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# Obstetric Belly Band

BME 201

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**Abstract**

The goal of this project is to design a belly band that both provides ultimate comfort for the mother and effectively holds the tocometer and ultrasound transducer in place. The current belly band, used in many hospitals, tends to bunch up during labor. This causes a great amount of discomfort to the mother. The tocometer, which measures uterine contractions, and the ultrasound transducer, which tracks the fetal heart rate, must be fastened securely to the mother's belly during labor to ensure accurate readings. In an effort to improve the existing belly band, several factors were considered. These factors include: size and shape of the band and fastening methods. Design matrices were used to evaluate the advantages and disadvantages of each element of design. From this information, it was concluded that a uniform, tapered band without any additional fastening mechanisms is the best design option. It is expected that additional elements will need to be added to this design. Such components could include a small amount of boning to help the band hold its structure and slits in the band to allow for facilitated movement of the devices during labor. Future tasks include choosing the best fabric, creating prototypes, and testing their effectiveness in a hospital setting.

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## BACKGROUND

### MOTIVATION

Every year more than 4 million babies are born in the United States (Births, 2011). In order to ensure the health of the prenatal infant, electronic monitoring is used when an expecting mother arrives at the hospital, until she has given birth (Minton, 2011). During this monitoring, the ultrasound transducer and tocodynamometer (tocometer) are held in place using very basic bands and belts. Unfortunately, these means of securing the devices are neither efficient nor comfortable for the laboring women. In order to assist the hospital staff with their task of monitoring, and keep women as comfortable as possible, a new obstetric belly band needs to be designed. Our mission is to redesign the obstetric belly band so that it has more rigidity in the transverse direction and will not roll up during use.

### ELECTRONIC FETAL MONITORING

Continuous electronic fetal monitoring is generally used for pregnancies with increased risk of prenatal death, cerebral palsy, or neonatal encephalopathy. It is also used when oxytocin is being used for induction of labor. It is recommended that electronic fetal monitoring records are inspected and documented every fifteen minutes in the active phase, and every five minutes in the second stage of labor (Liston, 2002).

Fetal heart rate and contraction monitoring are the most important vitals to monitor during labor. These are most commonly measured using an ultrasound transducer and tocometer, respectively (Schifin, 1990).

Figure 1. Ultrasound and tocometer transducers (Tocometers, 2011).

Ultrasound transducers use high frequency sound waves to reflect mechanical actions of the fetal heart (Tucker, 2002). The transducer emits a beam that reflects off the moving fetal heart valves, and the changes in frequency are used to count heart beats (Sweha, 1999). This method is limiting due to the fact that the sound waves can be reflected by any moving structure. It is essential to keep the mother and fetus steady to maintain the best signal. Any motion can cause distortion in the results (Afriat, 1989).

The tocometer monitors the frequency and duration of contractions through the use of a pressure-sensing device applied to the maternal abdomen (Tucker, 2002). During uterine contractions, the rigidity of the abdomen depresses a pressure sensitive button, sensitive button and the machine records the activity. The pressure applied to the instrument is essential because tightening the strap will be uncomfortable, and a strap that is too loose will miss contractions (Afriat, 1989). Tracking the contractions is an important tool in labor because it allows for the indication of fading contractions before the pain subsides (Fetal Monitoring, 2011).

## PROBLEM STATEMENT

Our mission is to redesign an obstetric belly band so that it has more rigidity in the transverse direction and will not roll up during use. During delivery, obstetric belly bands are placed around the abdomen to keep the tocometer and the ultrasound transducer in place.

Current methods for securing the instruments are inefficient for nurses and uncomfortable for patients. The team's solution will not only fit the needs of health care professionals using the device for monitoring purposes, but also ensure comfort for laboring women.

## COMPETITION

Our belly band will face tough competition from existing belly band and belly strap companies. Even with a design superior to that of the competition, we will have to compete at a very low price point. Our design will have a more specific and intensive design. It will require more advance stitching and a more complex belt design. To compensate for our product's higher cost, it is essential that it is more comfortable for the patient than the existing competition.

Figure 2. Roll of belly band material to be cut into bands (Fetal Monitoring Bands & Straps, 2011).

