Assessment of Endpoint Criteria and Perceived Barriers During Maximal Cardiorespiratory Testing Among Pregnant Women

Caitlin Hesse

Western Kentucky University, caitlin.hesse274@topper.wku.edu

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ASSESSMENT OF ENDPOINT CRITERIA AND PERCEIVED BARRIERS DURING MAXIMAL CARDIORESPIRATORY TESTING AMONG PREGNANT WOMEN

A Capstone Project Presented in Partial Fulfillment of the Requirements for the Degree Bachelor of Exercise Science with Honors College Graduate Distinction at Western Kentucky University

By
Caitlin M. Hesse
2017

*****

CE/T Committee:
Dr. Jill Maples
Dr. Rachel Tinius
Ms. Brittany Dodds
I dedicate this thesis to my parents, Jack and Laurie Hesse, who inspire me to strive for excellence every day. I also dedicate this work to my sister Danielle, who has been a constant source of encouragement and motivation.
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The successful completion of this project was made possible by the help and encouragement from so many people. I would like to thank my CE/T advisor, Dr. Maples, for the long hours of meetings and edits she put in to ensuring this project would be the best it could be. I am also grateful for my second reader, Dr. Tinius, for dedicating so much of her time into assisting me on this project. Her diligence and attention to detail took this project to another level.

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I am also thankful for the generous internal funding I received from a FUSE grant which allowed me to travel out of state to present my research findings, purchase statistical software for my computer, and fund the materials I needed to collect data for my study.

Finally, I would like to thank my family and friends for pushing me to stay determined to complete this project.
PURPOSE: Plateau in oxygen consumption (VO$_2$) is the primary indicator for determining if an individual has reached their true maximal aerobic capacity (Howley et al., 1995). Although age and gender-specific secondary criteria (i.e. additional criteria that can be used to identify one’s attainment of maximal effort) have been developed for the healthy population, no secondary criteria have been established for pregnant women (Edvaren et al., 2014). The primary purpose of this study was to analyze secondary endpoint criteria during VO$_{2\text{max}}$ testing among pregnant women during the 2nd trimester. A secondary purpose was to identify emotional and physical barriers pregnant women have that may prevent them from reaching maximal effort. METHODS: 25 pregnant women (age= 30.0±3.6yrs; gestation age= 22.1±1.4wks, pre-pregnancy BMI= 25.5±3.9kg/m$^2$) participated. Each participant completed a Bruce protocol treadmill test where heart rate (HR), VO$_2$, maximal respiratory exchange ratio (RER$_{\text{max}}$), and maximal rating of perceived exertion (RPE) were assessed. Immediate post-exercise lactate was also measured. RESULTS: The mean VO$_{2\text{max}}$ was 32.9±8.8 ml/kg/min. Mean RPE at maximal exertion was 17.6±1.8. HR$_{\text{max}}$ was 167.3±13.1 bpm. Maximal RER was 1.16±0.15 and lactate was 6.8±2.4mM. Barriers were assessed via standardized open-ended questions asked immediately upon completion of the exercise test. Physical barriers were grouped into 4 categories: protocol-related, muscular fatigue, breathing/pulmonary stress, and other. Emotional barriers were also put into four categories: no concerns, protocol-related, performance-related, and pregnancy-related. CONCLUSIONS: Our data provide preliminary evidence that secondary criteria may need to be adjusted for pregnant women. In addition, physical and emotional barriers may
be enhanced by pregnancy, and could be limiting the performance of pregnant women during maximal exercise testing.
VITA

EDUCATION

May 2017 | Western Kentucky University, Bowling Green, KY
          | B.S. in Exercise Science – Honors College
          | Graduate
          | Honors Capstone: Assessment of Endpoint
          | Criteria and Perceived Barriers During
          | Maximal Cardiorespiratory Testing Among
          | Pregnant Women

May 2013 | Whitefield Academy, K-12 Preparatory School,
          | Mableton, Georgia

PROFESSIONAL EXPERIENCE

Summer 2016 | Exercise Biochemistry Lab
            | – WKU Undergraduate Research Assistant

AWARDS & HONORS

2017 Excellence in Research in Exercise Science
2017 ROTC Leadership Award
2017 Female Scholar Athlete of the Year
2015, 2016 CoSIDA Academic All-District Team
2015 Conference USA Spirit of Service Award
2014, 2015, 2016 Conference USA All-Academic Team
2013-2017 Regents Tuition Scholarship

PROFESSIONAL MEMBERSHIPS

2017 American College of Sports Medicine (ACSM)

PRESENTATIONS


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CHAPTER 1

INTRODUCTION

Research has shown that it is safe and healthy for women to maintain their exercise regimens throughout pregnancy, even at high intensity levels (Clapp et al., 1980; Bagnall et al., 1983; Collings et al., 1983; Clapp et al., 2008). The measurement of maximal aerobic testing is the gold standard for assessing cardiorespiratory fitness capacity, and it provides useful information about an individual’s level of fitness and health (Howley et al., 1995). Previous research suggests maximal exercise testing during pregnancy does not pose risk for a pregnant woman or her fetus (assuming she has an uncomplicated, low-risk pregnancy) (ACOG, 1994; Lotgering et al., 1991; Lotgering et al., 1992; Heenan et al., 2001; Wolfe et al., 2003; Mottola et al., 2006). These studies conducted maximal intensity testing to assess the effect of pregnancy on lactate and RER responses (Heenan et al., 2001), pulmonary responses (Wolfe et al., 2003), the accuracy of estimated values of maximal heart rates (Lotgering et al., 1992), maximal aerobic power (Lotgering et al., 1991), target heart rate zones and guidelines (Mottola et al., 2006), and fetal responses to strenuous exercise (ACOG, 1994).

Plateau in oxygen consumption (VO\textsubscript{2}) is the primary indicator for determining if an individual has reached their true maximal aerobic capacity (Howley et al., 1995). While it is the gold standard in terms of indicators for reaching maximal consumption, only a small fraction of subjects exhibits a clearly defined plateau in oxygen consumption during maximal testing; therefore, secondary criteria have been used to determine VO\textsubscript{2\textsubscript{max}} (Doherty et al., 2003).
Well-defined and standardized secondary endpoint criteria used in other populations include: high post-exercise blood lactate concentration ($\geq 8$ mM), achievement of a certain maximum heart rate ($\geq 95\%$ of age-predicted maximum heart rate), elevated rate of perceived exertion ($RPE \geq 17$), and reaching a specific respiratory exchange ratio ($RER_{\text{max}} \geq 1.1$) (Howley et al., 1995). Previous studies in non-gravid populations use the achievement of at least 3 of the 5 endpoint criteria to determine each test a valid maximal test (Lotgering et al., 1992; Lotgering et al., 1991; Wood et al., 2010; Edvaren et al., 2014; ACSM, 2014). Other studies have also created standard secondary end-point criteria adjusted for differences in age, gender, body type, and training level (Doherty et al., 2003; Edvaren et al., 2014). For example, Edvaren et al. (2014), lowered the endpoint criterion of post exercise blood lactate to 7 mM for women ages 25 to 40 years old to adjust for differences found in their study. To date, no study has analyzed all secondary endpoint criteria for achievement of $VO_{2\text{max}}$ during pregnancy.

