Pulsenmore™

Filling the Void in Telehealth: **Teleultrasound for Prenatal Care**

Key Points

- **The use of telehealth has been shown to improve healthcare by providing better care, reducing costs, reducing travel time, and increasing patient and physician satisfaction.**
- **Telehealth has benefited antenatal care by improving high-risk patient monitoring and ensuring continuity of care from afar.**
- **Teleultrasound introduces a favorable addition to prenatal care for expectant mothers.**
- **Pulsenmore's self-scan ultrasound device has shown to be user friendly; captures adequate images; provides access for pregnant women; and increases convenience for physicians.**

Ultrasound: An Essential Diagnostic Tool

Since its introduction in diagnostic medicine, ultrasound has been a reliable and safe method of imaging for the diagnosis of various conditions. It has become the primary imaging modality in obstetrics due to its unique combination of usability advantages and safety profile: It is noninvasive, painless, and has repeatedly been shown to be safe for both fetus and mother. Ultrasound serves as an essential tool for verifying intrauterine pregnancy, assessing the development and wellbeing of the fetus, and identifying prenatal anomalies.

Present and Future

The Clear Case for Telehealth

In the early 1990s, telehealth (or telemedicine) was introduced as a new approach to enable more accessible, personalized, convenient, patient-centered, and cost-efficient healthcare. Telehealth is described as a structure of healthcare provided via telecommunication technologies. It allows for both asynchronous and synchronous communication using mobile apps and online systems to provide patients with virtual appointments, consultations with specialists, self-management, and remote monitoring. **Since roughly 75% of the world population has access to mobile communication, the ability to obtain and share medical information and services through technology has skyrocketed** (Lanssens et al., 2017).

Besides cost savings, accessibility, health equity, and care continuity, telehealth also promotes better communication between professionals. It allows healthcare professionals (HCPs) to interact and consult with fellow practitioners all over the world, expand support networks, and exchange knowledge, enabling them to provide better care to their patients (Haleem et al., 2021).

It is not surprising, therefore, that the use of telecommunication in healthcare delivery has grown tremendously over the last decade and continues to grow at a rapid pace, with many hospitals and healthcare facilities investigating the benefits of incorporating telehealth in daily practice.

Teleultrasound

Advancements in ultrasound technology and the evolution of digital communications have facilitated the development of **teleultrasound** (or telesonography), allowing for the examination of remotely generated ultrasound images. The ultrasound procedure can be performed at one site while the images are electronically transferred for review by a medical professional in a different geographical location. With advanced communications, teleultrasound platforms can enable simultaneous transmission of the images and real-time feedback (Pian et al., 2012). In the timeline of medical history, telehealth is one of the newest kids on the block - and teleultrasound even more so. Nevertheless, we can already grasp the impact that teleultrasound can have on prenatal healthcare, by looking at the positive results of studies assessing the efficiency of telehealth models for pregnancy care.

Teleultrasound Enabling Remote Fetal Evaluation

An accurate diagnosis is crucial when a fetal anomaly is suspected, often necessitating ultrasound scans. Yet in many regions around the world, women do not have access to tertiary centers where the necessary equipment and clinical support are available. A study in Queensland, Australia, examined the effectiveness of teleultrasound from a remote location. The study recruited 71 patients and performed 90 teleultrasound consultations. Each consultation consisted of a sonographer performing ultrasound on the patient and a clinician who remotely guided the sonographer throughout the procedure. The study evaluated cost-benefit, accuracy of diagnosis, quality of images, and equipment requirements. The project demonstrated that remote, real-time fetal ultrasound was not only achievable but came highly requested by physicians and patients. It allowed for the fetal medicine subspecialist to clarify the findings, diagnose, and discuss treatment plans with the sonographer and patient, all from a remote location (Chan et al., 2001).

