Pulsenmore™
Home Ultrasound

Clinical evidence and real world adoption of the Pulsenmore telehealth and home ultrasound platform

Advancing prenatal care with accessible hybrid solutions

Executive summary

Telehealth has been shown to improve access to care and reduce costs. Telehealth is especially beneficial in antenatal care, supporting high-risk patients and ensuring continuity of care. Pulsenmore's self-operated and clinician guided home ultrasound device represents a significant advancement in hybrid prenatal telehealth.

Clinical evidence outlined in this white paper demonstrate that the Pulsenmore system:

- Is safe, effective, and user-friendly for both patients and clinicians.
- Can be integrated into routine obstetric care.
- Supports remote monitoring for high-risk pregnancies.
- Reduces the duration of in-clinic visits.
- Decreases maternal anxiety and fosters stronger fetal-maternal attachment.
- Enhances the overall pregnancy experience & improves patient satisfaction.

Evidence-based advantages of telehealth in prenatal care

Overview: Challenges in prenatal care

Many expectant mothers face significant barriers to receiving timely and consistent care, which is essential for the well-being of both mother and fetus. Healthcare systems, already burdened by limited resources and high demand, often struggle to meet these needs with traditional in-person visits alone.

Since the 1990s, telehealth and virtual care have transformed healthcare delivery, enabling patients and providers to connect through digital platforms, mobile apps, and telecom technologies. This shift not only enhances convenience and cost efficiency but also offers personalized and patient-centered care models, significantly improving accessibility.

Evidence-based advantages of telehealth in prenatal care (Not specific to Pulsenmore)

Hybrid models in prenatal care: Enhancing safety & efficiency

The COVID-19 pandemic served as a catalyst, expanding the role of telehealth in prenatal care by reducing face-to-face visits. One example of an innovative prenatal care approach is a hybrid model, like the OB Nest program, which integrates telemedicine into the traditional visit schedule.[2] In this model, patients are offered a combination of virtual and in-person appointments, allowing for consistent prenatal monitoring without requiring frequent in-person visits. Virtual visits, which can be conducted with an obstetrician, advanced care practitioner, or nurse, are held via video or phone, providing more flexibility and convenience for patients. This approach maintains continuity of care while reducing the strain on clinic resources and enhancing patient satisfaction.

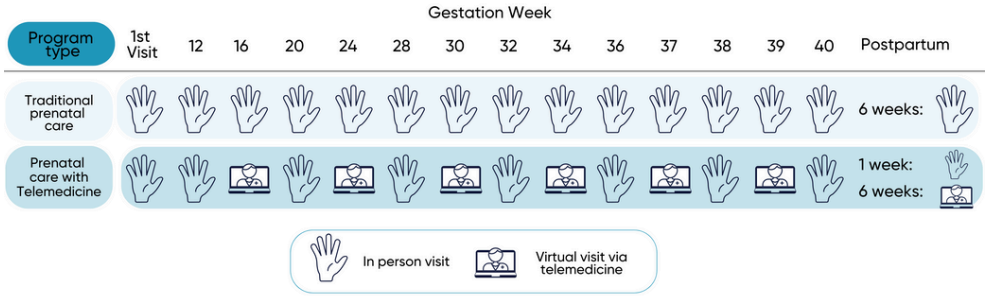


Figure 1: Example comparison of visit schedules using traditional vs. telemedicine models of prenatal care. OB Nest program at Mayo Clinic.[2]

A recent meta-analysis of 5 large studies involving up to 230,000 high-risk pregnancies, compared integrated telehealth with conventional care.[3] Multiple studies reveal that telehealth for obstetric care maintains a high standard of safety, with outcomes showing no increased risk of complications such as hypertension, preeclampsia, or preterm birth. Importantly, telehealth increases system efficiency, reduces the economic burden, and enhances patient satisfaction—empowering expectant mothers with self-monitoring options, and supporting healthcare providers with tools for effective remote care. Through telehealth, the field of prenatal care can advance without compromising clinical needs, while supporting patients' quality of life, reducing costs, and alleviating clinician burden.[4]