The existing belly band is simply an elastic band with no modifications. The woman steps into a "one-size fits all" band and pulls it around the pregnant belly. The transducers are then slid under the fabric and held against the belly by pressure. One of the largest benefits of this design is its cost. These bands can be easily mass-produced in rolls and then sold to hospitals in individual packages for at a low cost of $2-$3 (Frigge, 2011). Another large benefit to the band is its simple design. No special stitching or cuts to the band itself have to be made in order manufacture the product. This universally simple design also allows for the belly band to be very cheap. Unfortunately, these bands are not that comfortable and tend to bunch up in the back. This can cause the laboring woman to become very hot and uncomfortable. Furthermore, if a woman decides to have an epidural, the band gets in the way and must be adjusted to properly administer the epidural (Frigge, 2011).

Another competitor to our design is the belly strap. The transducers slide onto the straps and are then secured around the belly (Wendricks-House, 2011). The straps are made out of a soft, elastic material. They are then wrapped around the woman and held together by Velcro. This design is simple and universal, and therefore can also be easily mass produced. This mass production allows for the straps to be sold at very low prices, which will be difficult for our team to match. The benefits of the straps are that are too thin to bunch up: eliminating much of the discomfort that the belly bands produce. However, the straps could cause some discomfort by pinching the user. Another benefit is that they allow the woman's belly to be open to the air. This reduces the constriction around the belly which may be more comfortable to a woman in labor. The straps may be placed around the woman while she is lying down. While an epidural is being applied, the straps can be easily moved out of the middle of the back. However, these bands do cause some trouble with placement. At times, it can be hard to place the traducers in the correct location due to the round belly. In some cases, the straps may even slide off the belly (Minton, 2011).

Figure 3. Belly straps to hold ultrasound and tocometer transducers(Fetal Monitoring Bands & Straps, 2011).

In order to make our product competitive with these inexpensive alternatives, we need to solve the issues produced by both products. We need to design a comfortable band that will not bunch up in the back and will provide secure placement of the transducers. Our product needs to have additional benefits that make it worth the extra price.

## DESIGN CRITERIA

As with any product intended for medical use, the obstetric belly band must meet several different criteria. Because our product will be subjected to the stresses of labor, it is vital that the belly band is comfortable, reliable, and easy to use. In order for our product to be utilized by hospitals, the belly band must also be cost effective.

Our client was adamant that the patients comfort is the primary concern for our project. During labor, the current belly band rolls and absorbs sweat causing a great amount of discomfort for the laboring woman. Therefore, our product must be stiff enough to prevent rolling and possess water wicking properties. The belly band must also be elastic to increase patient comfort.

The obstetric belly band is worn for the entirety of labor. Our product must function properly and safely until it is removed after labor. The materials from which the band is made must be strong enough to withstand the movements of labor such as walking and pushing. Allergic reactions are also a major concern for laboring women. Therefore, we must use fabrics that do not cause irritation and maintain strength during prolonged stresses.

The obstetric belly band will be used on a wide variety of women. Our product must be universal. Women's bellies can vary in size and shape. In addition, multiples such as twins require two ultrasound transducers and two tocometers (Puccinelli, 2011). The band must be versatile enough to comfortably and reliably fit a very broad range of women.

To compete in the current market, our belly band must be cost effective. Hospitals can purchase belly bands for approximately two dollars per unit (Frigge, 2011). Therefore, our obstetric belly band must be producible for a similar price.

## FABRICS

When selecting a fabric for the belly band, patient safety and comfort must be considered. Many different fabrics cause discomfort or even allergic reactions. Fabrics such as wool and polyesters frequently cause rashes and irritation ("Formaldehyde", 2011). Olifin is a fabric that is commonly used in the medical field for bed sheets and gowns (Willbanks, 2011). Olifin is a strong, quick drying fabric that can be worn without causing irritation.

## ETHICAL CONSIDERATIONS

There are several ethical considerations to keep in mind throughout the course of the design project. The preexistence of the belly band as a product requires that the team be very careful not to infringe upon any current copyrights or patents. It is critical that all design ideas be original and different from those that are already on the market (from companies such as FetaMed). In addition, it is of utmost importance that the product designed is safe and comfortable for the patients. Careful thought should be put into the fabrics used, the sizing, and the structure of the band to avoid possible allergic reactions and injuries. Finally, in order to ethically test the product on human subjects, Institution Review Board approval must be obtained before the design is implemented in a hospital setting.