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Another benefit of teleultrasound exams at general medical/obstetrics centers that otherwise do not have the necessary professional staff available, is the reduced travel time for patients. A study in England showed that the median travel time to an obstetric unit was 20 minutes, compared to the 230-minute journey to a specialized fetal medicine center. The increased costs of the longer journey directly relate to leave from employment, a partner taking leave from employment, and/or supplemental childcare (Smith et al., 2021).

High-Risk Pregnancy

Studies have also focused on telemonitoring specifically for high-risk pregnancies. For example, since ~2% of pregnant women are affected by pregestational diabetes and ~9% are affected by gestational diabetes mellitus (GDM), it has been noted that telemonitoring can help reduce diabetes-related complications, such as macrosomia, fetal demise, cesarean delivery, and hypertensive disorders (Whittington & Magann 2020). As hypertensive disorders occur in 2% to 8% of pregnancies and are among the leading causes of maternal death, timely diagnosis and treatment is required to help avoid preeclampsia. The same authors have indicated that telemedicine may decrease the risk by remotely monitoring blood pressure throughout pregnancy (Whittington & Magann 2020).

Neonatal Outcomes

Studies of fetal outcomes demonstrate that antenatal telemonitoring can portend higher gestational age at delivery, and decrease the likelihood of low birth weight or NICU admission (Lanssens et al., 2017).

Cost Effectiveness

Another study in Jackson, Mississippi, evaluated the cost-effectiveness of telehealth vs. standard care for women with preterm labor. Motivating this study was the increasing cost of births in the U.S., which has risen at a staggering rate to making American obstetrics one of the most expensive maternal care fields in the world. The cost of natural childbirth has surged by 40% with an average of $30,000/pregnancy for Medicaid and $18,000 for private payers (de Mooij et al., 2018). The preterm labor study included 100 women (60 women in the telehealth arm and 40 women in the standard care arm) at 28.0 +/- 7.4 weeks of gestation. The researchers found that the cost per pregnancy for the women in the telehealth group was $7,225 while the women in the standard care group was $21,684 - representing **an average savings of $14,459 per pregnancy employing the telehealth care approach** (Morrison et al., 2001).

New Prenatal Care Models

In 2018, Mayo Clinic introduced the OB Nest prenatal care model, which has been designed to combine telehealth visits with in-person visits (Figure 1). Incorporating the OB Nest model has resulted in lower costs, greater access to care, a stronger connection to the healthcare team, improved continuity of care, increased satisfaction, and reduced travel time. This method enables women to feel in control of their prenatal course while still receiving the best care possible.

Incorporating the OB Nest model showed benefits of lower costs, increased access to care, stronger connections to the healthcare team, continuity of care, increased satisfaction, and reduced travel time.

Program Type	1st Visit	Week Gestation 12	16	20	24	28	30	32	34	36	37	38	39	40	Postpartum
Traditional* Prenatal Care	✋	✋	✋	✋	✋	✋	✋	✋	✋	✋	✋	✋	✋	✋	6 weeks: ✋
Prenatal Care with **Telemedicine**	✋	✋	💻	✋	💻	✋	💻	✋	💻	✋	💻	✋	💻	✋	1 week: ✋ 6 weeks: 💻

✋ In-person visit 💻 Virtual visit via telemedicine

NOTES: *Traditional models of prenatal care recommend 1 visit/month until 28 weeks, followed by 1 visit/2 weeks from 28-36 weeks, and 1 visit/week from week 35 until delivery. Prenatal care models using telemedicine vary in how many visits they recommend. "Virtual visits" may be with an obstetrician, advance care practitioner or nurse depending on the program, and may be conducted via video or phone.
SOURCE: Figure based on the prenatal care model (OB Nest program) at Mayo Clinic.