Multiple advantages of telehealth in prenatal care

- Enhanced patient satisfaction, increased access to care and cost savings: Telehealth visits improve patient satisfaction, streamline hospital and clinic workflows and promote better communication between patients and healthcare providers. Telehealth enhances access to care and saves patients travel time and costs, leading to better compliance with pregnancy monitoring.[5]

- Improved clinical outcomes: Telemonitoring can improve maternal and fetal outcomes, including reduced cases of low birth weight and NICU admissions.[6] It also reduces diabetes-related complications such as macrosomia, fetal demise, caesarean delivery and hypertensive disorders. Implementing telehealth has also shown a reduced risk of preeclampsia in patients with hypertensive disorders.[7]

- Cost reduction: Remote monitoring of pregnant women with gestational hypertensive diseases (GHD) can reduce healthcare costs by 15-23% compared to conventional care.[8] Another study found that telehealth monitoring for high-risk pregnant women was associated with an average saving of 19.7% compared to traditional antenatal care.[9]

- Hospitalization replacement: Replacing hospitalization with at-home remote monitoring for high-risk pregnant women resulted in a 30% cost saving per woman, largely due to a significant reduction in admitted days.[10]

Summary: A hybrid care plan that combines telehealth visits with in-person visits can lead to better access to care, stronger connections with the healthcare team, improved continuity of care, increased satisfaction, and reduced time and costs for both patients and healthcare providers.

Ultrasound in remote prenatal care

Since its introduction in obstetrics and gynecology, ultrasound has been the modality of choice for reliable and safe prenatal imaging, determining position of the embryo, verifying fetal viability and development, identifying anomalies and monitoring the wellbeing of the fetus throughout pregnancy.

Advances in ultrasound and digital communications have led to the development and introduction of teleultrasound for remote assessment of fetal wellbeing. This innovative approach is gradually being incorporated into various prenatal care models, exhibiting various benefits for clinicians and patients. With remote ultrasound, scans can be performed in one location and the images transferred for remote review and interpretation, or transmitted for real-time feedback.[11,12]
Results from 31 studies on innovations in ultrasound show promising results for tele-ultrasound applications. Most studies could demonstrate a benefit for pregnant women and/or healthcare providers.[13]

With recent advances in research and technology, remote ultrasound is being adopted into various prenatal care models, exhibiting various benefits for clinicians and patients alike.

The Pulsenmore solution expanding the capabilities of telehealth for antenatal care

Pulsenmore, a pioneer in connected home ultrasound technology, has developed a comprehensive digital prenatal care platform. This platform allows women during pregnancy to perform scans, which are then transmitted securely to clinicians for remote review and consultation.
The system consists of:

- An ultrasound cradle: A device that connects seamlessly to the user's personal smartphone.
- A mobile app: Offers step-by-step guidance for self scans and enables secure interaction with clinicians.
- A clinician dashboard: A secure, web-based platform that allows medical teams to interact with patients, review scans remotely and provide clinical feedback.

The handheld transducer captures ultrasound clips, which are processed by the smartphone and displayed on the clinician's dashboard as high-resolution B- and M-mode ultrasound clips, ready for clinical interpretation.

Figure 2: The solution's components

The solution captures essential fetal health parameters, including fetal heartbeat, movement, tone, breathing, and amniotic fluid levels, delivering comprehensive insights into fetal well-being.
Pulsenmore's device, optimized for ultrasound imaging at low frequencies (2-5 MHz), is intended for use by pregnant women with singleton pregnancies from 14 weeks of gestation onwards in non-clinical environment. The platform offers two scanning modes to cater patient and clinical needs:

Clinician-Guided (CG) mode:

This real-time telehealth feature allows the patient to connect with the clinician through a video meeting on the Pulsenmore app. During the session, the clinician can directly guide the scan, control ultrasound parameters, and provide immediate feedback and interpretation.

