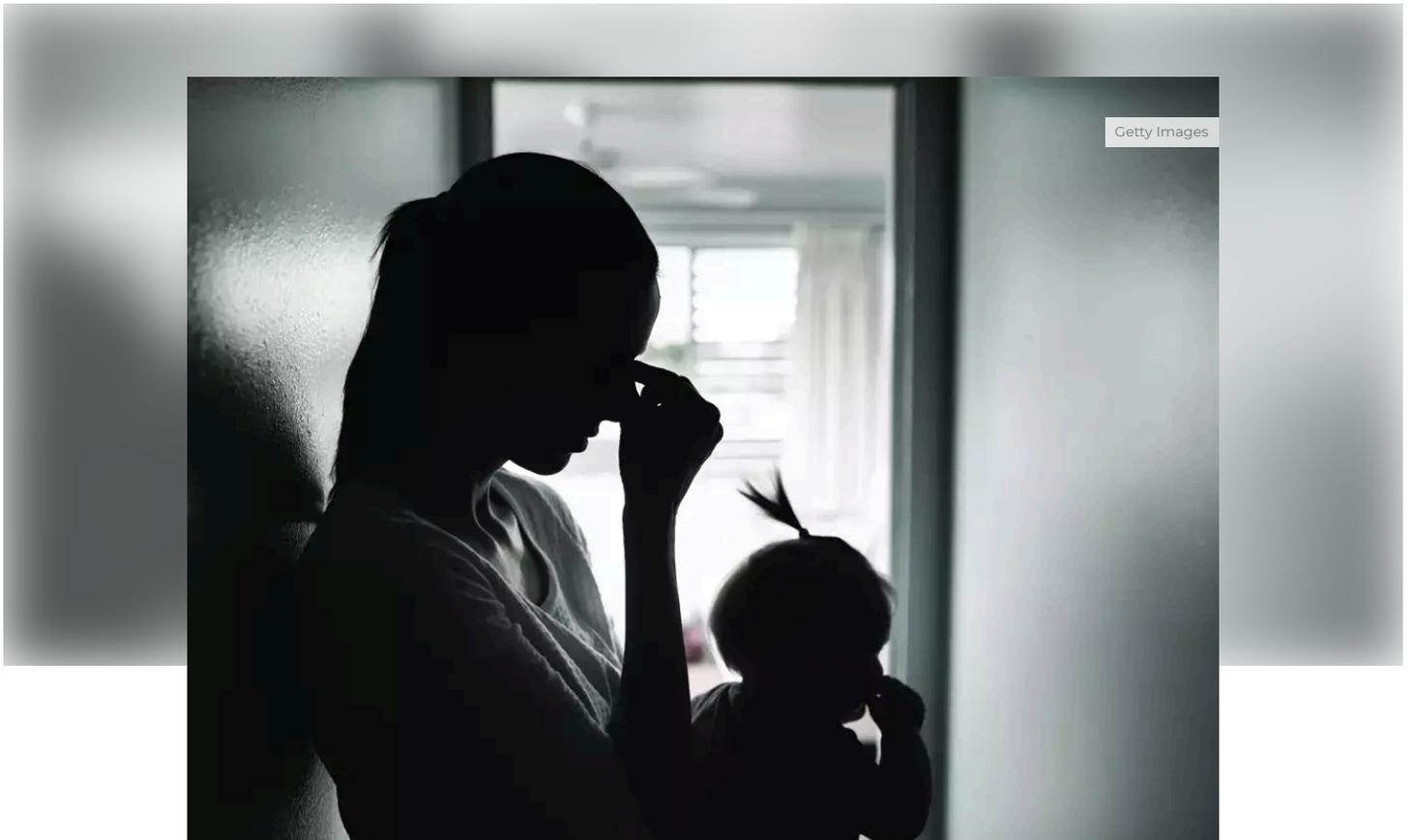


HEALTHCARE

Many new mothers face this problem that plucks the joy out of giving birth.

By Garima Manon Apr 08, 2024, 12:04:12 AM IST



Synopsis

An overlooked mental health challenge faced by new mothers. A powerful new drug could be critical in fighting back. It should have been an obvious match. Yet things may not turn out that way because of pharma industry's pricing vagaries as well as the lack of conversation around the condition itself.

It should have been the much-needed intervention for a ridiculously under-reported condition.

In August 2023, the USFDA approved Zuranolone, sold as **Zurzuvae**, the first oral medication for **postpartum depression (PPD)** developed by **Sage Therapeutics** and **Biogen**.

However, two things brought down the initial optimism.

First, the price for the complete treatment — once-a-day pill for 14 days — costs USD15,900 (around INR13.24 lakh) without insurance.

The second, especially for India, was the non-availability and the non-visibility of any future date for the launch of the medication.

So, why is this important?