## DESIGN ALTERNATIVES

The design options are split up into two categories: structure and fastening methods. The different structures and fastening methods can be combined in different ways to form many different design alternatives. The structure designs include a full band with boning, a tapered band, a formed hemisphere band, and a tracking system band. The fastening method designs include Velcro, zippers, small snaps, eye hooks, and no external fastening method.

### STRUCTURAL OPTIONS

The full band with boning is a uniform band, having a similar shape to the existing belly band, with thin wire boning integrated into the fabric to give it more structure and rigidity. This added structure would likely prevent the band from rolling up during use, but the boning could cause a great amount of discomfort due to its stiff, constricting nature.

The tapered band is longer in the front (about 18 inches) and gradually tapers off towards the back, leaving only a thin band of about 8 inches. With less fabric in the back of the band, it is likely that less bunching would be observed. In order to ensure that the fabric doesn't roll up as it begins to taper off, it is expected that a small piece of boning on each side will need to be introduced to this design.

The formed hemisphere band is made of two separate pieces of fabric. The front consists of a formed cup that fits snugly around the belly, and the back consists of a simple, slim band. This design would provide a lot of comfort to the patient; however, it would be very difficult to manufacture in sizes that would fit a wide variety of different belly sizes. The cupped component of this design would need to be custom made to fit the belly of nearly every mother.

The tracking system band consists of a network of thin pieces of fabric rather than one uniform band. There are several vertical straps running in-between two horizontal straps on the top and the bottom of the band. These vertical straps would allow for facilitated movement of the tocometer and ultrasound transducer during labor. However, having several straps could cause a lot of discomfort during labor. Due to the large amount of pressure the band must apply to the belly, these straps would fit very tightly, and could lead to pinched skin.

## FASTENING OPTIONS

A band with Velcro would allow from quick and easy fastening and, if strong enough, would hold very well. However, Velcro could become very uncomfortable for the mother if not aligned well. A band with a zipper would be a very reliable and secure form of fastening, but could be extremely uncomfortable. Especially in larger women, the skin could be pinched in the zipper, causing a lot of pain and discomfort. Small snaps could be fairly comfortable to the patient, but would not be very reliable, nor would they be fastened easily. As there is a lot of movement during labor, the snaps could very easily come undone. Furthermore, it could be a very tedious process for the nurses to have to snap the band into place on every patient. The use of eye hooks as a fastening method would be uncomfortable and unreliable. Being relatively large structures, these hooks would be likely to poke the patient, and could very easily come unhooked during the stresses of labor. A band with no fastening method would be very comfortable to the patient because it would not pinch, poke, or irritate the skin. However, the need to step into the band in order to put it on could cause complications, especially when the band needs to be changed in the middle of labor.

## DESIGN MATRIX

After brainstorming numerous design options, a design matrix (Table 1 and 2) was used to determine which ideas should be integrated into the final design. Two design matrices were created to narrow down both structural and fastening aspects. The combination of these two design matrices allowed us to choose what parts of our design quantitatively with minimal subjective bias. The following seven criteria were used to rank the four structural design alternatives. The fastening options were ranked by comfort, ease of use, reliability, and cost.

Comfort was the most important aspect of our design because of the setting it is used in. Laboring women are in a lot of pain and their skin is very sensitive. In order to ensure their comfort, proper materials must be used. The comfort of the patients has to be taken into consideration because we are creating this product for their use.

Another very important facet of the design is reliability. Monitoring the fetus is very important during labor, so nursing staff needs to be assured that the belly band will properly secure the instruments and prevent inaccurate readings. Women can be very active during labor, so the band needs to maintain the proper positioning of the ultrasound transducer and tocometer under any and all types of movement. There can be no risk of the band coming off or allowing the instruments to shift.

Cost is the yet another important feature of our design elements. It was highly weighted because obstetric belly bands currently being used at hospitals are very inexpensive. No matter how well our product works, unless it is affordable, hospitals will not purchase it. They are not willing to pay a premium unless our product presents exclusive benefits over the current band.

Another highly rated category was ease of use. It is important that our design can be used efficiently and effectively by health care professionals. The device should be easy to use in both initial placement and follow up adjustments. This category was ranked higher in terms of fastening because it is the main feature allowing or preventing the patient to put on the belly band.

