



**Give Life a
Better Beginning:**
Reinventing
Pregnancy Care
for the 21st Century

NUVOTM

The Current State of Pregnancy Care

The ability to protect the health of mothers and babies in childbirth is generally considered to be one of the fundamental indicators of a society's development^[1]. Over the past 25 years, the maternal mortality ratio (maternal deaths per 100,000 live births) has diminished by nearly 44 percent globally, with most maternal deaths occurring in developing countries^[2]. In stark contrast to global trends, the maternal mortality ratio in the U.S. has increased by more than 50 percent over the last 25 years – making the U.S. one of the only developed countries where the rate of maternal mortality has continued to rise^[3,4,5,6].

Maternal health is not the only area of childbirth experiencing troubling trends. According to the March of Dimes, the preterm birth rate in the U.S. has worsened for a third straight year, with 30 of 50 U.S. states reporting an increase in the number of premature births, one of the largest contributors to infant death^[7]. And while the overall rate of infant mortality has declined, the U.S. continues to lag behind other wealthy countries. According to the most recent data from the Organisation for Economic Co-operation and Development (OECD), babies in the U.S. are 76 percent less likely to reach their first birthday than babies born in other wealthy member countries^[8,9].

Driving these troubling trends are a growing number of challenges facing maternal-fetal care in the U.S. Rising incidence of chronic conditions amongst expectant mothers is driving up rates of high-risk pregnancy (HRP). Access to pregnancy care continues to diminish as obstetric units close and the number of practicing Ob-Gyns declines dramatically. Both parents and providers struggle to cope with the untenable costs of pregnancy and birth^[11,12]. And connecting all these challenges is a common fundamental issue—a standard of care that is in need of improvement, based on outdated and inefficient technology that has changed little in more than three decades. The result: an overburdened health system where parents and clinicians have minimal visibility into what's actually happening in the womb.

We can, and must, do better.

There are nearly four million births in the U.S. per year, and this number is expected to rise over the next decade^[12,13]. Daunting as the situation may seem, now more than ever it is imperative that we identify and understand the challenges facing maternal-fetal care and explore new and innovative opportunities to address them. It's time to radically transform how we approach pregnancy and take action to give life a better beginning.

“Richest country in the world, and we have this kind of [prenatal care] rate. It's just a travesty, to be honest with you.”

—Dr. Thomas Mayes, head of pediatrics at the UT Health Science Center, San Antonio, TX told the San Antonio Express News

In Bexar County, Texas, where San Antonio is located, nearly one in six women who gave birth in 2014 received no prenatal care – up from one in 40 three years earlier – according to the San Antonio Metropolitan Health District's latest statistics. Bexar County also has one of the highest premature birth rates in the nation.



A Broken System Crying Out for Change

Pregnancy Management Designed for a Bygone Age

In many areas of medicine, advancements in technology have made healthcare solutions commonplace that only a few decades ago seemed impossible. Unfortunately, while a significant number of practice areas such as oncology, cardiovascular medicine and chronic conditions have seen substantial technological innovation, maternal-fetal health is not one of them.

Doppler and Cardiotocography (CTG), the monitoring technology underpinning today's standard for pregnancy management, was designed and built for an analog age. Lacking portability and requiring active administration by a medical professional, this approach limits information about the health of a pregnancy that can be collected during monthly in-office visits. As a result, parents and physicians are left with a fragmented and episodic view of the pregnancy journey that makes it difficult to confidently chart the course of a pregnancy and identify potential problems that could impact the health of mother and baby.

Despite the serious implications of complications during pregnancy^[14], there exists no holistic platform for integrated, connected and continuous care. Instead, parents and physicians are left with a costly, inconvenient and dated standard of care.

