

**Transcutaneous Electrical Nerve Stimulation Units as a Pain Management Tool for End of  
Pregnancy and Early Labor: A Quality Improvement Project**

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### **Abstract**

This paper describes a quality improvement initiative aimed at increasing midwifery knowledge and patient access to Transcutaneous Electrical Nerve Stimulation (TENS) units for the management of late pregnancy and early labor pain. The project was designed using the Institute for Healthcare Improvement's Plan-Do-Study-Act (PDSA) model for quality improvement. Educational materials were created to guide discussions with pregnant patients at their 34-week prenatal visit on the efficacy of TENS units for late pregnancy and early labor pain. A workflow was also developed to assist midwives in ordering TENS units for insurance reimbursement. Data were collected on whether patients elected to proceed with TENS use and the project found that over 30% of patients desired to use TENS units for late pregnancy and early labor pain management. Future projects should focus on integrating this workflow sustainably into practice and adding flexibility for discussing TENS units at various points in pregnancy.

## **Transcutaneous Electrical Nerve Stimulation Units as a Pain Management Tool for End of Pregnancy and Early Labor**

Every day in the United States over 10,000 people give birth (National Vital Statistics, 2019). The state of Oregon accounts for roughly 115 of these daily deliveries (National Vital Statistics, 2019). What individuals are seeking out of their birth can vary widely but providing people with choice and an assortment of coping tools can lay a foundation for a positive and empowering experience.

Transcutaneous Electrical Nerve Stimulations (TENS) units are an example of a labor coping tool that although evidence-based has not been widely established as common practice in the United States. In an effort to address this lack of usage, this quality improvement project seeks to increase midwifery knowledge and patient access to TENS units for use at the end of pregnancy and in early labor.

Pain management with TENS therapy has been used for many decades to treat a variety of chronic and acute conditions, including dysmenorrhea and back pain (Dowswell, 2015). The tool has been used for labor pain management since the 1970s but has increased in popularity since the 1990s (Dowswell, 2015; Santos Santana, 2016). Use of TENS for labor pain varies widely based on geographic location, with higher rates of use in Europe (Santos Santana, 2016). A 2009 study done in the UK surveyed 139 birthing units and found that 100% of the units encouraged and supported the use of the TENS for labor pain relief (McMunn et al., 2009). More recent data on the rate of TENS unit use for labor pain in the United Kingdom is lacking, but strong evidence remains for its cultural acceptability, including being listed along-side epidural and nitrous oxide on the National Health Service webpage for labor pain relief (NHS, 2020). Unfortunately, there remains a lack of data on rates of TENS usage in the United States for patients giving birth in hospitals, at birth centers and at home.

While there is a lack of data on the rate of TENS unit use in both the UK and the US, an increasing amount of scientific evidence has been published that speaks to the efficacy of TENS units to reduce pain and promote coping in labor, without any evidence of harm or effect on birth outcomes (Báez-Suárez et al., 2018; Daniel et al., 2021, Santos Santana et al., 2016; Shahoei et al., 2017; Thuvakaran et al., 2020). Incorporating TENS units into practice would allow midwives to provide

another tool for support of laboring individuals with the goal of decreased pain and increased patient satisfaction. Additionally, there may be an opportunity for cost savings and lower rates of medical intervention if the use of TENS units in latent labor decreases triage visits and hospital admission prior to active labor. It is important to note that TENS units have not been officially FDA approved for use in labor and pregnancy. While this is an important barrier to understand, numerous, high-quality studies have shown no adverse impact of TENS units on neonatal or maternal outcomes. Although experts do not conjecture why there is no FDA approval, this author hypothesizes that it may be related to the absence of a financial incentive for more widespread TENS unit use in labor, which could contribute to shorter hospital stays and decreased use of epidural anesthesia.

### **Available Knowledge**

The analgesic effect of TENS is best understood through the gate control theory of pain (Coutaux, 2017). In the gate control theory, it is hypothesized that pain sensations must pass through ‘gates’ at the level of the spinal cord before being transmitted to the brain (Coutaux, 2017). These gates can be more open, increasing pain, or more closed, decreasing the perception of pain from a specific area of the body (Coutaux, 2017). Other sensations from the same area of discomfort, such as the electrical stimulation of TENS, have the ability to ‘close the gates’ and decrease the central nervous system’s perception of other sources of pain (Coutaux, 2017). As it pertains to labor, it is theorized that electrodes that are attached to TENS units and placed on the lower back, promote the closure of pain gates and therefore reduce the amount of pain that is perceived from uterine contraction (Doswell et al., 2015). This same mechanism of action can be applied to the use of TENS units for back pain. The patient’s brain is distracted by the electrical stimulation of the TENS units, reducing the amount of discomfort felt from lower back pain itself.