Heenan et al. (2001) analyzed the maximal RER, maximal heart rate, and peak post-exercise lactate levels during maximal a cycle ergometer test during pregnancy, but did not report $VO_{2\text{plateau}}$ or RPE. Sady et al. (1989) found that maximal heart rate of pregnant participants was lower compared to non-gravid participants during a cycle ergometer protocol. This pregnancy-specific alteration in maximal heart rate could make reaching $\geq 95\%$ of age-predicted maximum heart rate less attainable, despite maximal effort. It is likely that both primary (i.e. plateau in oxygen consumption) and secondary criteria commonly used during $VO_{2\text{max}}$ testing may be impacted during pregnancy as this period of a woman’s life is associated with unique anatomical and physiological changes.
Therefore, the main purpose of this study is to report primary and secondary end-point criteria for maximal aerobic testing among healthy pregnant women.

As a secondary objective, perceived emotional and physical barriers limiting performance during a maximal graded exercise test were assessed, as these may impact one’s ability to reach any of the above-mentioned criteria. Previous studies have examined barriers common among pregnant women to participation in general physical activity (Evenson et al., 2009; Mudd et al., 2009; Marshall et al., 2013; Redmond et al., 2015). With regards to investigating perceived barriers related to varying exercise intensities, Mudd et al. (2009) found that while a majority of their participants felt safe completing moderate intensity exercise, only 36% believed vigorous intensity exercise to be safe. To our knowledge, perceived barriers to maximal exercise performance have not been assessed during pregnancy. This study will identify perceived barriers among pregnant women to maximal intensity activity and compare the results to general physical activity barriers. We hypothesize that the pregnant women in our study will report perceived barriers to maximal exercise testing that are unique to pregnancy, and these could prevent pregnant women from reaching their true maximal aerobic capacity during testing.
CHAPTER 2

LITERATURE REVIEW

This chapter is dedicated to describing the safety of maximal aerobic testing for pregnant women, the criteria used to define maximal capacity, the need for adjusted criteria, and the common barriers to exercise amongst pregnant women.

Safety of High Intensity Exercise Among Pregnant Women

Previous exercise recommendations for pregnant women were actually to avoid high intensity exercise, however there has been substantial research indicating that high intensity exercise is safe for pregnant women (Bagnall et al., 1983; Clapp, 1983; Collins et al., 1983; Clapp, 2008). Only 30 years ago, American College of Obstetricians and Gynecologists (ACOG), the primary overseeing body of overall health recommendations during pregnancy, recommended that pregnant women keep their heart rate (HR) under 140 beats per minute (moderate intensity) and that high intensity exercise should be limited. Since then, ACOG has released new guidelines that abandon the “target heart rate concept” and suggest high intensity activities can be safely conducted throughout an uncomplicated pregnancy (ACOG committee opinion 650, Dec 2015).

Current recommendations for exercise during pregnancy have also been published by American College of Sports Medicine (ACSM) (2014), which is considered the leading organization for educational and practical applications of exercise science and sports medicine. Both sources recommend that throughout an uncomplicated pregnancy, women can exercise using the mode of exercise and to the level of exertion they were exercising before becoming pregnant (including maximal exertion).

Maximal Intensity Exercise Testing Among Pregnant Women
Studies including maximal exertion exercise testing with pregnant women are limited in number but have been safely completed without negative outcomes (Jovanovic et al., 1985; Sady et al., 1989; Heenan et al., 2001; Lotgering et al., 1991; Lotegering et al., 1992; Mottola et al., 2006; Szymanski & Satin, 2012). These studies confirm the safety of this type of testing and begin to identify differences among pregnant women compared to a normal population such as the standards of endpoint criteria defined by Howley et al. (1995). Studies involving maximal intensity cycle ergometer tests with pregnant women in their third trimester were completed by Jovanovic et al. (1985), Sady et al. (1989), and Heenan et al. (2001). Jovanovic et al. (1985) monitored fetal HR throughout the maximal intensity exercise test and during recovery and found that the high level of intensity did not appear to harm the fetus as determined by the recovery of fetal HR immediately after cessation of exercise. Sady et al. (1988) found that pregnant women achieved lower maximal heart rate on average compared to a normal population. Heenan et al. (2001) analyzed maximal HR, maximal blood lactate, RER values, and VO2 max during a cycle ergometer test in a non-pregnant control group and group of healthy pregnant women with similar physical and demographic characteristics, including age, height, and pre-pregnancy BMI. They found that means of both RER and lactate levels among the pregnant women were significantly lower than the control group. They reported no statistical differences in maximal HR and VO2 between the pregnant group and the control group.

Two different studies looking at cycle and treadmill maximal aerobic testing of pregnant women analyzed maximum HR and VO2 max (Lotgering et al., 1991; Lotgering et al., 1992), Lotgering et al. (1991) found maximal heart rate to be slightly lower
throughout pregnancy compared to the non-pregnant group and VO_{2\text{max}} to be unaffected by pregnancy. Lotgering et al. (1992), analyzed the accuracy of estimated values of maximal HR and oxygen consumption during pregnancy. Typically, there is a direct, linear relationship between increasing exercise intensity and HR during a graded exercise test. This relationship is commonly used to predict the VO_{2\text{max}} of an individual based on HR response during submaximal exercise intensity (Sady et al., 1988). The results of the second study showed that the altered HR (higher resting rate and slightly lower maximal rate) of pregnant women alters the linear relationship between heart rate and VO_{2\text{max}} and therefore diminishes one’s ability to predict their maximal oxygen consumption. The results showed lower maximal heart rates and VO_{2\text{max}} values than their predicted values based on submaximal tests established for a normal population.

In a different study involving maximal aerobic exercise testing on a treadmill with pregnant women, researchers validated a prediction equation for VO_{2\text{peak}} specifically for pregnant women (Mottola et al., 2006). This study included 156 women during their second trimester and analyzed maximal heart and VO_{2\text{peak}}. The equation adjusted target HR zones for differences in BMI and fitness levels among the pregnant participants. While the purpose of this study was not originally intended to result in the adjustment of standardized secondary endpoint criteria for maximal testing during pregnancy, this is the only known study to suggest that physiological variables associated with secondary endpoint criteria may need to be adjusted for women during pregnancy.

Szymanski and Statin. (2012) confirmed the safety of maximal intensity treadmill exercise testing with their study of 45 pregnant women varying in fitness levels (nonexercisers to highly active). They evaluated fetal well-being before and after testing
with umbilical artery Doppler indices, fetal heart tracing/rate, and biophysical profile. All results were reassuring and the study concluded that strenuous exercise will not cause harm to the health of the fetus.

**Endpoint Criteria for VO\textsubscript{2max} Testing**

There have been numerous studies defining the criteria needed to reach maximal oxygen consumption, including establishing standards for secondary end-point criteria for general, healthy, adult populations. Howley et al. (1995) completed an extensive review and commentary of commonly used endpoint criteria. This group of researchers sought to evaluate and further define the criteria of reaching maximal oxygen consumption: the primary being a plateau in oxygen intake and secondary endpoint criteria including elevated lactate levels, elevated respiratory exchange ratio (RER), and achievement of some percentage of the age-predicted maximal HR (Howley et al., 1995). The researchers defined plateau for different test protocols and showed that failure to meet the criteria of reaching a plateau is sometimes due to reasons other than failure to reach maximal exertion which brought about the need for secondary endpoint criteria.