High-Risk, High Cost

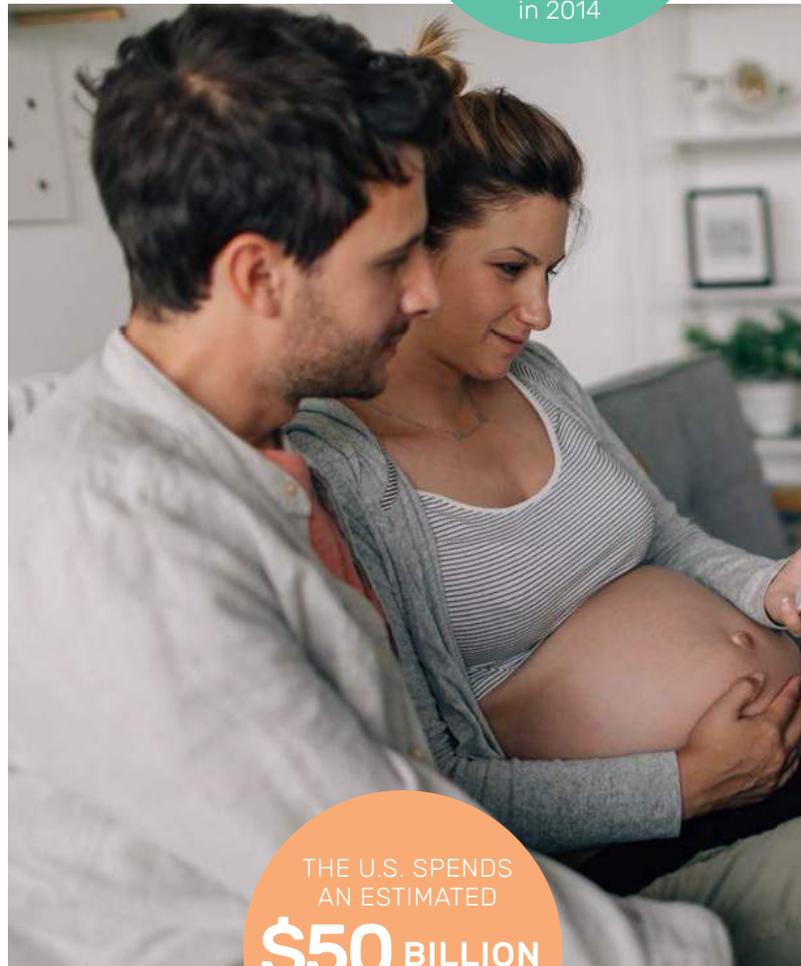
While most women in the U.S. give birth to healthy babies and without serious complications, pregnancy and childbirth come with a variety of health risks for both mother and baby. Even with today's modern medicine and technology, complications are common^[15].

In recent years, the U.S. has seen a growing trend in conditions contributing to HRP, including advancing maternal age, more multiple births due to IVF treatments and rising rates of chronic conditions such as obesity, diabetes and hypertension^[11,16]. Increased monitoring of the pregnancy's progression, which enables quicker and earlier intervention, is critical to protecting the health of mother and baby. However, limitations in the portability and administration of current monitoring technology means that even with additional prenatal visits, insight into HRP remains fragmented and makes charting a path towards better outcomes challenging. According to the CDC, rates of the most severe HRP cases (commonly referred to as severe maternal morbidity) have been steadily increasing in recent years and affected more than 50,000 women in the United States in 2014^[17].

These pregnancies not only pose significant risk to mother and baby, but also come at a high-cost for both parents and the healthcare system^[17] – a cost that can be traced back, in part, to the outdated technology and standard of care. The U.S. spends an estimated \$50 billion annually on prenatal, antenatal and postpartum care – more than almost any other country^[18]. More than half this, roughly \$26 billion, is spent on managing HRP and premature births^[19,20]. And healthcare systems are not the only ones feeling the cost; outdated technology also increases the burden on expectant parents with a HRP.

The limited nature of current pregnancy monitoring technologies, which require frequent in-office administration by a healthcare professional, means expectant parents must invest even more personal time and cost spent traveling to and from appointments. This can mean in-clinic or in-hospital visits ranging from twice monthly to weekly or more, which can quickly become cost-prohibitive for many women and ultimately drive down compliance – putting both mother and baby at risk^[11,21].

SEVERE HRP
CASES AFFECTED
50,000
WOMEN
in the U.S.
in 2014



THE U.S. SPENDS
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antenatal and
postpartum care

A Shortage of Ob-Gyns

Despite rising birth rates and cases of serious HRP, access to obstetrics services continues to decline – especially in rural communities^[12,17,22]. This is due in large part to a growing shortage of Ob-Gyns^[12]. The American College of Obstetricians and Gynecologists (ACOG) puts the current shortage at 6,000 to 9,000 Ob-Gyns countrywide and expects this number to grow to 22,000 by 2050^[23]. According to the most recent estimates, nearly half the counties in the U.S. don't have a single Ob-Gyn and 56 percent are without a nurse midwife^[12]. Not only is this burden being felt by the dwindling numbers of Ob-Gyns, but it's putting a growing number of families at a distance from care that is not just inconvenient, but also dangerous.