Figure 1: Comparison of visits in standard care vs. combined telehealth and in-person visits (Weigel et al., 2020)

Teleultrasound: Filling the Void in Telehealth

In March of 2020, the world was ubiquitously challenged by the COVID-19 pandemic. It confronted the entire healthcare system and forced organizations to reevaluate their structure of care. To minimize infection spread, the continuum of hospitals, private practices, urgent care centers, and any other essential services were forced to come up with delivery solutions that reduced in-person visits. Obstetric care in particular, serving a large yet vulnerable patient base, was in urgent need of remodeling during the pandemic.

As the dangers of COVID-19 were unknown, concern for pregnant women was heightened. The need to provide continuous and safe prenatal care forced rapid implementation of new technologies worldwide. The telehealth option that had only been edging its way gradually into the medical scene over decades, instantly took center stage as physicians were compelled to incorporate virtual prenatal care solutions to help reduce exposure to the virus.

Many aspects of pregnancy care could be accomplished without in-person clinic visits. For low-risk pregnancies, telehealth became the best method for measuring vital signs, evaluating symptoms or concerns, and monitoring hypertension or diabetes (Kern-Goldberger et al., 2022). Multiple tools have been incorporated into mixed prenatal care programs, such as handheld Doppler systems to track fetal heartbeat, blood pressure cuffs to monitor maternal hypertension, messaging platforms for communication with the proper medical teams, and video meetings for online consultations. In the evolution of telehealth, however, it consistently fell short of solutions enabling remote prenatal examinations such as ultrasound and blood tests from afar. Fortunately, with recent advances in research and technology, teleultrasound has become a feasible technique that was implemented during the pandemic and is gradually being incorporated into the medical field on a wider scale.

With recent advances in research and technology, teleultrasound has become an achievable and realistic technique.

Enabling Meaningful Telehealth for Prenatal Care

An Israeli start-up company, Pulsenmore, developed a telehealth solution that makes **home ultrasound available for remote and reliable professional care.** The handheld ultrasound device enables its users to transmit ultrasound videos of their fetus to clinical professionals for remote telemedicine consultation. Ongoing studies are currently investigating the potential benefit of this solution in improving fetal and maternal outcomes, demonstrating cost effectiveness, reducing parental anxiety, and increasing patient satisfaction. The device provides an additional tool for pregnancy care rather than a replacement. The patient is provided with a portable wireless ultrasound transducer that attaches to their personal smartphone. After downloading an app on the phone and entering a personal procedure code provided by the healthcare provider, the user can either follow an animated video on how to complete each step of the remote scan accurately or connect directly with a clinician who guides the patient in performing the ultrasound scan and views it in real-time.

The clinician accesses the ultrasound imaging via Pulsenmore's web-based clinician dashboard. An API enables integration with electronic medical records (EMR) so that the scans and any information added by the clinician can be entered in the patient's records.

Figure 2. The Pulsenmore mobile app guides the patient through a self-scan protocol developed by OBYGYNs.

Real-Time or Asynchronous Teleultrasound

Particularly in telehealth, healthcare providers and patients have varying preferences for how prenatal care is delivered. The Pulsenmore solution allows for both synchronous and asynchronous methods of communication.

Figure 3: Clinician-Guided Mode

The Clinician-Guided mode (Figure 3) allows the clinician to schedule a secure virtual appointment and then guide the patient in real-time using audio and video throughout the scan while viewing the ultrasound live. Once the visit is completed, the images can be securely uploaded to the cloud and added to the patient's electronic medical records. The images are not saved on the patient's smartphone.

Figure 4: App-Guided Mode

The App-Guided mode (Figure 4) allows the patient to self-scan as prescribed by their clinician, following a 5-step audio-visual guide from the Pulsenmore app on their personal smartphone. Once completed, the videos of the scans are automatically and securely uploaded to the cloud to be reviewed by a clinician. This mode is designed to enable the clinician to assess three primary parameters: fetal movement, amniotic fluid levels, and fetal heartbeat; and to document their clinical feedback in the patient's electronic medical records. The images are not saved on the patient's smartphone.

