

Florida's Pregnancy-Associated Mortality Review 2015 Update

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Division of Community Health Promotion Florida Department of Health July 2017

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Summary

Florida's Pregnancy-Associated Mortality Review (PAMR) is an ongoing surveillance process that involves data collection and examination of maternal deaths to promote evidence-based actions for individual behavioral changes, health care system improvements, and prevention of pregnancy-related deaths (PRDs). [For additional details about the PAMR committee and process, please refer to Appendix 2].

The 2015 Update provides an overview and comparisons of PRD data and trends for Florida between 2006 and 2015. Distributions of PRDs are shown by race/ethnicity, age, body mass index (BMI), timing of death, pregnancy outcome, type of delivery and cause of death, and, when applicable, pregnancy-related mortality ratios (PRMRs).

The data linkage process identified 160 Florida resident pregnancy-associated deaths (PADs) from January 1, 2015 to December 31, 2015. The PAMR case selection committee determined that 48 of these PADs in 2015 were most likely pregnancy-related. Upon full team review of these 48 death cases, the PAMR committee found that 38 (79.2%) actually were pregnancy-related.

The 2015 pregnancy-related mortality ratio (PRMR) in Florida was 16.9 per 100,000 live births. Although the 2015 PRMR was lower than the 2013 ratio (26.2 per 100,000 live births), the trend for the period 2006-2015 was not statistically significant.

For 2015:

- Of the 38 PRDs
 - o 52.6% were non-Hispanic White women
 - o 31.6% were non-Hispanic Black women
 - o 10.5% were Hispanic women
 - o 5.3% were non-Hispanic Other Races women
- The leading pregnancy-related causes of death in 2015 were hemorrhage (31.6%), infection (10.5%), and thrombotic embolism (10.5%)
- Of the 38 PRDs, 23 (60.5%) occurred during the postpartum period
 - \circ $\,$ 56.5% of postpartum PRDs occurred prior to hospital discharge
 - \circ $\,$ 43.5% of postpartum PRDs occurred after hospital discharge $\,$
- PRDs by pregnancy outcome
 - o 57.9% after a live birth delivery

- 13.2% while still pregnant (undelivered)
- o 10.5% after a miscarriage/abortion
- o 7.9% after a stillbirth
- 7.9% during or after an emergency delivery
- o 2.6% after an ectopic pregnancy
- 29 PRDs occurred during or after delivery
 - o 52.6% (20) had C-section as a delivery method
 - 40.0% were planned C-section deliveries
 - 60.0% were unplanned C-section deliveries
- 25 PRDs (65.8%) were overweight or obese women based on their BMI classifications

The leading recommendations in 2015 were:

- Facilities should institute protocols for early recognition and treatment for hemorrhage. The Florida Perinatal Quality Collaborative (FPQC) Obstetric Hemorrhage Tool Box contains resources, suggested protocols for risk screening, diagnosis and treatment and is available at: http://health.usf.edu/publichealth/chiles/fpqc/OHI.htm
- Providers should consider a thrombosis risk scoring system to identify high risk patients for preventative treatment for deep vein thrombosis (DVT).
- Facilities should institute a sepsis alert policy for early recognition and establishment of treatment of sepsis and activate the sepsis protocol for patients presenting with sepsis. Clinical practice guidelines, education, training, and screening tools are available at: <u>https://www.cdc.gov/sepsis/clinicaltools/</u>

The Department of Health (Department) collaborates with diverse public and private organizations to pursue multifaceted approaches to moving recommendations into tangible actions. After identifying the leading causes of PRD, the Department:

- Contracted with the Florida Perinatal Quality Collaborative (FPQC) to implement an Obstetric Hemorrhage Initiative (OHI) that addressed the leading cause of PRD during the 2014-2015 fiscal year. Round two of the OHI began February 2016.
- Contracted with the FPQC to implement a Hypertension in Pregnancy (HIP) initiative that began in July 2016 and will end in June 2017.
- Initiated a new contract in April 2017 with the FPQC to implement a postpartum Long-Acting Reversible Contraceptive (LARC) quality improvement initiative.