One of the largest contributing factors to this decline is the overburdening of Ob-Gyns, many of whom struggle to manage mounting patient loads with unpredictable hours and high liability^[23,24,25]. Rather than offer a solution, standard pregnancy care technology only serves to exacerbate these issues. Current clinical guidelines recommend about 12 – 14 prenatal visits over the course of a healthy pregnancy. Most of these visits simply confirm that the pregnancy is progressing as expected, but limitations in monitoring mean that all these visits must be done in-office with expensive technology regardless of the status of the pregnancy^[26]. With these limitations and episodic care, nearly 75 percent of expectant mothers make unscheduled obstetrics visits, contributing to a significant cost in time and unnecessary utilization of resources for clinicians, patients and health systems^[26,27].

These challenges have had profound implications for maternal-fetal health, but the opportunity exists to make a radical change. Already advancements in technology have made healthcare solutions commonplace that only a few decades ago seemed impossible. From robotic surgery and cutting-edge immunotherapies to wearable health devices and personalized data collection, we are constantly reinventing what healthcare looks like. It's time we do the same for pregnancy care.

“Having the right doctors, having the right care, having the right people that know about your diagnosis, that understand your diagnosis, that know what they're doing, it's life and death.”

- Alana Alvarez to USA Today

According to the New York Times, upon news of Twin Rivers closing, the waiting room of the only obstetrician in Kennett, who practiced out of the hospital, became “a scene of sadness and confusion as women worried about where they would go and how they would afford gas for weekly visits at distant hospitals, when they barely had enough money to pay electric bills and rent.”



The Power of Connected Technologies for Pregnancy Care

Fitness apps and digital devices are becoming increasingly popular in the consumer health sector, promising to track heart rate, sleep and other lifestyle decisions that impact your everyday health. But the power of remote monitoring extends far beyond fitness tracking, and at the clinical level holds the potential to help address many of the issues plaguing current pregnancy monitoring.

We need to develop and invest in innovative, connected solutions that enable a holistic approach to pregnancy management and help close the gaps in the continuum of care. Remote monitoring already exists in other areas of medicine, that if harnessed for pregnancy management, would allow us to radically transform the way people think about pregnancy care.

“I’m facing this fear daily. I’m terrified that I won’t walk away from it.”

– Donielle Bell of Atlanta, Georgia to USA Today.

Donielle says she “never got good answers” as to the cause of her hemorrhaging during childbirth in 2016, and whether it would happen again during the birth of her third child this past spring. She delivered a healthy baby but lost enough blood to require an emergency hysterectomy to save her life.

The Potential of Remote Monitoring and Digital Solutions

Enabling Better Insight in the Pursuit of Better Outcomes

Remote monitoring is quickly becoming a central part of care in many therapeutic areas, as physicians realize the benefits and convenience of replacing episodic, in-person visits with continuous, real-time data. To date, chronic conditions such as diabetes, hypertension and chronic heart failure have seen the widest adoption of remote monitoring solutions^[28], but there is significant opportunity in pregnancy management as well.

The current approach to pregnancy management forces physicians to rely on the tiny fraction of information that can be collected during in-office visits. Digital, remote monitoring technologies offer the potential to expand care beyond the clinic and into the home, enabling continuous data collection for a holistic view of pregnancy that closes the gaps between in-office points of care. Physicians will thus gain comprehensive insight into a pregnancy so they may more frequently observe changes, evaluate trends and ultimately make more accurate and informed care decisions. This potential is particularly important for HRP where the rapid identification of possible complications and proactive intervention are critical^[29].

And while remote monitoring has so far seen relatively limited use in pregnancy management, many institutions have begun implementing remote monitoring programs focusing on high-risk patient populations. The preliminary data have shown promising results:

- A recent Belgian study found that remote monitoring helped reduce prenatal hospitalization of women with gestational hypertensive disorders, as well as neonatal admissions to the NICU^[30].
- Another study of expecting mothers with gestational hypertensive disorders reported higher patient satisfaction, improved symptoms and reduced in-patient visits when using remote patient monitoring in prenatal care^[31].
- A University of Pittsburgh Medical Center study found that postpartum remote monitoring helped women who had experienced gestational hypertensive disorders stay more engaged in their postpartum health and reduced the number of one-week follow-up visits required. The hospital found that 88 percent of patients participating in the program returned for a six-week postpartum visit, compared to the 30 – 40 percent nationally. These findings are particularly promising given that women remain at risk for complications weeks after giving birth and postpartum care is often overlooked^[32].