Validation of the Pulsenmore Solution

Between July and December 2019, 100 pregnant women were recruited for a study conducted by Clalit Health Services, the largest HMO in Israel, to assess the feasibility of using the Pulsenmore teleultrasound system for the evaluation of fetal wellbeing.

Pulsenmore established three core parameters for remote assessment of fetal wellbeing: fetal heartbeat, amniotic fluid volume, and fetal body movements.

The criteria for participation included carrying a single fetus between 14 to 39 + 6 gestational weeks with no known anatomical malformations or genetic syndromes. Each participant received a smartphone installed with the Pulsenmore mobile app, the Pulsenmore self-scan device, and face-to-face instructions on how to use the device and mobile app. Each study participant was instructed to complete a minimum of one scan session per day, following the App-Guided five-step protocol, and a maximum of three scans within a 24-hour period. The scans were saved on the study smartphones and downloaded for analysis once the devices were returned at the end of the study period. The data that were gathered enabled analysis of 1,360 App-Guided self-scans to determine the detectability of 6 parameters in these scans: fetal heart activity, fetal body movement, fetal tone, amniotic fluid volume, fetal breathing movements, and fetal viability.

Sonographoc Parameter	Detectability	Interobserver Agreement
Fetal heart activity	95.3 (94.5-96.1)	94.4 (93.0-95.6)
Fetal body movement	88.3 (87.1-89.5)	85.9 (84.0-87.7)
Fetal tone	69.4 (67.7-71.2)	69.5 (67.0-71.9)
Amniotic fluid volume	92.2 (91.1-93.1)	86.9 (85.0-88.6)
Fetal breathing movements [a]	23.8 (20.8-27.1)	94.0 (92.6-95.2)
Fetus viability [b]	98.9 (98.4-99.2)	97.6 (96.6-98.3)

Data presented as percentages (95% CI).
a For women/fetuses at beyond 27+0 gestational weeks.
b Fetus viability was defined as a complete outcome including any one of the following: fetal heart activity, tone, body, or breathing movements.
CI, confidence interval.

Table 1: Detectability and Interobserver Agreement

The study found that in 95.3% of the scans fetal heart activity could be observed; fetal body movement could be observed in 88.3% of the scans; fetal tone in 69.4%; amniotic fluid volume in 92.2%; fetal breathing movements in 23.8%; and fetal viability in 98.9% (Hadar et al., 2022) (Table 1).

Based on these parameters, the device proved to be highly effective with a 70-95% detection rate for all parameters except for one. Although fetal breathing movement was inadequately discovered, observation of fetal viability was higher than expected. Based on the study, the company chose to apply the 3 most validated parameters in its guidelines for use of the system in its App-Guided mode: fetal heartbeat, amniotic fluid volume, and fetal body movements.

Once the participants had completed the study and returned the Pulsenmore device, they were asked to complete a questionnaire to rate their experience with the system, involving aspects of usability and of satisfaction, on a scale from 1 to 5. The results surpassed predetermined goals for user experience (Figure 5), enabling the study team to conclude that the Pulsenmore device can provide substantial benefits for patients and medical professionals as a safe, effective, and simple solution for fetal assessment.