Among the previously reported secondary endpoint criteria for VO\textsubscript{2max} testing, blood lactate is commonly perceived as a valid criterion. Howley et al. (1995) stated that blood lactate is a valid option for criterion because high levels are indicators of increased recruitment of fast-twitch muscle fibers and other physiological adaptations that occur during increased exercise intensity. Karlsson and Saltin (1970) inferred that lactate levels are a valid indicator of maximal oxygen consumption because the blood lactate increases as work intensity increases. In a more recent study of lactate levels, Gladden (2004) came to the conclusion that elevated levels of blood lactate are an indicator of hypoxia,
accelerated glycolysis, increased concentrations of adrenaline, escalating ATP demand, and fast twitch muscle fiber recruitment; which are all associated with high intensity exercise. Howley et al. (1995) reported that Per-Olaf Astrand used 7.9-8.4 mM for his blood lactate criterion, but there are differing opinions on which specific level to use to indicate maximal effort. The most commonly used endpoint criterion for blood lactate among a general, healthy adult population is 8mM.

Respiratory exchange ratio (RER) is also commonly used as secondary endpoint criteria because the ratio increases as ventilation increases and CO₂ is generated. Issekutz and Rodahl (1961) further studied the use of RER as criteria and saw the direct relationship with increasing intensity levels and lactate levels. They used an RER value ≥ 1.15 as criterion for maximal oxygen consumption and others have also adopted this value as a secondary VO₂max criterion (Howley et al., 1995; Wood et al., 2010) and others have used a standard of ≥ 1.1 (Doherty et al., 2003; Edvarsen et al., 2014).

While using the achievement of a certain percentage of maximal HR is commonly used, Howley et al. (1995) does not encourage its use because the standard deviation associated with it is ± 11 beats per minute, which is too broad of a range to be considered valid. Other studies have shown a maximal HR of or near the age-predicted maximal HR is an indicator of maximal or near maximal effort (American Thoracic Society/ American College of Chest Physicians, 2003; ACSM, 2014). Edvarsen et al. (2014) used fulfillment of 95% of age-predicted maximal HR as one of five standardized criteria for VO₂max achievement, in addition to plateau in VO₂, RPEmax ≥ 17, RER ≥ 1.1, and a blood lactate concentration ≥ 7mM.
It is interesting to note that the Howley et al. (1995) review does not include rate of perceived exertion (RPE) in its study over endpoint criteria. The Borg Scale is frequently used by studies examining responses to maximal intensity exercise (Borg, 1982). Eston and Williams (1988) determined that RPE is a reliable method of estimating maximal oxygen consumption. This study used the Borg 6-20 scale and found a correlation between intensity values and RPE levels reported at multiple exercise testing sessions. ACSM considers RPE to be a valuable indicator of impending fatigue. The use of an RPE scale is encouraged as a monitor of progress towards maximal exertion during exercise testing.

The importance of these secondary endpoint criteria is further refined by Wood et al. (2010). This study shows that even if a participant’s oxygen consumption does not plateau, maximum effort can still be achieved, which was proven through the attainment of three out of five secondary endpoint criteria. In this study, 67 male and 68 female participants completed a VO\(_{2}\text{max}\) test and only 46% saw a plateau in their VO\(_2\), but 89% reached an RER ≥ 1.15, 83% reached a HR within 12 beats of their age-predicted maximum, 70% reached a lactate level ≥ 8mM and 74% reached an RPE ≥ 18. Since this study defined a valid maximal test as the achievement of at least three out of five criteria, all participants met this requirement while less than half reached a plateau.

*Population Adjusted Endpoint Criteria*

While it is common to use certain thresholds of the five endpoint criteria (i.e. VO\(_2\) plateau, blood lactate, RER, RPE, and percentage of age-predicted HR\(_{\text{max}}\)) to determine if one has indeed obtained their maximal oxygen consumption level during testing, it has been suggested that secondary endpoint criteria be tailored to specific populations. In
relation to age and sex, Edvasren et al. (2014) administered a study with a sample size of 861 people (390 women) and an age range from 20-85 years old. The participants completed an exercise test on the treadmill until exhaustion while their HR, gas exchange, blood lactate, and RPE were measured. Different standards of criteria for reaching VO$_2$max were studied including VO$_2$ plateau, maximal RER values, immediate post-exercise lactate concentrations, RPE $\geq$17, and HRmax $> 95\%$ of age-predicted HRmax. Achievement of maximal exertion was defined as reaching at least three of the five endpoint criteria. The results of the study showed that of the participants who completed the test until volitional fatigue, the older population (50-85) had significantly lower RER values (1.12±0.12) and blood lactate concentrations (6.8±2.6mM) compared to the younger population (20-49). 63% of the participants 65-85 years old did not reach the lactate concentration criteria of 8mM. It also revealed that women had a 18% lower blood lactate concentration than men of the same age range. This shows that criteria threshold levels differ between sexes and age groups and need to be acknowledged during the assessment of physical fitness. This study created new standards for the secondary criteria of blood lactate concentration and maximal RER attained specific for varying genders and ages.

Doherty and Nobbs (2003) showed that calculating VO$_2$max with elite athletes also calls for adjustments. Only 39% of males and 25% of females “plateaued” but the average VO$_2$max values were among the highest in the world and the participants had high percentages of attainment for the secondary endpoint criteria used. For example, mean VO$_2$max values for males and females were 79.1±0.7ml/kg/min and 66.1±1.2ml/kg/min respectively, and the percentage of attainment of the criterion of 1.1
for $\text{RER}_{\max}$ was 72% and 56% respectively. The VO$_2$max normative values provided by ACSM categorize the mean VO$_2$max results achieved by the men and women in the study as “Superior” and in the 99th percentile (ACSM, 2014). Doherty and Nobbs (2003) demonstrated that the use of VO$_2$ plateau the criterion for determining maximal effort for elite effort is not accurate and the use of secondary criteria is necessary. Additionally, the high means reported for secondary endpoint criteria point to a need for an adjustment of secondary criteria to higher values to accurately assess maximal exertion in these extreme athletes.