These positive findings are echoed in other areas of care where remote monitoring is common. For example, early adoption of telemedicine in sleep apnea patients showed improvements in symptoms and the patient's adherence to treatment^[33]. A systematic review published in the British Medical Journal showed that remote monitoring programs for patients with chronic heart failure reduced hospital admissions and readmissions, symptom severity and mortality by nearly one-fifth, while improving health-related quality of life^[34].

But remote monitoring is only one piece of the puzzle. For remote monitoring to truly enable better clinical decision-making, it will be critical to incorporate other digital technologies such as artificial intelligence (AI) and data-analytics.

Leveraging the Power of Artificial Intelligence

AI has the potential to be a transformative force for the health of mothers and babies and is key to leveraging the full power and potential of remote monitoring.

Access to greater or continuous patient data, while informative, has quickly outpaced the capabilities of the average clinical staff^[35]. To help address this, AI is being employed to digitize and automate the current practice of documenting outputs into electronic medical records, making rule-based decisions, reducing human error, reducing physician liability and reducing manpower/costs. AI has already been incorporated into a variety of major disease areas such as cancer, neurology and cardiology for early detection and diagnosis, treatment, and even outcome prediction and prognosis evaluation^[36, 37, 38].

In pregnancy management, AI has the potential to empower physicians with more insightful data and trends that can be used to identify the optimum path of care for mom and baby. And in the future, it could enable physicians to predict outcomes or power population health.



Cost-Savings, Access and Managing Physician Workload

Beyond improving outcomes, remote patient monitoring is cost-effective for both healthcare systems and patients, and provides a solution to overburdened clinical staff and care providers. Remote monitoring is already demonstrating these benefits in several therapeutic areas.

In cardiovascular disease, studies have found that remote monitoring can help lower costs by managing resource utilization and reducing the number of hospital visits/readmissions and length of stay, with one study reporting a nearly 41 percent reduction in the annual cost of follow-up care^[39,40,41].

A study looking at the use of remote monitoring in elder care reported a reduction in hospital admissions and emergency room visits, not to mention increased reports of greater patient satisfaction^[42].

41%

reduction in the annual cost of follow-up care

In pregnancy care, benefits have been seen for both high-risk and low-risk pregnancies:

- A study from Hasselt University in Belgium found that remote monitoring of a HRP population (gestational hypertensive disorders) resulted in overall savings for both patients and the healthcare system, attributed to a reduction in use of healthcare resources such as laboratory testing, medication use, and maternal and neonatal admissions^[30].
- Participants in a remote monitoring program for low-risk pregnancies initiated at Mayo Clinic reported saving time and money by replacing some in-office visits with remote monitoring data. For physicians, the program helped lessen workloads and create efficiencies so that focus could be redirected to HRP cases^[43,44].

In addition to reducing cost and improving efficiencies, remote monitoring offers the potential to improve access to care^[44]. As the number of Ob-Gyns diminishes and rural hospitals cut back on obstetric care units, ensuring access will be critical to providing pregnancy care^[45]. In fact, according to the American Medical Association, telehealth and remote patient monitoring will become essential to ensuring access to care generally, especially in the U.S. health system which is marked by significant and persistent specialty shortages and geographic disparities^[46]. The good news is that programs like the one at Mayo Clinic are already showing potential, and public health officials believe it will improve convenience and accessibility for women in more remote areas^[43,44].



Patient Experience

Standard monitoring technology is pointedly at odds with the needs and expectations of modern parents. With the consumerization of healthcare, patients are increasingly looking for a clinical experience that fits into their digitally-driven lifestyle. Millennials expect efficient, affordable, tech-powered care with information that's readily accessible at their fingertips – their expectations for pregnancy are no different^[47,48].

Offering only an episodic relationship with their healthcare provider and a fragmented view of their pregnancy journey, the current standard of care leaves parents in the dark for much of their pregnancy. This can lead to stress, anxiety and unnecessary health visits, all of which can contribute to poorer health outcomes and increased cost of care.

Unsurprisingly, today's moms are using technology throughout their pregnancies more than ever before. Expectant millennials are turning to technology not only to stay informed, but also to become more involved in and connected throughout their pregnancy. For many patients, telehealth and remote patient monitoring help fill this need, and evaluations of the use of remote monitoring in pregnancy management typically show high patient satisfaction scores^[44,48].

Incorporating mobile technology will be a key factor in creating user-friendly and accessible remote monitoring solutions. The combination of connected devices and remote monitoring solutions will help create a connected community of care that today's expectant parents crave. With these types of tools, parents and physicians will have better insight into pregnancy, more easily share information and stay connected throughout the pregnancy journey^[48,49].