Next Steps:

- Ongoing surveillance
- Urgent messages
- Ongoing building of partnerships

Pregnancy-Related Mortality Findings — Florida, 2015

Pregnancy-Associated and Related Deaths

A pregnancy-associated death (PAD) is a death of a woman from any cause, while she is pregnant or within one year of termination of pregnancy, regardless of the duration and site of the pregnancy. A pregnancy-related death (PRD) is a death of a woman directly attributed to pregnancy and/or childbirth. PRDs are subsets of PADs [For PAMR processes see Appendix 2]. Florida's pregnancy-associated mortality ratios (PAMR) and pregnancy-related mortality ratios (PRMR) are shown in Figure 1.

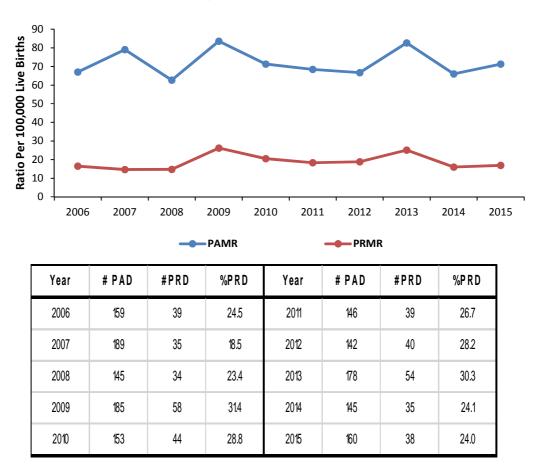


Figure 1. Pregnancy-Associated Mortality Ratios and Pregnancy-Related Mortality Ratios, Florida 2006-2015

• The total number of PADs in Florida ranged from 142 to 189 per year between 2006 and 2015. The number of PADs in 2015 was 160.

 The proportion of PADs that were pregnancy-related ranged from 18.5% to 31.4% between 2006 and 2015. In 2015, 24.0% of PADs were determined to be PRDs by the Florida PAMR committee.

Not-Pregnancy-Related Deaths

Not-Pregnancy-Related Deaths are a subset of PAD. The leading causes of maternal death in the not-pregnancy-related cases for 2010-2015, based on documentation in the death certificates, are shown in Figure 2. These maternal deaths were identified through the data identification process described in Appendix 2. In 2015, deaths due to certain types of cancer and other miscellaneous causes represented 39% of not-pregnancy-related cases, while drug related, motor vehicle accidents (MVA), and homicides had percentages from 13% to 23%. Suicides represented 11% of the not-pregnancy-related deaths.

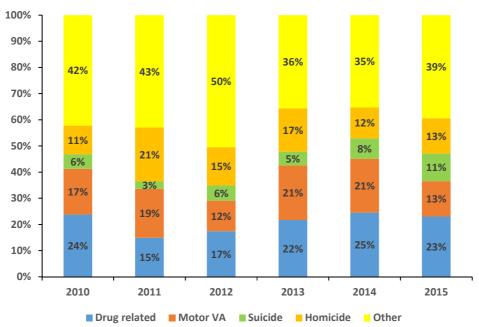


Figure 2. Not-Pregnancy-Related Death Cases by Cause of Death Florida, 2010-2015

Pregnancy-Related Mortality Ratios (PRMR)

A measure of PRDs is the PRMR. The PRMR is the number of PRDs per 100,000 live births. In assessing mortality, it is customary to view mortality measures over an extended period of time to identify increasing or decreasing trends. Figure 3 displays PRMRs for Florida between 2006 and 2015 by race and Hispanic ethnicity.