The use of the TENS unit for nonpharmacological pain reduction has been shown to be a safe and effective labor coping tool without harm to the birthing parent or fetus (Santos Santana, 2016). The recent evidence has shown either a positive or neutral effect on the management of labor pain (Báez-Suárez et al., 2018; Daniel et al., 2021, Santos Santana et al., 2016; Shahoei et al., 2017; Thuvarakan et al., 2020).

Most studies on this topic have been meta-analyses and randomized control trials (RCT), although it is important to note great variation in the designs of the included trials. Despite being meta-analysis and randomized control trials, study types that are typically highly regarded, these studies have some inherent limitations. These include small sample size and review of low-quality studies that leaves ample room for bias in outcome conclusions (Dowswell et al., 2015; Thuvarakan et al., 2020). Comprehensive analysis and conclusions from these studies is also challenging due to the variation in protocols for TENS unit use in labor. Variations included TENS directly to skin, TENS applied to acupuncture needles, TENS for limited time frames, TENS for the entirety of active labor, TENS compared to standard of care and TENS compared to placebo units (Báez-Suárez et al., 2018; Dowswell et al., 2015; Santos Santana et al., 2016; Shahoei et al., 2017; Thuvarakan et al., 2020). These interventional differences must be considered when drawing conclusions and creating protocols for the use of TENS units in labor.

The largest study on this topic, a 2020 meta-analysis that consisted of 26 RCTs with a total of 3,348 laboring patients, showed a statistically significant reduction (pooled RR 1.52, 95% CI [1.35; 1.70]) in pain for individuals in labor when the use of TENS was employed. The inclusion of three new studies, which had found a universal improvement in labor pain scores in individuals using TENS units in labor, accounts for the difference in outcome between the 2020 meta-analysis which showed a positive effect of TENS units on pain scores and the 2015 Cochrane review which showed a neutral effect (Báez-Suárez et al., 2018; Dowswell et al., 2015; Santos Santana et al., 2016; Shahoei, 2017) While different study protocols were identified, there was unanimous agreement that TENS units in labor decreased pain scores in both the first and second stage of labor (Báez-Suárez et al., 2018; Santos Santana et al., 2016; Shahoei et al., 2017). Limitations related to these papers are study size (ranging from 46 to 93), study population, as some included nulliparous individuals only, and cultural differences in birthing practices amongst study locations (Báez-Suárez et al., 2018; Santos Santana et al., 2016; Shahoei et al., 2017).

Similar to the results of the aforementioned RCTs, a recent prospective study in the United States evaluated the use of TENS units in early labor (Daniel et al., 2021). The researchers found a statistically significant ( $p=0.02$ ) reduction in pain scores after application of the TENS units and over 70% of

participants stated they would recommend TENS units for the management of early labor pain and would use TENS again in future births (Daniel et al., 2021). Satisfaction with TENS unit use in labor, regardless of changes in pain scores, was also seen in a 2015 Cochrane Review and a 2016 RCT (Doswell et al., 2015 & Santos Santana et al., 2016). This interest in repeat TENS use from both placebo and control groups suggests an alternative mechanism of use, including distraction, control and patient satisfaction with more pain management options

Another potential indicator of the efficacy of TENS unit's success in helping individuals cope with labor pain is the timing of other pain interventions, such as epidural analgesia, and decreased amount of time spend admitted in the hospital while in labor. The evidence is less conclusive on the outcome of delayed epidural with a 2016 RCT finding an increased time to epidural use, while the 2020 systematic review found overall no postponement in epidural usage (Santos Santana et al., 2016 & Thuvakaran et al., 2020). This secondary outcome remains less reflective of TENS unit efficacy as large variations existed amongst the study design as to the timing of the intervention and the participants plan for epidural pain management prior to the onset of labor. As is pertains to delayed hospital admission, a recent study done in the US found a statistically significant ( $p=0.048$ ) decrease in the amount of time individuals spent admitted and in the first stage of labor for participants who were given TENS units to use at home after being evaluated in triage for a labor check (Daniel et al., 2021). TENS units may pose an opportunity to increase active labor admission and promote physiologic birth by avoiding increased rates of labor augmentation and cesarean delivery associated with hospital admission prior to 5cm (Frey et al., 2015).