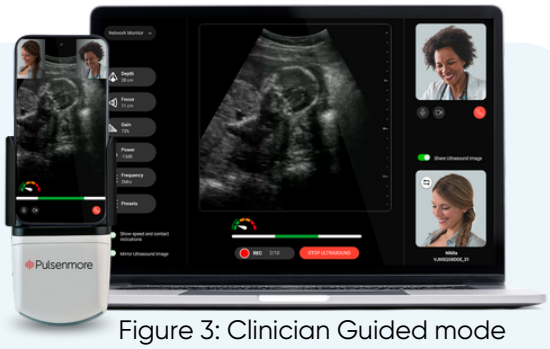


Figure 3: Clinician Guided mode

App-Guided (AG) mode:

This mode provides step-by-step video tutorials through the Pulsenmore app, allowing the user to complete the scan, based on the 'Six Step blind swipe protocol'.[14] Once the scan is completed, files are securely uploaded to a cloud, enabling the clinician to review three essential fetal parameters—heartbeat, movement, and amniotic fluid volume—asynchronously.

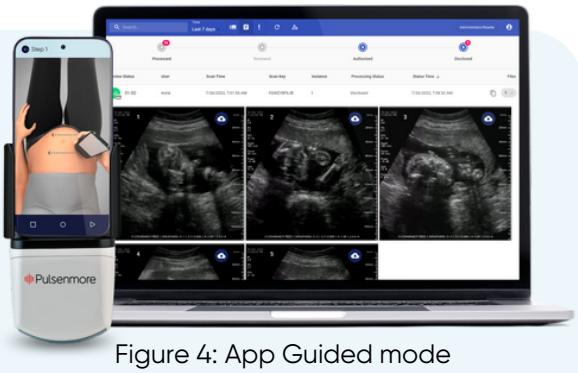


Figure 4: App Guided mode

Figure 5: The Pulsenmore app guides the patient

Pulsenmore's solution is an innovative step forward in prenatal telehealth, combining advanced ultrasound technology with a user-friendly interface to support hybrid models of prenatal care and extend clinical capabilities beyond traditional healthcare settings.

Clinical evidence for Pulsenmore: Feasibility, validation & user acceptance

Is Pulsenmore a feasible and accepted option for remote prenatal care?

Several studies suggest that Pulsenmore's device is both feasible and well-accepted by users. A study at Beilinson Hospital in Israel assessed Pulsenmore's effectiveness in monitoring fetal well-being across 100 pregnant women (14-40 weeks gestation).[15] Over a week-long period, each participant conducted 1-3 self-scans daily, totaling 1,360 scans across the group. The results were compelling: 95.3% of scans detected fetal heart activity, 88.3% captured body movements, 69.4% evaluated fetal tone, and 92.2% assessed amniotic fluid volume, with no serious device-related adverse events reported. Participants rated their experience highly, with user satisfaction scoring 4.4/5. Following the study, the App guided mode was adopted to the prenatal care offering by Clalit health services, the largest HMO in Israel with the 3 highest ranked features.

Can Pulsenmore reduce prenatal clinic visits?