While previous research has shown that different age groups, genders, and fitness levels require adjusted standards for endpoint criteria of VO$_2$max attainment, no study has investigated whether maximal testing criteria for pregnant women needs to be adjusted. Considering the drastic physiological changes that occur during pregnancy provides some rational for exploring whether or not criteria for maximal oxygen testing should be adjusted for this population. For example, pregnant women have altered HR responses to exercise conditions compared with non-gravid populations (Wolfe, 2003). Heenan et al. (2001) found significant differences in lactate levels and RER values during exercise for pregnant women compared to non-pregnant women. Multiple studies found differences in maximal heart rate (Sady et al., 1989; Lotgering et al., 1991; Lotgering et al., 1992; Mottola et al., 2006) between pregnant women and non-pregnant women. Other physiological changes that could alter women’s responses to exercise during pregnancy include increase in weight, lumbar lordosis, and increases in resting heart rate, blood volume, stroke volume, oxygen consumption, and mean arterial pressure (Connolly et al., 2014).
Barriers to Exercise Specific to Pregnant Women

Previous studies have examined barriers common among pregnant women to participation in physical activity (Evenson et al., 2009; Mudd et al., 2009; Marshall et al., 2013; Redmond et al., 2015). Evenson et al. (2009) reported responses to open-ended questions about barriers to exercise and categorized these responses. One-third of the women in this study reported that risks and dangers associated with physical activity caused them to fear potential harm to their baby and prevented them from activity. Other frequently reported barriers to exercise included lack of time, feelings of fatigue, pain/discomfort, and lack of support. This study recommended interventions for pregnant women to provide support and increase their awareness of the importance of exercising while pregnant. Marshall et al. (2013) provided a physical activity questionnaire for 89 pregnant women and asked them to respond to an open-ended question about personal barriers to participation in regular physical activity. Seven themes emerged from the reported barriers including: symptoms of pregnancy, family and child rearing activities, lack of personal motivation, lack of time, perceptions of adequate activity from activities of daily living, fear of injury, and lack of habit of activity. This study was completed in a rural setting and shows that there is a need to raise the awareness of the benefits and importance of exercising during pregnancy, especially in rural areas. Redman et al. (2015) further added support to the topic of barriers among pregnant women. Women in their study reported perceiving physical activity as a threat to the health of their unborn child. While another study by Mudd et al. (2009) found that the majority of their pregnant participants felt safe completing moderate intensity exercise, only 36% believed vigorous intensity exercise to be safe during pregnancy. The ACOG and ACSM have determined
healthy guidelines for exercising during pregnancy, but several studies show a lack of knowledge and awareness on the subject.

**Summary**

Research has shown that exercise at all levels of intensity, including high intensity, is safe and healthy for women during low-risk pregnancies who were participating in high intensity exercise before their pregnancy. VO$_{2\text{max}}$ testing is the gold standard for aerobic fitness testing. There are commonly five different endpoint criteria used to assess attainment of maximal effort in these tests including VO$_2$ plateau, immediate post-exercise blood lactate concentration, RER$_{\text{max}}$, achievement of a percentage of HR$_{\text{max}}$, and RPE$_{\text{max}}$. The values of these criteria are not standardized for all populations and need to be adjusted for people of different ages, sexes, and fitness levels. Anatomical and physiological differences of pregnant women may cause a need for adjusted criteria. Previous research has indicated that pregnancy alters the physiological responses of variables commonly reported as secondary endpoint criteria during maximal testing. More research needs to be conducted in this specific area to confirm stated criteria thresholds and assess the validity of previous studies.
CHAPTER 3

METHODOLOGY

Participants and Study Procedures

Nineteen pregnant women between 18-24 weeks gestation were recruited for this study. We posted flyers at Western Kentucky University and recruited via word of mouth (study flyer is attached, Appendix A). Inclusion criteria were a lean, healthy pre-pregnancy BMI (between 18 and 25 kg/m²), confirmed singleton viable pregnancy with no identified fetal abnormalities (as determined by routine standard of care ultrasonography), receiving prenatal care and provide clearance from their overseeing physician (Physician release attached, Appendix B), aged 18-44 years, and regularly exercised (3-4x week) and 18-24 weeks gestation at data collection. Exclusion criteria were restrictive lung disease, incompetent cervix/cerclage, multiple gestation at risk for premature labor, persistent 2nd trimester bleeding, ruptured membranes (ROM), preeclampsia/Pregnancy-induced hypertension, hemodynamically-significant heart disease, inability to provide voluntary informed consent (Informed consent attached, Appendix C), currently using illegal drugs (cocaine, methamphetamine, opiates, etc.), current smoker who does not consent to cessation, or the patients’ treating physician does not consent to their participation. Before participation in the testing session participants were required to acquire signed, clearance from their overseeing physician. When participants arrived for the testing session, a preliminary health screening was performed. Informed consent was obtained and the following resting/baseline measures were collected: blood pressure, heart rate, blood lactate and glucose, height, and weight. After a general warm-up, participants completed the maximal cardiorespiratory test, and were
then instructed to cool down until their heart rates approached resting levels. RPE was assessed at each stage during the exercise testing using the Borg Scale6-20 rating (Borg, 1982). Participants were reminded that they could stop the test at any time, while also encouraged to reach maximal effort. Blood pressure, glucose and lactate were assessed immediately and 15 minutes post-exercise.

**Location**

All data collection took place at the DPT research laboratory on the Medical Center Health Complex.

**Clinician Oversight**

All study procedures were supervised by Dr. Blankenship – a doctor of nursing practice. Dr. Blankenship provided clinical expertise in supervising the patient to ensure safety.

**Maximal Cardiorespiratory Testing and Endpoint Criteria**

To assess VO2max, participants completed a graded exercise test according to the Bruce Protocol on a treadmill (ACSM, 2014) with the initial settings at 1.7 mph and grade at 10%. Both speed and grade were increased incrementally every 3 minutes until volitional fatigue. The specific testing protocol is outlined in Table 1. During the test, heart rate was continuously monitored via a chest mounted heart rate monitor (Polar, USA) and breath-by-breath oxygen consumption and carbon dioxide (CO2) production were assessed using the K4b2 portable metabolic system (COSMED, USA). Respiratory gases sampled every 15 seconds were used to estimate RER.

Primary and secondary endpoint criteria were evaluated. VO2 plateau, heart rate, and RER were assessed by analyzing the data obtained from the K4b2 portable metabolic
The presence or absence of plateau was defined as any two 30-sec VO\textsubscript{2} values in which the second was not higher than the first, provided an increase in ventilation at maximal effort (Edvarsen et al., 2014). Maximal heart rate and RER were estimated by selecting the highest values reported in the data (Edvarsen et al., 2014). We calculated maximal heart rate by adjusting for age as recommended by Londeree & Moeschberger (1984) and used the equation: (220-age) * 95%, to obtain 95% of age-predicted maximal heart rate (ACSM, 2014). Maximal RPE and post-exercise blood lactate (Lactate Plus, The Lactate Experts, U.S.A) were measured immediately post-exercise.

Mean primary and secondary criteria values were compared to non-gravid recommendations (VO\textsubscript{2} plateau, post-exercise blood lactate concentration ≥ 7 mmol/L, HR\textsubscript{max} ≥ 95% of age-predicted maximum heart rate, RPE\textsubscript{max} ≥ 17, and RER\textsubscript{max} ≥ 1.1) (Howley et al., 1995; Lotgering et al., 1992). Standard criteria for RER and blood lactate concentration were adjusted to age and sex (Edvarsen et al., 2014). The number of primary and secondary criteria met by the each of the current study participants was tallied and the percentage of participants in the study achieving 0 to 5 primary and secondary criteria were reported. To determine statistical significance between this cohort of pregnant women and the standard, the sample was compared to the standard value using one-sample t-tests in SPSS.