While the data regarding TENS units in labor has been extensively discussed above, the evidence regarding TENS units for back pain in the third trimester of pregnancy is less robust. A study done in Turkey found a significantly greater degree of pain relief for lower back pain in pregnancy for patients that used TENS units versus those that used exercise and Tylenol (Keskin et al., 2012). As there are limited data to specifically address the efficacy of TENS units for reducing back pain at the end of pregnancy, studies related to TENS unit for other types of pain may be extrapolated to assess the benefit of their use. Historically, data related to TENS units to address chronic and acute pain, besides labor pain,

have been inconsistent and of poor quality, with most meta-analysis and systemic reviews incorporating an insufficient number of studies and studies with poor design (Paley et al., 2021). In an effort to bring clarity to a somewhat murky clinical question, a recent comprehensive review found that when they evaluated over 160 meta-analysis and systemic reviews and sorted those that included sufficient data, there was a clear benefit to the use of TENS units for the management of chronic and acute pain (Paley et al., 2021).

### **Rationale**

Midwifery-led pregnancy care presents a clinical opportunity to promote patient-centered, cost effective and evidenced based care. Guided by the Institute of Medicine's report on improving healthcare quality, improvement initiatives in maternity care are founded on principles of safety, effectiveness, patient-centeredness, timeliness, efficiency and equity (Institute of Medicine, 2001). In an effort to bring these principles into focus and to elaborate on their significance in the setting of pregnancy care, a team comprised of midwives, doulas, nurses, doctors and public health experts created the 2020 Vision for a High-Quality, High-Value Maternity Care System (Carter et al., 2010). While this action plan provides guidance on various components of pregnancy care, the commitment to choice, physiologic birth and evidence driven care are of particular interest to this project. As described in this framework, laboring individuals should be guaranteed the right to make informed choices regarding their care (Carter et al., 2010). This choice should include all labor pain coping tools that are safe, evidenced-based and promote physiologic birth (Carter et al., 2010). A commitment to the principles of equitable access to patient driven choices are at the foundation of expanding TENS unit access to pregnant patients in their third trimester with low back pain and labor patients.

In addition to the 2020 Vision framework, this project was guided by the Institute for Healthcare Improvement's (IHI) Model for Improvement. This model emphasizes measurement to accelerate changes across a variety of healthcare settings (IHI, n.d.). As seen in Appendix A, the Model for Improvement uses the Plan-Do-Study-Act (PDSA) cycles to guide incremental changes that can quickly adapt to feedback and the realities of the healthcare system (IHI, n.d.). As encouraged by this model, quality

improvement measures in this project were broken down to specific steps and evaluated individually in an effort to create larger systems change.

### **Specific Aims**

This project aimed to develop a workflow that facilitated TENS unit use among midwifery patients at a midwifery-led practice in the Pacific Northwest. The stated goals of the quality improvement project were that by September 2021, 100% of the midwives would be provided educational materials on the efficacy and safety of TENS units as a labor pain coping tool and demonstrate increased knowledge through the use of pre- and post-survey. By December 2021, 80% of eligible patients would be provided information on the availability of TENS units at their 34-week appointment.

### **Methods**

#### **Context**

This quality improvement project took place in a hospital-based midwifery practice in the Pacific Northwest. It is located in an urban center and functions as a tertiary, critical access and academic teaching hospital. There are four care teams offering perinatal care at this institution including the maternal fetal medicine practice, generalist obstetrician practice, the family medicine practice and the midwifery practice.

The midwifery service consists of 14 faculty midwives, several per diem midwives, and office staff, including nurses and medical assistants. Student midwives provide care in the inpatient and outpatient setting under the supervision of faculty midwives. The midwives provide full-scope pregnancy care as well as sexual, reproductive and gynecological care for patients. They attend approximately 40 births per month. The midwives are familiar and receptive to quality improvement work through their own training and by their involvement with doctor of nursing practice (DNP) student education. The midwives work with students to develop quality improvement projects they themselves have identified as areas for practice improvement; this project was suggested and approved by the faculty midwives. As of 2020, the patient population in this clinic was predominantly covered by private health insurance (73.5%), followed by Medicaid (21.9%) and then Managed Care Plan (3.8%). This variability in insurance



coverage will affect patient eligibility for insurance reimbursement for TENS units. The primary participants in this project were the full time and per diem attending midwives, and student midwives who provide care in the outpatient setting. Patients who desired TENS units for at home use prior to hospital admission were the recipients of this quality improvement project, but not the focus of qualitative data collection.