Ease of production, while still important, was ranked lower than the aforementioned aspects. The final design must be easy to manufacture and produce on a large scale. The easier the product is to produce, the cheaper the cost of the product.

Versatility is not as highly ranked because it is an additional aspect of comfort. In hospitals, all types of women will be using the belly band. The design needs to accommodate all shapes of bellies, size of women, and positions of the fetus. In terms of position, sometimes fetuses are in different positions which means that tocometer and ultrasound transducer need to be in different positions to monitor properly. The final design needs to ensure that in all cases the instruments are able to monitor accurately.

Size is another design aspect that was considered. The device needs to be scaled to fit all pregnant women. This would increase the usability of our product.

| | Weight | Full Band with Boning | Tapered Band | Formed Hemisphere | Tracking System |
|---|---|---|---|---|---|
| Comfort | 1 | 2 | 4 | 5 | 3 |
| Reliability | 1 | 5 | 5 | 4 | 3 |
| Cost | 1 | 3 | 4 | 2 | 3 |
| Ease of Use | 0.75 | 3 | 4 | 3 | 3 |
| Ease of Production | 0.5 | 4 | 4 | 2 | 3 |
| Versatility | 0.5 | 3 | 4 | 2 | 2 |
| Size Ranges | 0.25 | 5 | 4 | 3 | 4 |
| **Total** | **5** | **15.5** | **19** | **15** | **13.75** |

Table 1. Design Matrix of Structural Elements

| | Weight | None | Zipper | Velcro | Snaps | Pegs |
|---|---|---|---|---|---|---|
| Comfort | 1 | 5 | 2 | 3 | 3 | 1 |
| Ease of Use | 1 | 3 | 4 | 4 | 3 | 2 |
| Reliability | 1 | 5 | 5 | 3 | 2 | 2 |
| Cost | 1 | 5 | 3 | 3 | 2 | 2 |
| **Total** | **4** | **18** | **14** | **13** | **10** | **7** |

Table 2. Design Matrix of Fastening Elements

## FINAL DESIGN

After thoroughly evaluating our designs with matrices, we decided our final design should be a tapered band with slits and boning and no external fastening method. The structure of this band will meet all of the design criteria while reducing the per unit cost.

The final design has a tapering structure compared to the cylindrical structure of the original belly band (Figure 1). The front of the band will be approximately 18 inches long, while the back will be approximately 8 inches long. The band will have an unstretched diameter 10 inches. These base measurements will be adjusted accordingly to accommodate our wide range of sizes. The tapering will reduce the amount of material that rolls up and absorbs water during labor. This design will increase the comfort for the patient. Additionally, the design will be tighter at the top and bottom of the band, making it easier to place the ultrasound transducer and tocometer.

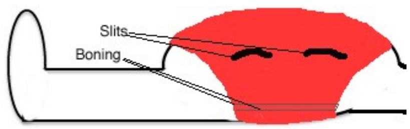


Figure 4. Final design of obstetric belly band with tapering, slits and boning.

While the tapering of the band will give a better fit on the front of the women, it may have the tendency to increase rolling in the back. To prevent this, we have included thin, metal boning on the lower side of the band. This boning will be flexible enough that it will not cause discomfort. The boning will be sewn into the side of the band; as a result, it will not restrict the patients' movements.

Due to the difficulty of maneuvering the ultrasound transducer and tocometer during labor, we have included four slits on the front of the obstetric belly band. These slits will run horizontally on the patient and will be approximately four inches wide: large enough to accommodate the devices and their cords. Two of the slits will be on the upper half of the band and two will be on the lower half. These slits will be sewn with a button hole stitch to maintain the integrity of the cloth (Heinselman, 2011). While the slits are not in use, they can be closed using metallic snaps.

## FUTURE WORK

For our project to successfully move ahead, we need to achieve four goals. Creating an effective prototype will be vital to showing our product's worth. Once we have the prototype, we need to perform tests on the prototype to find any aspects of our design that need improvements. We would also like to take our prototype into the hospitals and ask for their opinion about our new design. Once this is done, we will attempt to streamline production for our belly band. This would allow us to make our belly band's price comparable to our competitors. If successful, our belly band could be used by hospitals.