One in every five women suffers from postpartum **depression** in India. It is a mood disorder, which after childbirth, women may experience. It ranges from severe mood swings, sadness, intense anger and irritability, changes in appetite, suicidal ideations, difficulty bonding with their baby to the thoughts of harming the baby.

That is a serious and under-reported issue. The sheer number of mothers who go through it underscores the urgency for accessible treatment and policy reforms in maternal care. Lack of diagnostic as well as treatment paradigms for PPD have a direct impact on the mental and physical health of future generations, according to public health experts.

One of the reasons why it remains an underdiagnosed issue is the taboo around being identified with such a condition when juxtaposed with the joy of becoming a parent. That is where normalisation of conversations around this condition can help.

To change the status quo, the first step would be to understand PPD in depth. How did it become so prevalent?

Joy and sorrow

Bringing a newborn baby home is an occasion of immense joy for parents, marking one of life's most cherished experiences. However, amidst this joy lies a harsh reality about childbirth. While all attention is directed towards the infant, the needs of the birth givers are frequently overlooked and under-cared for.

Ananya (name changed on the condition of anonymity), a 36-year-old technology consultant from Mumbai, was diagnosed with dengue shortly after childbirth. Her infant also contracted the illness, leading to separate ICU admissions and a delayed mother-child bonding period by 10 days.

These complications caused physical weakness and sleep disturbances, while Ananya also felt emotionally unsupported by her in-laws. She experienced thoughts of self-harm, prompting her parents to seek psychiatric evaluation and support for her wellbeing.

Ananya was diagnosed with PPD.

Symptoms typically develop within the first few weeks after childbirth, but they can also start earlier, during pregnancy, or later, up to a year postpartum.

Symptoms of PPD

- Feeling sad, worthless, hopeless or guilty
- Worrying excessively
- Loss of interest in hobbies or things you once enjoyed
- Changes in appetite
- Loss of energy and motivation
- Trouble sleeping or wanting to sleep all the time
- Crying for no reason or excessively
- Difficulty thinking or focusing
- Thoughts of self harm
- Lack of interest in your baby or feeling anxious around your baby
- Thoughts of harming your baby or feeling like you don't want your baby



Source: ET Prime research

ETPrime

K. Srinath Reddy, honorary distinguished professor at the **Public Health Foundation of India** and former head of the cardiology department at AIIMS, New Delhi, asserts that inadequate nutrition and social stressors, such as interpersonal conflicts, the stress of poverty, or caste discrimination, can significantly affect women's mental wellbeing. Furthermore, prolonged high levels of stress during pregnancy and delivery are likely to have impact on both the foetus and the mother.

A study published in ScienceDirect reports that PPD affects 10%–30% of mothers globally, with 22% of mothers in India experiencing it. But most remain undiagnosed.

Doctor Nandita Palshetkar, head of IVF department at Lilavati Hospital, Mumbai, explains that inadequate sleep and challenges of nursing a newborn can exacerbate the situation, further increasing women's vulnerability to depression.

According to **The Guardian**, an estimated **one in seven women** can develop some form of PPD – postpartum blues, postpartum depression, or postpartum psychosis.

Women who have untreated PPD over the long term are at the risk of developing chronic depressive disorder, and their babies may also develop issues, says Dr. Anjali Kumar, director, obstetrics and gynaecology and head, hospital advisory council director, at C K Birla Hospital, Gurugram.

She adds that “these can range from learning disabilities and behavioural problems to potential setbacks in language comprehension and development, particularly when the mother's progressive disorder remains untreated”.

The pill challenge

Zuranolone, sold as **Zurzuvae**, was supposed to be a game changer.

Initially, the pricing for the drug was anticipated to fall below USD10,000, based

on the assumption that the USFDA would grant approval for Major Depressive Disorder (MDD), encompassing a broader spectrum of mood disorders, affecting **approximately 264 million people worldwide.**

The **global market size for MDD** was projected to be around USD3,985 million in 2021 and is anticipated to reach USD6,647 million by 2027. In an ideal world, market opportunities should not dictate the availability and accessibility of critical medical interventions, but then we don't live in an ideal world. MDD represents a significantly larger patient population compared to the often-underdiagnosed PPD.

However, the US pharmaceutical regulator sanctioned the drug only for PPD, disrupting Sage Therapeutics' pricing strategies. The FDA communicated to the partners that their application lacked "substantial evidence of effectiveness," for MDD, necessitating further studies.

This development compelled the company to undertake workforce restructuring as it grappled with assessing the drug's potential.

As of today, there is no visibility on the introduction of this drug in India. *ET Prime's email to the pharma company remained unanswered.*

Even if it is launched, the cost will be a major impediment and curtail access. If the company doesn't bring down the prices, it might be a prudent option for public health officials to work on figuring out if there could be alternative funding channel that can help those who need this the most find access to it.