### **Intervention**

The main intervention of this quality improvement project was the creation of educational materials and workflow instructions for midwives and patients to facilitate the use of TENS units for pregnant patients in labor prior to admission to the hospital (Appendix B). This intervention was implemented over various stages between September 2021 and December 2021. Prior to project implementation all outpatient midwives were provided educational materials on the efficacy of TENS units for coping with labor pain and provided information on QI project goals. Additionally, this QI project developed a set of instructions to facilitate efficient ordering of TENS units for pain management.

After development of all pre-implementation materials by the DNP student, the midwives began ordering TENS units for pregnant patients who were eligible and desired to use the units. Midwives engaged in discussion over TENS unit use at the 34-week prenatal appointment. Patients were provided information on the benefits of this coping mechanism as well as projected cost by insurance provider. If interested, TENS units were ordered by the 36 weeks of gestation visit to ensure delivery for late pregnancy pain and prior to onset of labor. Prior to the start of the clinic day, outpatient midwives were given a list of patients who met project criteria. After the completion of the clinic session, the midwives reported via email to the project coordinators about whether TENS unit information was discussed in each eligible visit (Appendix C). This documentation was then used to assess overall patient interest and workflow issues that could be adjusted in later PDSA cycles. Over the three months of implementation, PDSA cycles were used to modify and improve workflow and educational materials.

### **Study of the Intervention**

Study of the intervention was done using pre-and post-educational surveys and observation of workflow pitfalls (Appendix D). Prior to the informational seminar, midwives were provided a pre-survey to assess knowledge of TENS unit use in labor. After completing the education seminar provided in the form of a voice over slide set, midwives who work in the outpatient setting were asked to assess their new knowledge and competence with this tool using a post-survey. Midwives were provided the opportunity to give regular feedback through daily email communication in regards to project implementation and alterations. This quality improvement project utilized the Plan-Do-Study-Act (PDSA) framework to modify workflow and education materials pertaining to TENS units for pregnancy and labor pain after the midwives began ordering them for patient use.

### **Measures**

The primary outcome measure for this quality improvement project was the percentage of outpatient midwives who had the necessary knowledge to educate patients on the efficacy of TENS unit usage for the management of labor pain. A secondary outcome was the percent of patients who received education regarding TENS units at the 34-week prenatal appointment as well as the number of patients who acquired and used TENS units in early labor or third trimester pain. Both of these outcomes were assessed between September and December 2021. Process measures for this project included the availability of midwives to review education and workflow materials. Balancing measures for this project were the amount of time needed to place the TENS unit orders and the perceived time constraints of providing this education to patients.

### **Analysis**

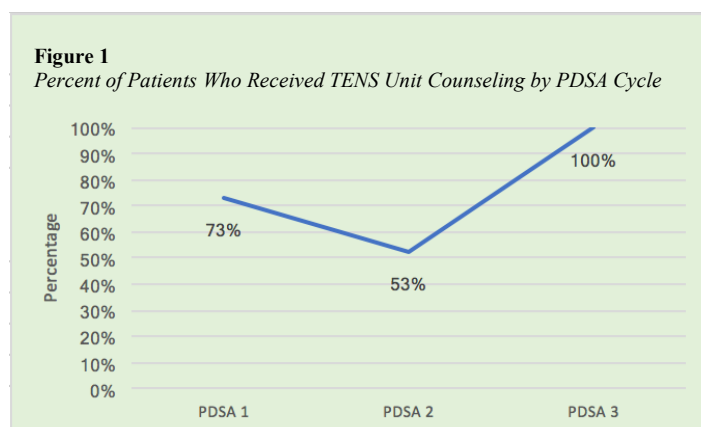
Data regarding the measures of this quality improvement project were collected at regular intervals between September and December 2021. Pre-and post-educational seminar surveys were used to quantitatively track changes in midwives' knowledge and competence with TENS units for labor pain. Qualitative measures were used to elicit feedback on implementation of TENS unit workflow. Data from these questions will be used to guide future TENS project development.

### **Ethical Considerations**

The largest ethical consideration for this quality improvement project was the variation in reimbursement that exists across insurance providers. While some insurance providers will reimburse for the cost of TENS unit for pregnancy-related uses in its entirety, other insurance carriers will not reimburse at all. Unfortunately, Medicaid insurance does not provide coverage for TENS units creating a system of inequity, in which low-income individuals are forced to pay out of pocket for this labor pain tool. To address this limitation, a long-term goal of this program is to engage Oregon Health Plan in discussions surrounding the effectiveness, safety of TENS units and discussing the importance of providing high quality healthcare options to the individuals they cover. Addressing inequities in healthcare through policy change and advocacy is an important component of quality improvement work. A request for determination was submitted to the OHSU Investigational Review Board and they found the proposal to be QI project and therefore, IRB approval was not required.