**Assessment of Perceived Barriers**

Immediately after the participants cooled-down post-exercise, they were verbally asked one yes/no question and two open-ended questions by a research team member. The questions were designed to assess perceived barriers to maximal exercise testing and uncover potential concerns regarding the maximal testing. Data was collected on 16
participants. The first question was “Do you feel that you achieved your maximal effort during the test?” The second, open-ended question was “What are some of the barriers you had to overcome to reach your max effort- could be anything- physical, emotional?” Lastly, the participants were asked to elaborate on any concerns that they may have had about performing the maximal exercise test by the verbal prompts “Did you have any overall thoughts or concerns about doing a maximal effort test? Did anything cross your mind during the test?” Modeled after the procedure used by Evenson et al. (2009), responses to these questions were recorded verbatim, then analyzed by two separate reviewers. The reviewers categorized the responses separately, then collaborated on each decision, resolving each disagreement through discussion. The same two reviewers coded each response to the appropriate identified category/categories.
CHAPTER 4
RESULTS

Participants

Twenty-five women completed the study, and all women went on to have uncomplicated pregnancies and healthy neonates. No adverse events were reported. Subject characteristics are summarized in Table 1. The average age of our participants was 30.0±3.6 years with a gestation age of 22.1±1.4 weeks and a pre-pregnancy BMI of 25.5±3.9 kg/m².

Endpoint Criteria

Figure 1 shows the percentage of participants who attained each of the five criteria for VO₂max. For the present study, only 33% of participants attained the primary endpoint for determining whether an individual reached their true maximal effort - a plateau in VO₂. However, 80% of participants attained an RPE ≥17, 16% attained HRmax ≥ 95% of age-predicted maximal HR, 62% reached an RER ≥ 1.1, and 32% of participants attained a blood lactate concentration ≥ 7 mmol/L. One participant attained all five criteria, one participant attained four of the criteria, seven participants attained three of the criteria, seven participants attained two of the criteria, seven participants attained one criterion, and two participants did not attain any of the primary or secondary criteria.

Figure 2 shows the mean and standard deviation of our participants for each criterion. It also shows the established standard for non-gravid populations for attainment of that criteria. The mean for maximum percent of age-predicted maximum HR in our population 88.0±6.8% versus the standard criteria of 95% of age-predicted maximum HR
(p<0.001). The mean RPE$_{\text{max}}$ for our sample was 17.6±1.8 compared with the standard of 17 (p=0.12). The mean RER$_{\text{max}}$ was 1.16±0.15, which is slightly greater the standard of 1.1 (p=0.08). The mean post-exercise blood lactate concentration was 6.8±2.4mM in our cohort versus the criterion of 7mM (p=0.76).

**Emotional and Physical Barriers**

TABLE 3 shows the qualitative data from the post-testing questionnaire pertaining to the physical and emotional barriers to maximal exercise testing. Direct quotes from the participants are reported in the table. For the question: “What are some barriers you had to overcome to reach your maximal effort—could be anything—physical, emotional?”, the responses were organized into the categories: protocol-related (grade/incline, mask), muscular fatigue, breathing/pulmonary stress, and physical other. Twelve barriers reported (52%) were protocol related. Seven responses (30%) referenced muscular fatigue as a barrier. This included various lower extremity pains. Fourteen responses (61%) pertained to breathing/pulmonary stress, and five responses (22%) fell into the “Other” category. The second group of participant answers were categorized in response to the questions, “Did you have any overall thoughts or concerns about doing a maximal effort test? Did anything cross your mind during the test?” The categories created were: no concerns/emotional barriers, protocol-related, performance related (nerves, poor/good performance), and pregnancy-related. Seven participants (30%) reported no concerns/emotional barriers. Four participants (17%) reported protocol-related concerns. These participants did not like the incline and felt like they needed to hold on because of the incline. Nine participants (39%) had performance-related concerns. These concerns included thoughts about not making a certain time, being
nervous, not giving their best effort, and not being prepared with the right clothing. Three responses (13%) fell into the last category which was pregnancy-related concerns (e.g. heart rate/exercise recommendations during pregnancy; baby’s well-being). These responses included “nervous about running because not a previous runner”, “heard that heart rate should not go over 150bpm”, and “I may have felt differently if this were not my first baby; didn’t exercise because of it.”

In addition, all women were asked if they felt they reached their true maximal exercise ability. Of the 23 women who were asked, 17 responded “yes, I reached my true maximal effort”.

**TABLE 1. Bruce Protocol**

<table>
<thead>
<tr>
<th>Stage</th>
<th>1</th>
<th>2</th>
<th>3</th>
<th>4</th>
<th>5</th>
</tr>
</thead>
<tbody>
<tr>
<td>Time</td>
<td>3 min</td>
<td>3 min</td>
<td>3 min</td>
<td>3 min</td>
<td>3 min</td>
</tr>
<tr>
<td>Speed</td>
<td>1.7 mph</td>
<td>2.4 mph</td>
<td>3.4 mph</td>
<td>4.2 mph</td>
<td>5 mph</td>
</tr>
<tr>
<td>Grade</td>
<td>10%</td>
<td>12%</td>
<td>14%</td>
<td>16%</td>
<td>18%</td>
</tr>
</tbody>
</table>

**TABLE 2. Characteristics of the participants and means for the secondary criteria attainment**

<table>
<thead>
<tr>
<th>Participant Characteristics (n=25)</th>
<th>Mean±SD</th>
</tr>
</thead>
<tbody>
<tr>
<td>Age (years)</td>
<td>30.0±3.6</td>
</tr>
<tr>
<td>Gestation age (weeks)</td>
<td>22.1±1.4</td>
</tr>
<tr>
<td>Pre-pregnancy BMI</td>
<td>25.5±3.9</td>
</tr>
<tr>
<td>Resting HR (bpm)</td>
<td>81.7±10.2</td>
</tr>
<tr>
<td>Baseline Systolic BP</td>
<td>119.9±10.2</td>
</tr>
<tr>
<td>Baseline Diastolic BP</td>
<td>71.2±7.0</td>
</tr>
<tr>
<td>VO₂max (ml/kg/min)</td>
<td>32.9±8.8</td>
</tr>
<tr>
<td>Maximum RPE</td>
<td>17.6±1.8</td>
</tr>
<tr>
<td>Percent of Age Predicted HRmax</td>
<td>88±6.8</td>
</tr>
<tr>
<td>Maximum RER</td>
<td>1.16±0.15</td>
</tr>
<tr>
<td>Lactate immediate post (mM)</td>
<td>6.8±2.4</td>
</tr>
</tbody>
</table>
Figure 1 – Proportion of participants attaining the previously reported standard for each of the five criteria (primary and secondary)

<table>
<thead>
<tr>
<th>Endpoint Criteria</th>
<th>Percentage Achieving</th>
</tr>
</thead>
<tbody>
<tr>
<td>Plateau (n=21)</td>
<td>7%</td>
</tr>
<tr>
<td>RPE$_{max}$ (n=25)</td>
<td>20%</td>
</tr>
<tr>
<td>HR$_{max}$ (n=25)</td>
<td>4%</td>
</tr>
<tr>
<td>RER$_{max}$ (n=21)</td>
<td>13%</td>
</tr>
<tr>
<td>Lactate (n=22)</td>
<td>7%</td>
</tr>
</tbody>
</table>
Figure 2 – Secondary criteria during VO2max testing for pregnant women compared to established standards for non-gravid populations