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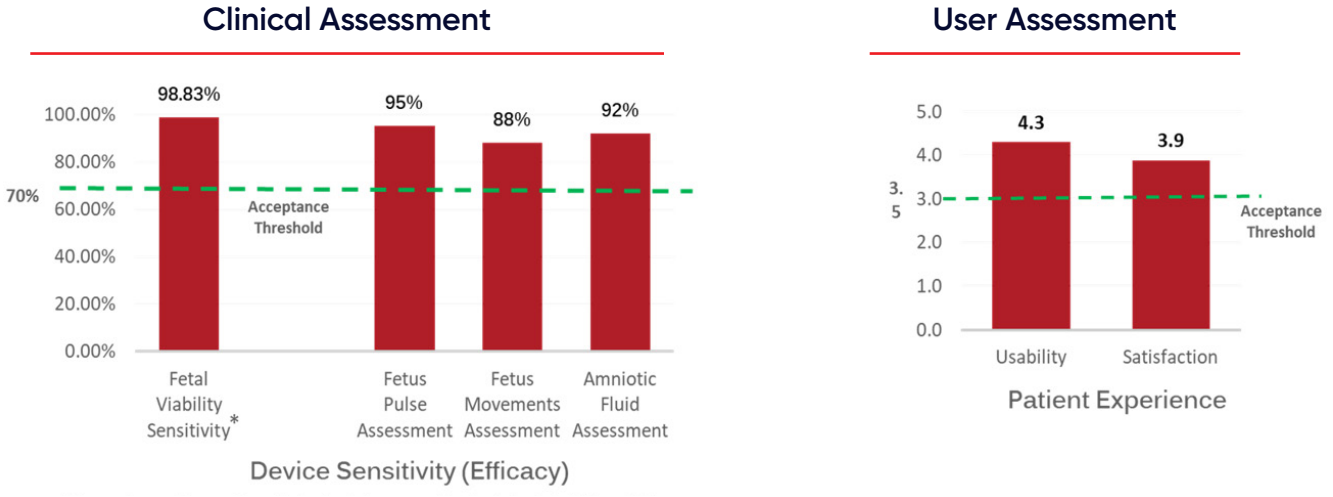


Figure 5: Overview of clinical assessment of scans and of patient experience feedback

Further Validation – Real-Life Clinical Data

Based on the above findings and boosted by the necessity for virtual care during the COVID-19 pandemic, Clalit Health Services launched the Pulsenmore solution for its pregnant customers. Clalit, covering more than 80,000 births per year, chose to provide this solution not only to deliver better services but also to help reduce emergency room visits.

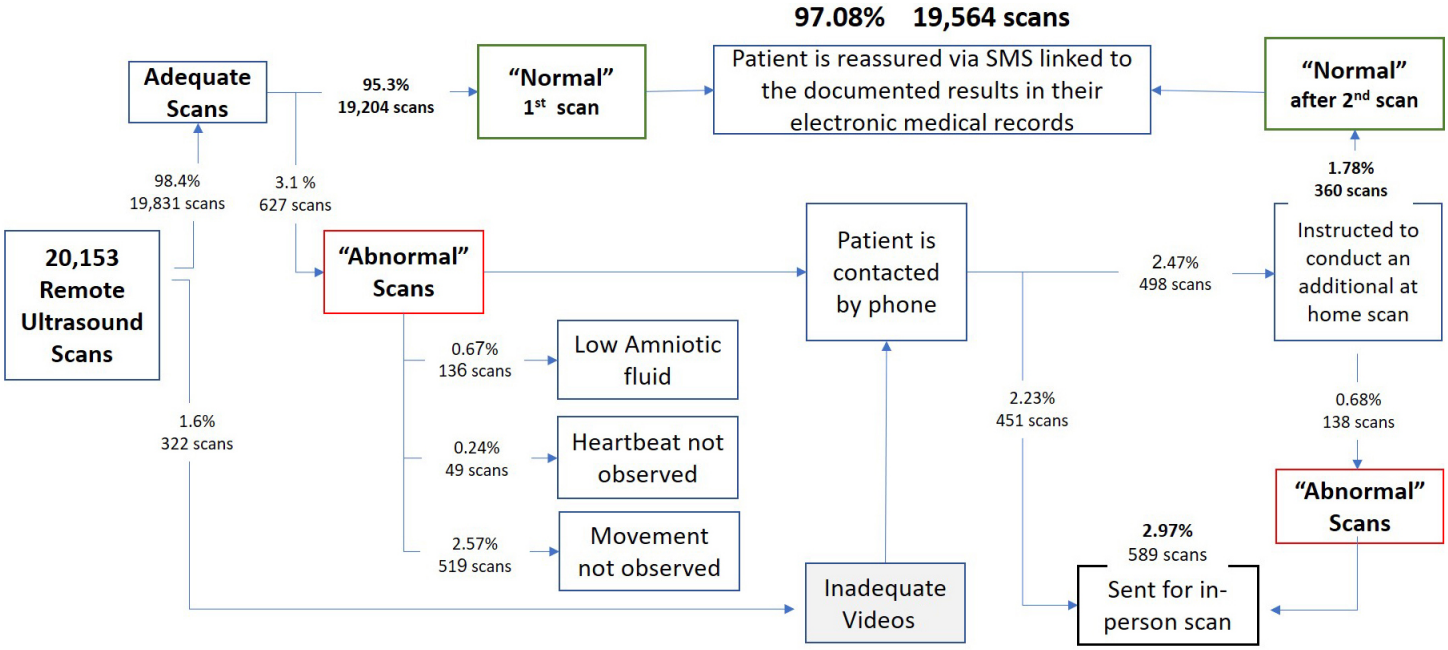
Between April 2021 and March 2022, Clalit customers performed 20,153 remote ultrasound scans with the Pulsenmore system. The data from these scans were accessed and interpreted. 98.4% of the scans were considered 'adequate', meaning the three parameters (fetal heartbeat, amniotic fluid volume, and fetal body movements) could be identified. The 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 fetal heart rate, fetal movement and/or amount of amniotic fluid. Of the adequate exams, 95.3% were categorized normal, while 3.1% were categorized abnormal.