### **Results**

The midwives began providing information on TENS units for late pregnancy and early labor pain coping in October 2021. Prior to the start of each clinic day, they were provided a list of patients that met criteria for this quality improvement project. This included individuals at their 34-week prenatal visit who had not previously been informed about TENS units. They were then asked to provide the patient with the informational handout and document the response. Based on the data collected, a total of 40 patients were eligible to receive information regarding TENS units during the course of the quality improvement project. There were 15 patients who were eligible in the first PDSA cycle, 19 in the second PDSA cycle and 6 in third PDSA cycle. The specific aim of this QI project was that 80% of eligible patients would receive the TENS unit informational handout. As Figure 1 shows, this goal was only met in the third PDSA cycle.



Of the patients who received information on TENS units for late pregnancy discomfort and early labor pain, seven (26%) desired a prescription for the unit, two (7%) elected to purchase the units independently and eighteen (67%) were unsure if they desired to use a TENS unit at the time of the visit. The project was not designed to assess the nature of patient interest or satisfaction. Thirteen (33%) eligible patients did not receive the information regarding TENS unit at their eligible visit. In six cases (46%) the provider forgot, in five cases (38%) there was not enough time and in two cases (15%) the patient had already received counseling. This information highlights one of the challenges related to this quality improvement project in that workflow modification on the part of the provider was challenging and by pre-selecting a target gestational age, there was little room for flexibility.

This quality improvement project aimed to have 100% of the outpatient midwives receive information on the efficacy and functionality of TENS units for pregnancy related discomfort. Providers were asked to take a brief pre-and post-survey after exposure to the information. While eleven midwives were provided the voice-over slide set related to the intervention, only five (45%) completed the pre-survey and three (27%) completed the post-survey. The data regarding how many midwives viewed the slide set but did not complete the pre- and post-survey are unknown. This low response rate limits our ability to assess a growth in knowledge related to TENS units. Of the midwives who did complete both a pre- and post-survey, there was a significant positive shift in knowledge about how TENS units provide relief in late pregnancy and early labor as well as increased comfort discussing TENS with patients. For example, when asked how competent they felt explaining the mechanism of action of TENS units for

management of pregnancy related pain all five respondents on the pre-survey selected somewhat incompetent or very incompetent. When asked this same question on the post-survey, all three respondents selected very competent or somewhat competent. This same trend was evident in the questions pertaining to comfort describing the efficacy of TENS units as well as comfort with helping a patient use a TENS unit.

Over the course of the three PDSA cycles, slight modifications were made in the workflow process for ordering TENS units based on feedback from TENS supplier and midwives: changes to midwife documentation required for insurance approval and the addition of a patient face sheet for the TENS unit supplier. The largest challenge presented in this quality improvement project was ensuring providers used proper documentation and followed appropriate guidelines for ordering TENS unit. Many providers omitted required text in the visit note and attempted to prescribe electronically or fax prescription without additional required documents. These deviations resulted in delays in the patients receiving their units and delays in supplier reimbursement. Another challenge to consider as we interpret the data regarding project success is the issue of missing data. This quality improvement project relied on the providers to report if the patients received the TENS unit information and the outcome of the visit. There was not a 100% response in the data, meaning there are some missing data for patients that were eligible to receive information regarding TENS units.

## **Discussion**

### **Summary**

This quality improvement project involving TENS unit use for late pregnancy and labor pain was an effort to increase awareness and utilization of an evidenced-based, low-risk tool. The project centered on creating a provider workflow for educating patients and prescribing TENS units with insurance reimbursement. We sought to increase midwife knowledge and comfort in discussing TENS units and facilitating their use with patients. While low survey completion rates posed a challenge for accomplishing this specific aim, the limited data that were collected showed a positive shift in provider knowledge and comfort with TENS units as an effective pain management tool. The project found that

over one-third of patients who were offered TENS unit, desired to use them. After completion of the three PDSA cycles, a presentation was made to midwifery faculty with the results of project implementation and suggestions for the continued integration of TENS unit counseling into the midwifery practice. Individual meetings were also completed with the practice manager to discuss logistics and sustainability of TENS unit program.