Figure legend: The mean for each secondary criteria is represented by the blue dots, standard deviation is shown by the black bars and the red line shows the accepted standard for that criterion. *The difference between the sample and the criterion value is significant, p<0.001
TABLE 3. Physical and Emotional Barriers to Maximal Exercise Testing during Pregnancy

<table>
<thead>
<tr>
<th>Categories</th>
<th>N (%)</th>
<th>Selected Quotes / Responses</th>
</tr>
</thead>
<tbody>
<tr>
<td>1 Protocol-Related (e.g. grade/incline, mask)</td>
<td>12 (52%)</td>
<td>&quot;Worry about tripping&quot;; &quot;Breathing in/with the mask&quot;; &quot;Felt the need to hold on to the rails because of the incline&quot;; “the mask restricted”</td>
</tr>
<tr>
<td>2 Muscular Fatigue</td>
<td>7 (30%)</td>
<td>&quot;Cramping in legs&quot;; &quot;Burning calves&quot;; &quot;Legs really burning&quot;; “Tired legs”; “Calves/legs felt tight”</td>
</tr>
<tr>
<td>3 Breathing / Pulmonary Stress</td>
<td>14 (61%)</td>
<td>&quot;Hard to breathe&quot;; &quot;Out of breath&quot;; &quot;Chest and shortness of breath&quot;; “dry mouth”</td>
</tr>
<tr>
<td>4 Other</td>
<td>5 (22%)</td>
<td>&quot;I'm emotional now&quot;; “Too hot and sweaty”; &quot;Not used to change in body weight when working out&quot;; &quot;It was my 4th workout of the day&quot;; “Not used to that workout”</td>
</tr>
</tbody>
</table>

Did you have any overall thoughts or concerns about doing a maximal effort test? Did anything cross your mind during the test?

<table>
<thead>
<tr>
<th>Categories</th>
<th>N (%)</th>
<th>Selected Quotes / Responses</th>
</tr>
</thead>
<tbody>
<tr>
<td>1 No Concerns</td>
<td>7 (30%)</td>
<td>&quot;No&quot;</td>
</tr>
<tr>
<td>2 Protocol-Related (e.g. grade/incline)</td>
<td>4 (17%)</td>
<td>&quot;Didn't like the incline&quot;; &quot;I needed to hold on with the incline&quot;; “Equipment was bothersome”; “Need to work on incline”</td>
</tr>
<tr>
<td>3 Performance-Related (e.g. nerves, poor/good performance)</td>
<td>9 (39%)</td>
<td>&quot;I wanted to do well&quot;; &quot;Just hoping to get as much out of the testing as possible&quot;; &quot;Wish I had better clothes&quot;; &quot;I'm not going to make it 12 minutes&quot;; &quot;I was nervous&quot;; &quot;I gave it 100%, but not 110%&quot;;&quot;I hope I can make it to the end&quot;; “Wondered how long I could go”; “I can push harder. I can keep up with my pre-pregnancy accomplishments.”; “Trying not to faint.”</td>
</tr>
<tr>
<td>4 Pregnancy-Related (e.g. heart rate/exercise recommendations during pregnancy; baby's well-being)</td>
<td>3 (13%)</td>
<td>&quot;Heard that heart rate should not go over 150bpm&quot;;&quot;Nervous about running, because I'm not a runner&quot;; &quot;I may have felt differently if this were not my first baby; didn't exercise because of it”</td>
</tr>
</tbody>
</table>
CHAPTER 5

DISCUSSION

The results of this study suggest that secondary criteria for determining whether maximal effort was reached during exercise testing may need to be adjusted for pregnant women. In addition, physical and emotional barriers to maximal exercise testing exist during pregnancy, and these could limit one’s ability to reach their true VO2max.

Previous studies in non-gravid populations use the achievement of at least 3 of the 5 endpoint criteria to determine each test a valid maximal test (Lotgering et al., 1992; Lotgering et al., 1991; Wood et al., 2010; Edvarsen et al., 2014; ACSM, 2014). If we used this determination criterion for the current population of pregnant women, only 7 out of 25 participants would have valid maximal tests, even without adjusted our endpoint criteria for age and sex as recommended by Edvarsen et al. (2014). As previously reported, over half of our participants attained only one or 2 criteria. This suggests that these values need to be adjusted or there is some barrier preventing the participants to reach maximal effort. This is problematic as nearly 75% of the women reported reaching their true maximal effort during pregnancy, yet the criterion would suggest only 30% reached maximal exertion.

It is also interesting to compare the percent achievement for each of the endpoint criteria to a study of a non-gravid population women of similar age-range (Edvarsen et al., 2014). In our study, 33% of participants attained a plateau in VO2, while 42% of the participants in the non-gravid attained a plateau; 80% of participants attained a maximum RPE ≥17 matching the 80% in the non-gravid study; 16% attained maximal HR ≥ 95% of age-predicted maximal HR while 62% attained this criterion in the non-gravid study;
62% reached an $\text{RER}_{\text{max}} \geq 1.1$ in comparison with the 84% in the non-gravid population; and 32% of participants attained a post-exercise blood lactate concentration $\geq 8 \text{ mmol/L}$ while 90% of the participants in the non-gravid study attained this criterion. The only criterion that had similar percentages between our pregnant women and the non-gravid women was RPE. Interestingly, RPE is the only subjective criterion used in both studies. While the women feel like they are reaching their maximal effort, the lack of achievement of the other criteria set for the non-gravid would suggest that they are not, or that other more objective criteria need to be adjusted as a result of the unique physiological changes that occur during pregnancy.

Only one other study, to our knowledge, has assessed endpoint criteria during pregnancy. In comparison to the endpoint criteria data gathered by Heenan et al. (2001) using a cycle ergometer maximal exercise test, the participants in our study have lower values. Their participants had a mean $\text{HR}_{\text{max}}$ of 178±2 bpm, a mean $\text{RER}_{\text{max}}$ of 1.19±0.02, and a mean peak lactate of 9.5±0.7. The lower maximal HR and lower lactate values found in our study could be explained by the fact that we utilized a treadmill protocol and were testing during the 2nd trimester. It is possible that the pregnant women in the Heenan et al. (2001) study were able to push themselves harder with a cycle protocol as there was no risk of falling or steep incline to overcome, and a cycle protocol would alleviate the concerns about running that were apparent in our study population. In addition, the higher heart rate noted by Heenan et al. (2001) could be explained by the fact the pregnant women were tested in the in 3rd trimester when heart rate responses to exercise are the most-pronounced as heart rate increases linearly throughout pregnancy (Wolfe, 2003).
Looking more closely at the endpoint criteria in the present study, the mean values of the endpoint criteria are similar to the standards for a similar non-gravid population (Edvarsen, 2014). In Figure 2, the standards for each established criterion fit within one standard deviation of the means for all secondary criteria, and p-values between the study group and the standard were not significant, except for achievement of 95% of age—predicted HRmax (p<0.001). This suggests that if any of the secondary criteria need to be adjusted, it may be the attainment of 95% of age-predicted maximal HR. The need to alter this criterion can potentially be explained by the fact that pregnant women have altered HR responses to exercise conditions compared with non-gravid populations (Wolfe, 2003).