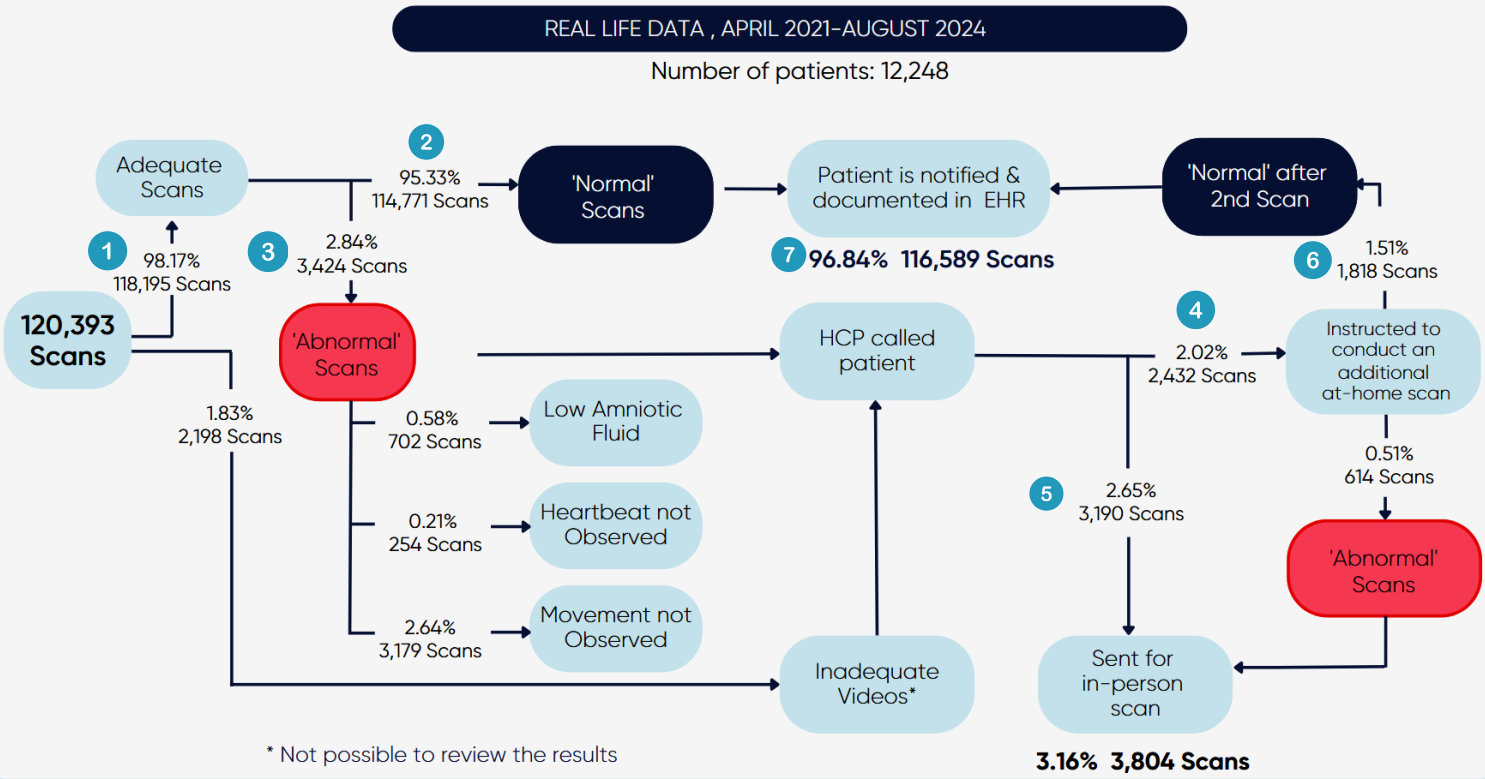
At Charité Hospital in Germany, a study involving 50 women in late-term pregnancies (40-41 weeks) assessed Pulsenmore ES's potential to reduce clinic visits.[16] The device proved safe, with 88% of scans showing normal results. Additionally, 98% of participants expressed willingness to use the device during pregnancy, and 82% noted it would reduce their need for in-person visits. These results suggest that Pulsenmore ES could streamline prenatal care and potentially lower healthcare costs.

How accurate are Pulsenmore's measurement of obstetric parameters compared to standard clinical scans?

In a study comparing Pulsenmore's home ultrasound with conventional clinical ultrasounds, 28 participants performed self-scans that were then analyzed, measurment of obstetric parameters - FHR and Maximal Vertical Pocket (MVP) were compared.[17] The agreement between the Pulsenmore and in-clinic scans in FHR and MVP measurements, were within the predefined errors, with FHR and AFV visualized in over 94% of cases. The device also demonstrated high sensitivity and specificity, proving non-inferior to in-clinic assessments, suggesting it is reliable for at-home fetal monitoring.

What do large-scale real-world data show about Pulsenmore's safety and clinical utility?

Data from Clalit, where Pulsenmore is widely used, demonstrates its value and reliability. Of 120,393 remote scans analyzed, 98.17% were deemed technically adequate, with 95.33% of those showing normal results. Only 2.84% of scans were categorized as abnormal, requiring additional care, while inadequate scans were followed up per protocol. Clalit's swift follow-up approach for abnormal findings highlights Pulsenmore's effectiveness as a safe and dependable solution for remote fetal health monitoring.[18]



1. 98.17% adequate scans were further categorized into groups of 'normal' and 'abnormal'; Normal scans confirmed that all three parameters were satisfactory, while abnormal scans indicated an abnormal parameter (fetal heart rate, fetal movement and/or amount of amniotic fluid).
2. 95.3% of all scans were categorized normal, 3. 2.84% were categorized abnormal.
The patients whose scans were categorized as normal received a link to view the results. Those whose scans were categorized as abnormal received a phone call from a physician.
5. Of those who were categorized abnormal, 4. 2.02% were directed to perform a repeat self-scan and 2.65% were referred for an in-clinic visit to follow up.
7. Following the repeated scans, an additional 6. 1.51% were categorized normal, resulting in a final count of 116,589 normal scans out of 120,393.