### **Interpretation**

This QI project set out to accomplish two specific aims: develop educational materials for midwives and patients regarding the use of TENS units for late pregnancy discomfort and early labor pain and establish a workflow that would allow providers to prescribe TENS units for insurance reimbursement. Through this project there has been a direct link between the interventions and increased knowledge and familiarity among midwives and patients regarding the efficacy and utility of TENS units. For example, one midwife shared an experience of working alongside a nurse who was concerned about the safety of TENS unit for coping with early labor pain. Due to her exposure to TENS units through this quality improvement project, she was able to provide education to the nurse on their safety and provide support to the patient using the unit. At least nine patients who previously would not have had this as a tool to manage pain, achieved access with little to no cost. Increasing midwifery knowledge about TENS units means that providers can provide more options in their future practice and potentially increase patient satisfaction with pregnancy and birth. This notion is in line with a recent Canadian study that assessed the factors associated with increased prenatal care satisfaction and found that patient-centered information sharing and decision making were strong predictors of a positive perception (Gregory et al., 2019). Assessment of patient satisfaction with TENS units was not an aim of this project, but could be included in future projects.

A thorough assessment of a quality improvement project evaluates the specific aims as well as the balancing measures. This project identified the additional time burden for midwives required for patient education as a possible balancing measuring. The data show that provider accidental omission and inadequate time during patient encounters were identified as the two most likely reasons a patient did not

receive the TENS information. The project also required the providers to take additional time to fill out correct prescription and utilize specific documentation in their visit note. If completed incorrectly initially, midwives were asked to edit their documentation, requiring additional time. Similarly, by selecting a specific gestational age for introduction to patients, midwives were asked to discuss labor pain management at a visit in which it might not have fit in with patient priorities. The gestational age was chosen, in part, to accommodate the introduction of other student doctoral projects in the clinic workflow. This lack of flexibility in timing of patient education may have deterred midwives from fully engaging in the project. Additionally, the variability in percentage of reached patients by PDSA cycle may have been related to a variety of factors including inaccurate documentation, competing demands for midwifery time and/or comfort with the counseling by the third PDSA cycle. The low number of eligible patients in PDSA cycle three could have been related to inaccurate data collection or affected by proximity to the Christmas holiday with fewer visits overall.

Post-project meetings with midwifery faculty and the practice manager revealed an interest in seeking sustainable ways to integrate TENS unit knowledge into routine patient counseling, as well as continuing to improve workflow for prescribing TENS unit for insurance reimbursement. The next steps will include transitioning coordination of accurate documentation and prescribing away from the QI project coordinator and to the midwifery practice itself. This will most likely include additional training for medical assistants to become familiar with TENS unit workflow and be responsible for ensuring correct documentation and faxing necessary forms. As the quality improvement project transitions to an established practice, more flexibility in timing of patient education regarding TENS units for end of pregnancy and early labor pain will also be crucial. The possibility of a hospital based program that would provide TENS units for patient discharged home in early labor has also been suggested.

### **Limitations**

This quality improvement project was designed for a specific midwifery practice. While the educational materials may be generalizable to other obstetrical practices, the workflow for ordering the TENS units was unique to the specific clinic and unit supplier. A full picture of the success of the quality

improvement project and interest in the TENS units may have been limited by imperfect reporting leading to missing data. Frequent attempts were made to follow-up on missing data in order to accurately assess the meeting project goals. Limitations were also identified in the response rate of midwives to the pre-and post-educational survey. Infrequent reminders, lack of time or technological difficulties may have accounted for the limited response. Future efforts to assess midwifery knowledge may consider optimal ways to achieve survey completion and efforts to develop workflows should aim to alter data collection to ensure accurate results. Further research is needed to address the lack of studies related to the use of TENS units specifically for the management of low back pain at the end of pregnancy.

### **Conclusions**

Although limited in time and scope, this quality improvement project improved knowledge and use of a nonpharmacological pain management tool at the end of pregnancy and in early labor. Over one third of patients who received information on TENS units followed through with acquiring a unit. This initial data suggests an investment should be made to incorporate this information and workflow in a sustainable manner. During the quality improvement project, the project coordinator ensured that correct documentation was used in the electronic medical record and that appropriate paperwork was sent to supplier. In order for this project to become integrated in the midwifery practice, alterations to the workflow will be needed to encourage midwives, with the help of support staff, to independently document and prescribe the units. Next steps should include a transition to a more sustainable workflow, flexibility on timing of TENS unit discussion based on provider preference and assessment of patient satisfaction with TENS units for late pregnancy discomforts and early labor pain.