A **study published** by the US-based National Center for Biotechnology Information (NCBI), delves into the financial impact of untreated postpartum mood and anxiety disorders among births in the US in 2017. The average cost per affected woman was approximately USD32,300. Unfortunately, similar studies are not available in our country.

The under-reporting problem

In Ambala Cantt, a small town in Haryana, 34-year-old Sakshi Arora found herself grappling with a profound sense of isolation during her pregnancy. A sudden medical emergency in her family diverted attention away from her, leaving her feeling neglected at a time when she needed care the most. These sudden changes took a toll on her mental wellbeing. Shortly after giving birth, she received the diagnosis of Sjögren's syndrome, an autoimmune disorder, further adding to her anxiety.

"I used to wake up feeling sad. I can barely recall waking up feeling happy," Sakshi adds.

Dr. Kumar says that PPD is often mistaken for the mother being "tired or worked up after delivering the baby", resulting in it being underdiagnosed.

While the exact cause and pathophysiology remain unclear, several risk factors are associated with the disorder including perinatal anxiety, a history of depression, family history of depression, preterm labour and delivery, and difficulty conceiving. Dr. Kumar further explains, "A sudden drop in the hormones estrogen and progesterone in a woman's body can signal changes in neurochemistry, leading to these alterations."

Stressful life events, low social support, marital discord, domestic violence, and isolation are often overlooked risk factors that can impact mental wellbeing.

Saumya Pahwa, a consultant clinical psychologist from Noida, says, "Clinical observations suggest that psychosocial stressors also play a significant role in PPD."

According to a **study published by NCBI**, suicide is a leading cause of death in the perinatal period (pregnancy and first year postpartum). **In a study** on an Indian cohort of pregnant women, 7.6% of the mothers exhibited signs of self-harm.

Why drugs like Zurzuvae are important

Currently, the primary treatment approach for women experiencing mild-to-moderate symptoms involves a combination of psychotherapy and 'off-label' use of antidepressants. The dosage and duration of treatment vary based on symptom severity, with antidepressants typically prescribed for a course lasting 3 to 6 months.

Current treatment paradigm

Generic name	Common side-effects
Sertraline	Nausea, drowsiness, dry mouth, loss of appetite
Fluoxetine	Insomnia, headache, feeling tired
Duloxetine	Nausea, drowsiness, dry mouth, loss of appetite
Bupropion	Anxiety, dry mouth, restlessness
Amitriptyline	Constipation, dry mouth, headache



Note: A doctor can help you decide what medicine is right for you based on your symptoms and if you're nursing.

Source: ET Prime research

 ETPrime

Although Sakshi's doctors advised her to seek additional emotional support from her family, she found solace by carving out time for herself and sharing baby responsibilities with her partner. However, many women struggle to access such support.

The development of the first oral pill marks a significant step in reducing the stigma by recognising the biological roots of PPD, emphasising that it is not the fault of women.

This approval for oral medication could encourage more women to seek care. Clinical trials suggest it works swiftly, beginning to alleviate depression in about three days, much faster than regular antidepressants.

In 2019, the only USFDA-approved treatment for PPD was an IV injection called Brexanolone, marketed as **Zulresso**, also developed by Sage. It requires a hospital-based 60-hour treatment costing USD34,000. In the US, this faced insurance payout issues. It is also currently available only through a restricted program because of a plethora of associated risks. This is not available in India currently.

Zurzuva is a fast-acting medication. The pill can be taken at home, eliminating the need for prolonged separation of mother and baby.

However, with the drug currently unavailable in India, a question lingers: How can the treatment be made accessible and affordable for new moms?

Beyond drugs

Implementing early screening and diagnosis by nationwide development of structured screening systems, reducing the treatment gap by training healthcare staff, improving access to counselling services, and prioritising research on population prevalence are crucial steps toward fight PPD.

While some institutions and states are working towards creating structured facilities; fighting PPD requires a multifaceted approach by the government, healthcare providers, policymakers, communities, and families.

Prabha Chandra, senior professor of psychiatry and dean of behavioural sciences at National Institute of Mental Health and Neurosciences (Nimhans), Bengaluru, says that in many high-income countries of the global North, antepartum and postpartum mental health are routinely assessed at various stages throughout maternity care, beginning from the initial booking during pregnancy until the child reaches one year of age. "Such structured care is not commonly implemented in our country," she adds.

Nimhans, in collaboration with UNICEF and the Government of Telangana, is working towards integrating mental-health screening into routine maternity care in the public health system for the entire state. Chandra explains that "this approach can effectively identify risk factors in pregnancy, potentially preventing postpartum depression and ensuring women receive the necessary support."

That is light at the end of the tunnel.

(With inputs from Vikas Dandekar; graphics by Mohammad Arshad)