Realizing the Benefit of Remote Monitoring

Remote monitoring solutions hold significant potential for addressing many of the issues contributing to the current maternal-fetal health crisis. However, not all remote monitoring is created equal. It will be important for the maternal-fetal health community to invest in remote monitoring solutions that move beyond the commercial health-tracking apps and digital devices that have become so pervasive. To make a difference, the maternal-fetal health community must adopt a remote monitoring system that goes beyond tracking to:

- Create a roadmap of meaningful data that can inform the physician
- Paint an accurate picture of the patient's health
- Be actionable and predictive for more insightful care decisions
- Be helpful in collecting data for the overall future of maternal-fetal health

It is only with these features that remote monitoring will be able to impact outcomes at the clinical level.

“Advances in technology for pregnancy management indeed have the potential to improve upon the current standard of care. However, it is essential that parents and clinicians insist upon medical-grade technologies that undergo clinical validation to ensure accuracy.

Moreover, while remote monitoring can empower women to have a more active role in their care, pregnancy monitoring in a vacuum could possibly increase patient anxiety and cause unnecessary medical interventions. Therefore, such novel approaches should only be pursued in partnership with clinical providers and in situations where such monitoring have been shown to provide medical benefit without unintended harm.”

*- Dr. Nadav Schwartz,
MD, an obstetrician-gynecologist*

Challenges and Considerations to Implementing Remote Monitoring and Digital Solutions

Although remote patient monitoring suggests promising outcomes for pregnancy management, challenges remain in developing a solution for the unique needs of maternity patients. While the benefits of continuous, real-time data are profound, it's only useful if it can be interpreted for insights. Additionally, the sheer amount of data can be overwhelming and potentially off-putting for some clinicians. For a remote monitoring solution to be truly worthwhile to parents and clinicians, it must be integrated into a complete platform that includes data analytic capabilities to help process the large amounts of incoming information^[50].

Another potential challenge to remote monitoring is overcoming a lack of system interoperability with existing technology, and threats to patient confidentiality as continuous data is shared across platforms. Given that health systems are already challenged with how to manage EHR data, it will be critical to ensure that remote monitoring solutions are designed to integrate with current systems in a way that promotes rather than threatens operating efficiency. In fact, in a recent survey nearly 44 percent of clinicians surveyed cited operating efficiency as a top priority^[36].

Concerns over usability and decreased personal interactions between patient and physician will require that any effective remote pregnancy monitoring system be patient-friendly, intuitive and easy to use, so that parents remain engaged and informed throughout their pregnancy.



Summary – Reinventing Pregnancy Care

“There is so much we don’t know due to the absence of proper tools; therefore, there is so much we can’t do.”

- Dr. Jack Rychik, MD, Director Fetal Heart Program, Children’s Hospital of Philadelphia (CHOP)

The U.S. is in the midst of a maternal-fetal health crisis. Despite spending more than any other country on hospital-based maternity care^[5], maternal mortality and preterm births continue to rise in the U.S.^[2,7]. It is a crisis driven by a variety of factors but underpinning it all is an outdated standard of pregnancy care based on technology that offers an incomplete picture of the health of mother and baby.

What is needed is investment in new tools that capture comprehensive, high fidelity data across multiple physiologic measures, combined with a digital platform that expands access to a medical grade standard of care. Imagine a world of “connected pregnancy” where mothers are the points of care and data seamlessly connects visits across the home, workplace, doctor’s office and hospital. The potential result? Reduced costs, increased patient satisfaction and improved clinical outcomes.

Nuvo recognizes this need to reinvent pregnancy for the modern era. Our vision is to be the world’s transformational leader in advancing maternal-fetal connected health. We want to make the womb transparent to a community of care through data views. This is why we are working to revolutionize pregnancy management with an AI-powered pregnancy monitoring and management platform.

The Nuvo platform, under development and in the FDA clearance pathway, includes proprietary wearable technology, data algorithms and innovative digital tools designed to extend access to the medical-grade standard of care, anywhere.

There is significant potential for connected solutions in pregnancy management. By collecting and connecting to patient data and insights, this type of technology not only offers parents and clinicians a more complete picture of each individual pregnancy journey, but also a way to gather information that can help inform new maternity care protocols and advance population health.

Imagine a world where we can collect better information to make better decisions, give mom peace of mind and create better access to care, all while reducing the burden on the healthcare system. We can and must improve pre- and postnatal outcomes for every woman regardless of race, income or geographic location to give life a better beginning.

It’s time for the next generation of parents and clinicians to meet the next generation of maternal-fetal care.

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