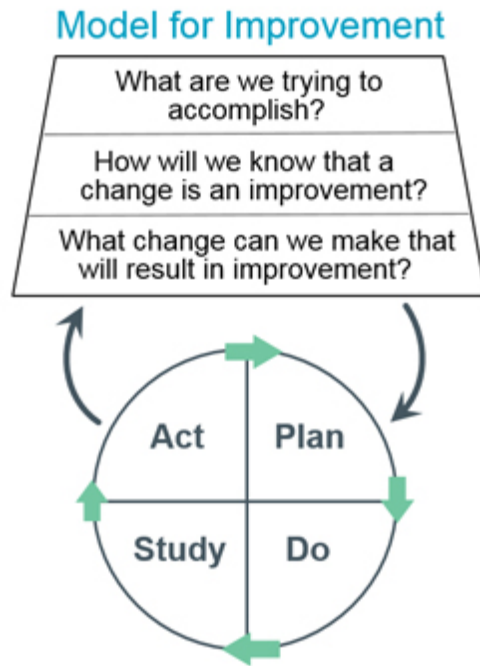
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## Appendix A

### IHI Model for Improvement



*Source: ihi.org*

## Appendix B

### TENS Unit Informational Handout

# TENS UNITS FOR PREGNANCY RELATED PAIN AND EARLY LABOR COPING

Midwifery Faculty Practice

## WHAT IS A TENS UNIT?

A Transcutaneous Electrical Nerve Stimulator (TENS) unit is a hand-held device that provides electrical stimulation to the skin through electrodes. The unit functions by sending small electrical signals through the skin that are recognized by the brain and spinal cord. It is a non-pharmacological tool to help manage pregnancy and early labor pain and discomfort. Most patients perceive a tingling sensation where the electrodes are in contact with the skin and do not find it to be painful.

## HOW DOES A TENS UNIT WORK?

TENS units work in two ways to cope with pregnancy related pain and early labor. One mechanism is that the stimulation from the electrodes causes your body to release its own endorphins. Endorphins are pain relieving hormones that help reduce overall pain sensations in the body. The second mechanism is through what is called the Gate Control Theory. This is the idea that your brain can only interpret so many pain signals at one time. If your brain is being flooded with the tingling sensations of the TENS unit, it does not feel the contractions or pregnancy related back pain as much. Additionally when it comes to labor, it is thought that TENS units provide individuals with a sense of control and distraction that are helpful for coping.

## HOW WELL DOES IT WORK IN LABOR?

In addition to decades of anecdotal evidence to support the effectiveness of TENS units for early labor pain, some recent studies have shown a positive effect as well. Randomized controlled trials in 2016 and 2017 both showed decreased pain scores for participants who used TENS units in labor (Santos Santana et al., 2016 & Shahoei et al., 2017). As recently as this year, a study done in the U.S. found decreased pain scores for laboring people who used TENS units and over 70% of participants reported they would use TENS unit again in a future labor (Daniel et al., 2021).

## IS IT SAFE TO USE IN PREGNANCY AND LABOR?

While TENS units have not been FDA approved for use in pregnancy or labor, decades of studies and use have not shown any increased risk of poor maternal or neonatal outcomes. It is also important to know that TENS units are not compatible with water. You must remove TENS units before entering the water and ensure your skin is completely dry before placing electrode pads. Individuals with epilepsy, cardiac pacemakers or heart dysrhythmias should speak to their provider prior to using TENS unit.

## WHERE CAN I GET MORE INFORMATION?

More information can be found at the following sites:

**Evidence Based Birth:** <https://evidencebasedbirth.com/transcutaneous-electrical-nerve-stimulation-tens-for-pain-relief-during-labor/>

**Mater Mothers' UK:** <https://www.youtube.com/watch?v=40lv-WANbtM>

**Alice Turner, Doula:** <https://www.youtube.com/watch?v=QdDR5n64jyY>

# TENS UNITS FOR PREGNANCY RELATED PAIN AND EARLY LABOR COPING

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## ARE ALL TENS UNITS THE SAME?

TENS units have large variability in quality, function and price. While some TENS units are made specifically for labor pain and include a BOOST button to use during contractions, other units are designed for chronic pain management, such as low back pain in pregnancy. While some people may desire TENS units specific to labor, any TENS unit will work for pain management in pregnancy and early labor. TENS units can range in cost from \$25 to over \$200.

