Pacific region, South America and the Middle East.

The company recently launched Brilliance Pro, a phototherapy device to treat infants with jaundice. The device has features to provide consistent intensity across the baby's skin, regardless of the angle at which the light head is oriented.

Mumbai-based Zeal Medical, an ISO 13485 certified organisation, provides neonatal and paediatric intensive care equipment like radiant heat warmers, neonatal resuscitation units, intensive care infant incubators, high-intensity LED phototherapy systems, and non-invasive ventilation systems, smart interfaces and consumables, resuscitation equipment, resuscitation accessories and kits.

Ernakulam-based Ibis Medical Equipment & Systems is an Indian organisation established in the year 2008 and has been engaged in manufacturing high-quality neonatology-focussed equipment. The company has an R&D tie-up with the National Institute of Technology, Calicut (NIT-Calicut). One of the major products is LED Phototherapy machines which the company exports primarily to South Asia and Africa.

Chennai-based Triviron Healthcare was recently conferred with the prestigious India Medical Device Award under the India Medical Device Company of the Year category at the 7th India Pharma and India Medical Device Awards 2022, by the Department of Pharmaceuticals under the Ministry of Chemicals & Fertilizers, Government of India. The company is also into the manufacturing of medical devices for neonates and provides a wide range of newborn screening instruments, including modular and fully automated NBS instrumentation, manual and automated equipment and reagent kits.

Delhi-based startup iNICU Medical is on a mission for early diagnosis of critical diseases and to improve the overall quality of healthcare being provided to neonates. The team of Dr Harpreet Singh, Ravneet Kaur and Dr Gautam Yadav have created a solution that captures data from diversified devices connected to the preterm infant and provides a well-structured user interface for the medical staff to perform calculations for prescriptions, nutrition, and neonatal scores. The iNICU cloud platform also integrates laboratory results, and bedside clinical observations.

Challenges

India imports more than 70 per cent of medical devices, which are not only too expensive to buy and operate but also misaligned with the infrastructure and HR availability in low-resource settings. The situation is even worse in the neonatal care space, due to the super-specialised nature of the field, which has restricted the product offerings available to the Indian market. This has led to the non-availability of essential diagnostic and treatment interventions for newborns, in resource-constrained settings in India and globally.

Wilson Ponnian, Founder and MD, nice Neotech Medical Systems said, "The Central Drug Standard Control Organisation (CDSCO) has brought up the Indian Medical Device Rules (MDR) which is also posing challenges in the Regulatory Affairs of Medical Devices. Only very few devices have been announced to be 'Notified' while there are over 1000 medical devices in the market yet to be added to the list. The delay and the initial phases of trial and error in the process of perfecting the Indian regulatory system for medical devices pose challenges to manufacturers in more aspects rather than financial aspects in particular."

Affordability issues are challenging the neonatal and prenatal devices market growth in India. The cost of NICU care per patient per day is \$125 (Rs 5,450) in India. Middle-class families find it difficult to bear this cost. Hence, such devices are inaccessible and unaffordable in hospitals and primary healthcare centres, especially in remote locations of the country.

Despite the COVID-19 pandemic, the neonatal medical sector was not that impacted. Though there were delays and unreliability at the screening centres that hindered the market, the sector continued to thrive at a high rate even with all the difficulties during the outbreak.

Says **Prof. Dr R Kishore Kumar, Founder and Chairman, Cloudnine Group of Hospitals, India and Senior Consultant Neonatologist at Cloudnine Hospital, Bengaluru**, “The lack of skilled human resources, service delivery challenges, insufficient financial resources, and a lack of community ownership are the most significant impediments to effective scale-up of neonatal interventions in reducing NMRs. Due to gaps in the public health sector's coverage and quality of services, the rural population still seeks healthcare from informal health care providers (IHCPs). Not only this, but there are numerous medical errors due to which neonatal care is affected. For instance, the amount of drug dosage is different for babies and children, since the babies are given their doses according to their weight.”

The way forward

Dr Karthik Nagesh, Chairman & HOD - Neonatal ICUs, Manipal Hospitals & Manipal Advanced Children's Centre, Manipal Hospital Old Airport Road, Bengaluru mentions, “Innovations and transformations in technology have tremendously helped in providing advanced treatment and care to neonates improving their intact survival especially, these last three decades.”

According to Grand View Research, increasing government initiatives in developing countries such as India are favouring the growth of the market in the Asia Pacific. Opportunities are more for medical device companies in a country like India, however, the pricing of these devices can be a deterrent for many as the question of affordability comes into our minds.

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