Specifically, Sady et al. (1989) and Lotgering et al. (1991) found that pregnant women achieved lower maximal heart rates than a control group. This adds to the evidence that maximal HR is lower in pregnant women; and suggests that perhaps a lower percentage of age-predicted HRmax should be used to determine maximal aerobic capacity, or that heart rate responses to exercise should not be included in determining aerobic capacity during pregnancy.

Regarding physical and emotional barriers to maximal exercise during pregnancy, several important themes emerged. The mask and the grade of the treadmill were reported as physical barriers by many participants (i.e. it made the test physically challenging) it was not an emotional barrier/concern. Thus, the participants felt like their performance was hindered by the incline of the treadmill and the difficulty of breathing in the mask; however, they did not cause them to feel unsafe or worry about the health of their unborn baby. The most commonly reported physical barriers were not pregnancy-specific (albeit
physiological changes associated with pregnancy could certainly make breathing and/or walking at an incline more challenging).

Three responses (13%) fell into the last category which was pregnancy-related concerns. These responses included “nervous about running because not a previous runner” and “I heard that heart rate should not go over 150bpm”. The concerns of these women are valid, but can be reduced by informing them of the previous studies that included maximal testing and the minimal risk involved, as well as disseminating the most recent exercise guidelines. Regarding the heart rate concern, this concern may result from the dissemination of old guidelines from the media and/or health care providers. Only 30 years ago, the American Congress of Obstetricians and Gynecologists (ACOG), the primary overseeing body of recommendations for exercise during pregnancy, suggested pregnant women keep their heart rate under 140 beats per minute and that high intensity exercise should be limited (ACOG, 1994). Since then, ACOG has released new guidelines that abandon the “target heart rate concept” and suggest high intensity activities can be safely conducted in an uncomplicated pregnancy (ACOG committee opinion 650, Dec 2015). Regarding the concern for running when not previously a runner, the American College of Sports Medicine (ACSM, 2014) and ACOG (1994) both recommend that pregnant women can exercise to the level of exertion, and with the mode of exercise, that they were exercising before becoming pregnant. Thus, this is a legitimate concern for stopping the test when the participant who was “not a previous runner” began to have to run. Overall, the research suggests that high intensity exercise during pregnancy does not harm pregnant women or their fetuses (Lotgering et al., 1991;
Lotgering et al., 1992; Szymanski et al., 2012; Lotgering, 2014). Lotgering concluded “the millennia-old perspective has changed.” (Lotgering, 2014).

**Limitations.** We had a small sample size and were missing endpoint criteria for several participants.

**Practical implications.** VO$_{2\text{max}}$ is commonly used to assess cardiorespiratory fitness and build a subsequent fitness plan or intervention for non-gravid populations. It is well-established that exercise during pregnancy has many important maternal and neonatal benefits (Clapp, 1980; Bagnall et al., 1983; Collings et al., 1983; Clapp, 2008). Thus, maximizing the safety and accuracy of VO$_{2\text{max}}$ testing during pregnancy is critical to creating tailored exercise interventions that will improve the health of pregnant women and their infants. Establishing secondary criteria for pregnant women will allow clinicians to accurately and confidently assess the cardiorespiratory fitness of pregnant women and then prescribe personalized exercise plans. Pregnant women are an understudied population and there is a need for more research to be done to fully understand how pregnancy affects maximal aerobic exercise.
REFERENCES


APPENDIX A: PHYSICIAN RELEASE FORM
PHYSICIAN’S RELEASE

Patient's Name _______________________

This page will give you the information you will need to understand why this study is being done and why your patient is being invited to participate. **Your patient qualifies to participate because her ongoing pregnancy is very healthy, and because she lives a physically active lifestyle where she participates in regular moderate-to-high intensity exercise.** This form will also describe any known risks, inconveniences or discomforts that your patient may have while participating. We encourage you to ask questions at any time, including via email or phone.

1. **PURPOSE AND BACKGROUND**
Maximal oxygen uptake (VO$_{2\text{max}}$) is the gold standard for measuring cardiorespiratory fitness. The ability to directly measure an individual’s VO$_{2\text{max}}$ can be extremely important for determining health status or prescribing exercise. It is also a key measurement for testing the effectiveness of an exercise or lifestyle intervention. However, directly measuring VO$_{2\text{max}}$ is not always feasible, particularly in high-risk patients. Therefore, the ability to accurately predict VO$_{2\text{max}}$ using submaximal protocols is very important in many circumstances, including during pregnancy. Currently, numerous tests can reasonably estimate or predict VO$_{2\text{peak}}$, including the 6 minute walk test (6MWT) and the YMCA cycle ergometry test; however, neither of these tests have been validated in pregnancy. Clinicians need a validated test to predict their pregnant patients’ fitness level; thus, allowing them to tailor their patients’ exercise prescriptions in order to maximize the benefits of exercise in both the mother and her offspring.

Therefore, the purpose of this study is to determine the validity of the 6MWT and the YMCA submaximal cycle test in pregnancy, and determine which test more accurately predicts VO$_{2\text{max}}$. If neither test appears to be valid based on previously used equations, we will develop and validate our own equation using whichever test more accurately predicts VO$_{2\text{max}}$. 


2. PROCEDURES
The patient will report to the exercise laboratory in the Physical Therapy Program, located within the Medical Center Health Complex, for 2 study visits. At study visit 1, they will complete the 6-minute walk test and the YMCA submaximal cycle test (both low-intensity exercise test that last 6 and 9 minutes, respectively. At visit 2, they will complete a graded exercise test (high intensity test that lasts between 8-12 minutes) on a stationary bicycle. Blood pressure, blood sugar, and perceived exertion will be carefully monitored throughout all study visits. Participants will be allowed to stop at any time.

3. RISKS
Potential risks from participation in the study are typical of those related to participating in physical activity. Specifically, there is a risk of physical injury or discomfort, including muscle soreness. However, your patient is already physically active and thus, we believe she will tolerate the study visits very well. We will monitor vitals carefully and will refer her back to you if any issues arise.

4. BENEFITS
The patient will be compensated for her time and effort. There are no direct benefits to the patient, but we believe the knowledge we gain will improve the quality of exercise testing and prescription during pregnancy for many future women and their neonates.

➢ QUESTIONS
If you have any questions or concerns about your patient’s participation in this program, please call Dr. Rachel Tinius at 270-745-5026. rachel.tinius@wku.edu

Physician’s Signature _________________________ Date __________________________

Printed name _______________________________
APPENDIX B: STUDY FLYER
PREGNANT WOMEN NEEDED FOR A RESEARCH STUDY!

To qualify, you must be:
- 18-44 years of age
- Pregnant (18-24 weeks)
- Non-Smoker
- Regular Exerciser

The study will test whether two low-intensity exercise tests are accurate predictors of fitness level during pregnancy. Knowing the accuracy of these tests can help physical therapists and physicians better prescribe exercise to pregnant patients.

The study involves two study visits to the WKU Physical Therapy Exercise Laboratory. It involves two low-intensity exercise tests (walk test and bicycle test) and a high intensity exercise test (treadmill).