## I'M INTERESTED! HOW DO I GET A TENS UNIT?

If you are interested in independently purchasing a TENS unit specific for labor, some brands are listed below. These labor specific TENS units will also work to provide relief for back pain in pregnancy. If you want to purchase your own TENS unit, but do not specifically desire a unit designed for labor, they can be found at various retailers including Target, Amazon and CVS.

1. BabyCare TENS
2. Perfect Mama Tens Care
3. Elle TENS (some have a built in contraction timer)

Depending on your insurance coverage, we may be able to help you get a TENS unit at no cost! If you are interested in pursuing a TENS unit covered by insurance, please let your midwife know and we will get the paperwork started.

Also, let your midwife know if you are planning on using TENS units for early labor and we will provide you with information on maximizing effect!

## REFERENCES

Daniel, L., Benson, J., & Hoover, S. (2021). Transcutaneous Electrical Nerve Stimulation for Pain Management for Women in Labor. *The American Journal of Maternal Child Nursing*, 46 (2), 76-81. DOI: 10.1097/nmc.0000000000000702

Santos Santana, L., Gallo, R.B.S., Ferreira, C. H. J., Duarte, G., Quintana, S.M., & Marcolin, A.C. (2016). Transcutaneous electrical nerve stimulation (TENS) reduces pain and postpones the need for pharmacological analgesia during labour: a randomized trial. *Journal of Physiotherapy*, 62, 29-34

Shahoei, R., Shahghebi, S., Rezaei, M., & Naqshbandi, S. (2017) The effect of transcutaneous electrical nerve stimulation on the severity of labor pain among nulliparous women: a clinical trial. *Complementary Therapies in Clinical Practice*, 28, 176-180.

**Appendix C**  
**Reporting Tool**

Appointment Time	Patient Initials	Gestational Age	DNP Project
11:00	H.C.	32wks	TENS
<p>1. Did the patient receive the TENS Unit handout and counseling today?</p> <p><input type="checkbox"/> Yes</p> <p><input type="checkbox"/> No, select reason why</p> <p style="padding-left: 40px;"><input type="checkbox"/> Had received information about TENS unit at previous visit</p> <p style="padding-left: 40px;"><input type="checkbox"/> Not enough time to discuss during visit</p> <p style="padding-left: 40px;"><input type="checkbox"/> Patient uninterested in discussing TENS unit</p> <p style="padding-left: 40px;"><input type="checkbox"/> Provider forgot to discuss TENS unit</p> <p style="padding-left: 40px;"><input type="checkbox"/> Other: _____</p> <p>2. Today, did the patient express interest in using the TENS unit in early labor?</p> <p><input type="checkbox"/> Yes, Rx filled out</p> <p><input type="checkbox"/> Patient was unsure (document that TENS unit was offered and to reassess at next visit)</p> <p><input type="checkbox"/> Not interested</p>			

Were there any other patients who desired discussion about TENS units (i.e., pt who received a handout at a previous PNV or who inquired on their own)?

- Yes  
 No

If yes, please identify these patients in the appropriate rows:

TENS Unit			
Appointment Time	Patient Initials	Gestational Age	Pt desires TENS?
			<input type="checkbox"/> Yes, Rx filled out <input type="checkbox"/> Yes, patient will get own unit <input type="checkbox"/> Unsure, reassess at next visit

## Appendix D

### Pre-and Post-Survey for CNMs

How familiar are you with the evidence on the use of Transcutaneous Electrical Nerve Stimulation (TENS) Units for pain relief in labor?

- Very Familiar
- Somewhat Familiar
- Not Familiar

How competent do you feel explaining the mechanism of action of Transcutaneous Electrical Nerve Stimulation (TENS) Units for pain relief in labor to patients?

- Very Competent
- Somewhat Competent
- Somewhat Incompetent
- Very Incompetent

How competent do you feel explaining the efficacy of Transcutaneous Electrical Nerve Stimulation (TENS) Units for pain relief in labor to patients?

- Very Competent
- Somewhat Competent
- Somewhat Incompetent
- Very Incompetent

How competent do you feel explaining to patients how to use Transcutaneous Electrical Nerve Stimulation (TENS) Units in labor?

- Very Competent
- Somewhat Competent
- Somewhat Incompetent
- Very Incompetent

How competent do you feel helping a patient use Transcutaneous Electrical Nerve Stimulation (TENS) Units in labor for pain relief?

- Very Competent
- Somewhat Competent
- Somewhat Incompetent
- Very Incompetent





### Appendix F

### TENS Unit Quality Improvement Project Cause and Effect Diagram