The first step to moving our project ahead is to make an actual prototype. This will require the correct fabric. We have begun meeting with the University of Wisconsin-Madison Textile Department to discuss various types of material and stitching patterns and we will continue to communicate them as we work on our prototype. We will also have to experiment on our own to acquire proper sewing techniques.

Testing will need to be conducted on our belly band prototype to ensure the versatility and durability. Our product needs to be tested to ensure that it can withstand any condition that it may be subject to during labor. The stitching on the band should not rupture given an excessive force applied to it. One test is to suspend a large amount of weight from the band. Furthermore, the band needs to be able to withstand any liquid it may encounter during labor: bath water, sweat, or other bodily fluids (Marshall, 2011). To test this we will have to get our band damp and evaluate how the fabric changes. It should not be itchy or uncomfortable, even when wet.

We also need to test how comfortable the band is. This testing can be performed first on ourselves, and then at local hospitals. We are working on obtaining a fake pregnancy belly from the Theatre Department to test our prototype.  If we can’t find a fake belly, a ball or pillow could be used to model a pregnant woman. The band must not cause discomfort to the user for any reason. This means that the stitching should not be itchy and that the fabric should fit well over all different types of bellies. We also need to simulate how the transducers would be supported with our belly band. We can do this placing hockey pucks or another object similar to the shape of the transducers into our belly band. This will allow us to determine if enough pressure is being applied to hold them in place.

If we are able to obtain an IRB, it would be very beneficial to test the band on actual pregnant women. Both of the hospitals we visited were interested in testing our belly bands on their patients. Patient feedback could become a vital part of our project and give us necessary feedback. Any problems that we find in the testing stage will be addressed and a solution will be integrated into the final design.

Once we arrive at a final design, it would beneficial to figure out a way to streamline the production process. Having a systematic way of cutting and sewing our belly band would allow our product to compete with our competitors. We also need to calculate the exact cost of material that can be compared with that of our competitors.

## CONCLUSIONS

The construction of a new obstetric belly band will assist nursing staff in proper fetal monitoring by allowing more secure, accurate placement of the ultrasound transducer and tocometer. In addition, the band is designed to greatly increase patient comfort. By making changes to this rather elementary design, we will be able to positively affect many people. Additional effort has to be made to make sure the design has no ethical repercussions, is cost effective, and will function properly in the designated environment.

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## APPENDIX A

**Project Design Specifications**

**#43- Obstetric Belly Band**

February 3, 2011

Team: Kelsey Duxstad, Michael Stitgen, Andrew Pierce, Emma Weinberger

Client: Dr. John Webster

Advisor: Professor Willis Tompkins

**Function:**

Our mission is to redesign an obstetric belly band so that it has more rigidity in the transverse direction and will not roll up during use. Obstetric belly bands are placed around the abdomen, during delivery, to keep in place the tocometer and the ultrasound transducer.

**Client Requirements:**

- Cost effective
- Comfortable
- Effective

**Design Requirements:**

1) Physical and Operational Characteristics

a) *Performance requirements*

i. To hold the tocometer and ultrasound transducer in place during labor

ii. Breathable, durable fabric that ensures comfort for the user

ii. Must withstand a damp environment

iii. Must withstand stress and movement

iv. Can be adjusted to change location and angle

b) *Safety*

i. Can be easily removed

c) *Accuracy and Reliability*

i. Must secure instruments and allow for adjustments when necessary

d) *Life in Service*

i. 1-2 days

e) *Shelf Life*

i. 5-10 years

f) *Operating Environment*

i. Patient hospital rooms

g) *Ergonomics*

i. Easily put on

h) *Size*

i. 36-55” width

i) *Weight*

i. Less than 1 pound

j) *Materials*

i. No latex

ii. Elastic

iii. Breathable

iv. Quick drying

k) *Aesthetics*

i. Pleasing to the eye

2) Production Characteristics

a) *Quantity*

i. One model

b) *Target Product Cost*

i. under $5

3) Miscellaneous

a) *Standards and Specifications*

i. Must be tested to ensure patient comfort and product performance

b) *Customer*

i. Medical schools

ii. Hospitals

c) *Patient-related concerns*

i. Skin irritation

ii. Discomfort (bunching of fabric)

d) *Competition*

i. Feta Med

ii. Cooper Surgical

iii. Pedi Corporation