Of 20,153 remote ultrasound scans, 98.4% enabled clinical assessment of fetal heartbeat, fetal movement, and amniotic fluid volume.

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 at Clalit's Home Ultrasound Center. Of those who were called, 2.47% were directed to perform a repeat self-scan and 2.23% were referred for an in-clinic visit to follow up. Following the repeated scans, an additional 1.78% were categorized normal, resulting in a final count of 19,564 normal scans out of 25,274.

These figures point to the utility of the self-scan ultrasound device for end users as well as the high level of clinical significance derived from almost all scans.

Real-life Clinical Data, April 2021 - March 2022 (Hadar et al., 2022)



Prospective Study

A prospective study conducted by Sheba Medical Center, Israel, recruited 10 women between 40+1 and 40+6 weeks of gestation and scheduled them for self-operated remote fetal monitoring together with remote ultrasound. The purpose of this study was to measure the total time of in-person visits vs. telehealth visits when examining the deepest vertical pocket measurement of amniotic fluid with the Pulsenmore device, alongside other prenatal tests.

Results showed that the single deepest vertical pocket measurement was achieved for all 10 participants. The telehealth visit was significantly shorter in length (93.1 ±33.1 minutes) than the in-person visit (247.2 ±104.7 minutes). **This study demonstrated that remote assessment of fetal wellbeing using a self-scan device is achievable, time saving and associated with high patient satisfaction.** (Nir et al., 2022).

The Future of Teleultrasound

To further validate teleultrasound's role in prenatal care, various studies are also evaluating the benefits of teleultrasound in reducing maternal anxiety, the cost-effectiveness of teleultrasound, and the ability to monitor high-risk pregnancies, such as those complicated by maternal gestational diabetes mellitus.

Telehealth will not and should not substitute in-person care, but when combined with in-person visits, this mode of healthcare delivery can increase access in remote areas and where tertiary centers are lacking, improve quality of care, and reduce healthcare costs.

As presented above, there is already evidence demonstrating teleultrasound's ability to fill a void in the medical field, with the potential to take a major foothold in medical diagnostics. Data shows that it is a reliable diagnostic tool that is becoming favored by both patients and healthcare professionals to be incorporated into telehealth models and the prenatal care experience.

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