For more information, please contact:
Rachel Tinius, PhD
270-745-5026
rachel.tinius@wku.edu

CO-Is: Don Hoover, PT, PhD
Maire Blankenship, DNP, NP-C, OCN

Participants will be compensated for their time and effort.
APPENDIX C: INFORMED CONSENT DOCUMENT
INFORMED CONSENT DOCUMENT

Project Title: Validation of the Six Minute Walk Test and YMCA Cycle Test to Predict Peak Oxygen Consumption in Pregnancy

Investigator: Rachel Tinius, PhD, ACSM-EP-C
Kinesiology, Recreation, and Sport
(270) 745-5026

You are being asked to participate in a project conducted through Western Kentucky University. The University requires that you give your signed agreement to participate in this project.

The investigator will explain to you in detail the purpose of the project, the procedures to be used, and the potential benefits and possible risks of participation. You may ask any questions you have to help you understand the project. A basic explanation of the project is written below. Please read this explanation and discuss with the researcher any questions you may have.

If you then decide to participate in the project, please sign on the last page of this form in the presence of the person who explained the project to you. You should be given a copy of this form to keep.

1. **Nature and Purpose of the Project:**
   The purpose of this research study is to look at two different light intensity (where you do not feel very fatigued) exercise tests in predicting fitness level during pregnancy. The two exercise tests are called the 6 Minute Walk Test and the YMCA submaximal cycle test. Both of these tests are used for numerous different populations, but neither has been confirmed as a way to precisely measure fitness during pregnancy. We believe that confirming the effectiveness of these tests during pregnancy will allow health care providers to better prescribe exercise to their pregnant patients. When physicians are allowed to develop personalized interventions based on the person’s fitness level, it may help improve prenatal care and infant outcomes during and after pregnancy.

2. **Explanation of Procedures:**

39
All procedures will take place in the DPT research laboratory between 18-24 weeks of pregnancy. You will be asked to come in for 2 study visits, each of which will last about 30 minutes.

For one of your visits, you will complete the 6 Minute Walk Test and the YMCA submaximal cycle test. You will receive a small finger stick before the testing to measure your blood sugar and ensure it is safe to exercise. You will be given several surveys about physical activity levels and asked to bring them back with you on your second visit.

A. The 6 Minute Walk Test:
You will be asked to walk between two cones in a hallway for 6 minutes as fast as possible (without running). Your heart rate and blood pressure will be monitored at the start of the 6 minutes and again when the 6 minutes have ended.

B. The YMCA submaximal cycle ergometer test: You will sit comfortably on a bicycle. The study team will adjust the pedals and the bike so that you are comfortable and can pedal easily. A heart rate monitor will be placed around your chest. You will then be asked to pedal at a very light intensity at 50 rotations per minute (the cycle will count this for you) for several minutes while we record your heart rate. After several minutes, we will adjust the resistance on the bicycle to make it slightly more difficult while we continue to measure your heart rate. The entire test will last 6-12 minutes depending on your heart rate. The test should never reach high intensity (where you feel extremely fatigued). You will be asked to take a short survey on exercise enjoyment at the end of the session.

For your other visit, you will complete a graded exercise test on a treadmill. Before the test, you will receive a finger stick to check your blood sugar levels. If you opt to receive the blood draw, you will also have blood draw taken. The blood will be drawn by putting a needle into a vein in your arm. Two small tubes of blood will be taken. This will take about five minutes. This will be repeated again after the graded exercise test is complete. All blood draws will be performed by a Doctor of Nursing Practice. You will also be asked to take several surveys about your mood and exercise enjoyment after the exercise session.

A. A maximal graded exercise test:
For this test, you will be given a 3 minute warm up on a physical therapy-grade treadmill. The treadmill will have safety rails and you will wear a safety belt around your waist. After your warm-up, we will slowly increase the incline and the speed of the treadmill until you report that you are too fatigued to continue. This test will take between 8 and 12 minutes. During this test, you will have a mask over your nose and mouth so we can monitor air consumption. You will monitored very closely by a nurse practitioner during this test. You will also be asked to take several surveys about your mood and exercise enjoyment after the exercise session.
You will be served a snack and monitored closely before you leave.

Do we have permission to take photos during your study visits for educational purposes?

_____ Yes  _____ No
Initials    Initials

Do we have permission to take a blood sample before and after the exercise test?

_____ Yes  _____ No
Initials    Initials

My blood may be stored and used for future research on this topic by our study team.

_____ Yes  _____ No
Initials    Initials

3. **Discomfort and Risks:**

**Likely/Common**

*Mild*

- Feeling light-headed or fatigued during or after the exercise sessions.
- Muscle soreness of the legs during or after exercise
- Discomfort from finger sticks
- If consent to blood draw, pain from needle stick

**Less Likely/Less Common**

*Serious*

- Musculoskeletal injury as a result of the exercise testing (ex: strained muscle)
- If consent to blood draws, bruising or fainting

**Rare**

*Life Threatening*

- Life threatening arrhythmia which may lead to a heart attack, and possibly death.
- If consent to blood draw, infection
One risk of participating in this study is that confidential information about you may be accidentally disclosed. We will use our best efforts to keep the information about you secure, and we are confident the risk of accidental disclosure is very small. Please see the section in this consent form titled “Confidentiality” for more information.

4. **Benefits:**

You will learn valuable information about your fitness levels.

We hope that, in the future, other people might benefit from this study because the results will allow healthcare professional to precisely measure fitness levels in their patients, thus, allowing them to more safely and effectively prescribe exercise during pregnancy. This will hopefully improve the health of women during pregnancy as well as improve the health of their infants.

You will be paid $25 at each visit for participation in the study.

5. **Confidentiality:**

To help protect your confidentiality, we will do everything we can to keep your information private and protected. Your research file will contain identifiable information such as your name, patient ID#, and birthday. Protected Health Information (PHI) will be created by the study. Study PHI will be kept in your research record and only the research team will have access to the information. The data obtained from this study will be kept confidential. Patients are assigned a study specific identifying number (PID) upon entry to the study, after which all medical information is referenced by this number. Databases that contain private health, medical or research information are behind firewalls, require password/username for access, are maintained using the PID, and only the PI and Co-PIs, have access to the code that matches the PID with other patient identifiers. All hardcopy data records are stored in locked file cabinets and kept in a locked office. If we write a report or article about this study or share the study data set with others, we will do so in such a way that you cannot be identified.

6. **Refusal/Withdrawal:**

Refusal to participate in this study will have no effect on any future services you may be entitled to from the University. Anyone who agrees to participate in this study is free to withdraw from the study at any time with no penalty.

(consent form continued)

*You understand also that it is not possible to identify all potential risks in an experimental procedure, and you believe that reasonable safeguards have been taken to minimize both the known and potential but unknown risks.*
THE DATED APPROVAL ON THIS CONSENT FORM INDICATES THAT
THIS PROJECT HAS BEEN REVIEWED AND APPROVED BY
THE WESTERN KENTUCKY UNIVERSITY INSTITUTIONAL REVIEW BOARD
Paul Mooney, Human Protections Administrator
TELEPHONE: (270) 745-212