According to a survey conducted by Clalit among users of the home ultrasound service:
90% of users reported a significant reduction in anxiety and stress related to pregnancy.
86.3% of users reported an overall improved pregnancy experience.
These findings highlight the positive impact of home ultrasound services on emotional well-being and the overall pregnancy journey.

Can mobile Ultrasound systems provide adequate imaging for prenatal assessments?

A German study from Erlangen University compared Pulsenmore ES with another teleultrasound device, the Butterfly iQ, among 46 pregnant women (17-30 weeks gestation).[19] The findings highlighted Pulsenmore ES's suitability for assessing amniotic fluid and fetal heart activity. The results supported the device's potential to enhance access to prenatal imaging, and a phase II study is underway to further evaluate its implementation and clinical impact.

Can Pulsenmore enhance care for specific high-risk pregnancies?

- Gestational diabetes management: In a study of 20 women with gestational diabetes at 32+ weeks, Pulsenmore was used in a hybrid model alternating between remote and in-clinic visits.[20] Findings showed improved patient satisfaction, time savings, and better compliance with glycemic control, demonstrating the feasibility of integrating remote care in high-risk pregnancies.

- Reducing anxiety in women with recurrent pregnancy loss: A study involving women with a history of pregnancy loss evaluated Pulsenmore's impact on anxiety and attachment.[21] Women who used Pulsenmore reported significantly lower anxiety scores and improved maternal attachment. This suggests that the device not only provides clinical value but also supports psychological well-being in high-risk patients.

Is remote BPP assessment feasible with Pulsenmore?

The Biophysical Profile (BPP) is a non-invasive antepartum test that evaluates fetal well-being, commonly performed for high-risk pregnancies. The standard BPP combines two components:

- Nonstress Test (NST): Continuous 30-minute fetal heart rate (FHR) monitoring using an abdominal Doppler belt.
- Ultrasound imaging: Assessment of four parameters—fetal movement, fetal tone, fetal breathing, and amniotic fluid volume (AFV).

Several clinical alternatives to the full BPP exist.
Some have been evaluated using Pulsenmore technology:

1. Modified BPP (mBPP) approach

The mBPP includes NST and AFV assessment via ultrasound. It is considered abnormal if either the NST is non-reactive, or the deepest vertical pocket of amniotic fluid is ≤2 cm.
This mBPP test was evaluated remotely in a pilot study using the Pulsenmore device for AFV assessment and a remote NST belt for FHR evaluation. 10 women (40 GW) were recruited.[22] 9 women (90%) successfully completed the remote mBPP assessment.

2. Selective NST use

This approach is based on extensive data demonstrating that once all 4 ultrasonographic variables are normal, the NST can be excluded. If one or more ultrasonographic variables are abnormal, the NST should be performed. This approach reduces reliance on NST, lowering costs, saving time, and minimizing care burden.

This remote BPP approach is currently evaluated in a multicenter study with 55 subjects in Israel and the USA, who underwent remote BPP test evaluating the four sonographic variables (fetal movement, fetal breathing, fetal tone, and AFV).[23] Following the remote session with the Pulsenmore device in a CG mode, patients underwent a standard in-clinic BPP test by an independent physician blinded to the remote session results. Over 90% agreement was found between the BPP scores obtained by the two modalities. The study demonstrates the feasibility of the Pulsenmore technology to conduct effectively remote BPP.

The future of self-performed ultrasound

Pulsenmore represents a promising future for prenatal telemedicine. The technology enhances access and continuity of care, especially in underserved areas, and addresses psychological and logistical challenges of prenatal monitoring. Pulsenmore has demonstrated safety, effectiveness, and patient-centered approach, benefiting clinicians and patients alike.

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