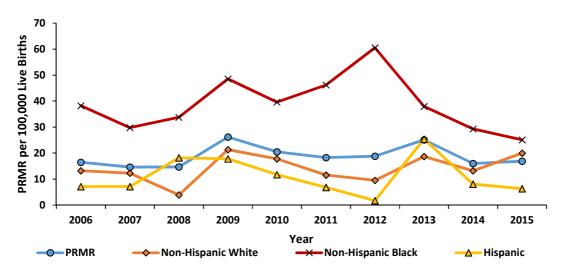


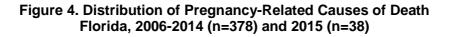
Figure 3. Pregnancy-Related Mortality Ratios (PRMRs) by Race/Ethnicity Florida, 2006-2015

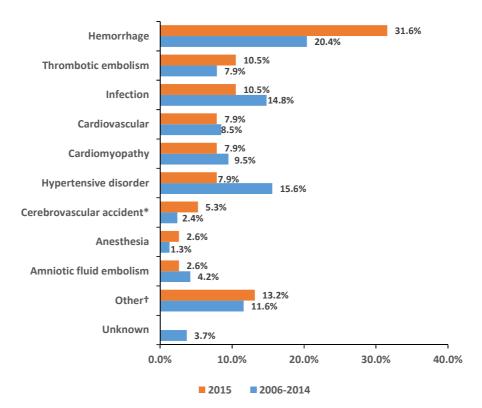
- During the period 2006-2015, the overall Florida PRMR fluctuated from 16.4 deaths per 100,000 live births in 2006 to a high of 26.2 in 2009 and a low of 15.9 in 2014. The PRMR in 2015 was 16.9 deaths per 100,000 live births.
- As evidenced in Figure 3, Florida PRMRs exhibit consistent racial disparities but the gap between non-Hispanic Blacks and non-Hispanic Whites between 2006 and 2015 has decreased from 8.7 in 2008 to 1.3 in 2015. Throughout this study period, non-Hispanic Black women exhibited higher PRMRs than non-Hispanic White or Hispanic women. During 2012, the PRMR for non-Hispanic Black women was 60.5, an all-time high. In 2015, the PRMR per 100,000 live births was 25.1 for non-Hispanic Black women, 20.0 for non-Hispanic White women, and 6.3 for Hispanic women.

Cause of Pregnancy-Related Deaths

The PAMR committee determined a primary cause of death for each PRD they reviewed.

- In 2015, the leading causes of PRDs were hemorrhage 31.6%, thrombotic embolism, and infection, the last two with 10.5% each.
- Figure 4 and Table 1 show how the percentage of deaths for hemorrhage, thrombotic embolism, and other remaining causes were higher in 2015 compared with the period 2006-2014. Also, Figure 4 and Table 1 show decreases in the percentage of deaths in 2015 due to infection, cardiovascular problems, cardiomyopathy, hypertensive disorders, and amniotic fluid embolism compared with 2006-2014.





*Cerebrovascular accident no known hypertensive disorders.

†Other is comprised of various causes of deaths not easily captured with sufficient numbers in a homogeneous category.

Causes of Deaths	2006-2014	2015	Change in Percentage
	N (
Hemorrhage	77 (20.4)	12 (31.6)	54.9
Thrombotic Embolism	30 (7.9)	4 (10.5)	32.9
Infection	56 (14.8)	4 (10.5)	-29.1
Cardiovascular	32 (8.5)	3 (7.9)	-7.1
Cardiomyopathy	36 (9.5)	3 (7.9)	-16.8
Hypertensive disorders	59 (15.6)	3 (7.9)	-49.4
Cerebrovascular accident	9 (2.4)	2 (5.3)	120.8
Amniotic Fluid Embolism	16 (4.2)	1 (2.6)	-38.1
Anesthesia	5 (1.3)	1 (2.6)	100.0
Other remaining causes*	44 (11.6)	5 (13.2)	13.8
Total	378**	38	

Table 1. Distribution of Causes of Pregnancy-Related DeathFlorida, 2006-2014 and 2015

*Other remaining causes include: hematopoietic, collagen vascular diseases, metabolic (pregnancy related or not related), injury, cancer, pulmonary problems, neurologic/neurovascular problems, multiple organ/system failure, gastrointestinal disorders, and other conditions. ** Total includes unknowns.

Pregnancy-Related Deaths by Age

Examination of age at death can point toward the presence and types of PRD protective or risk factors among age groups, such as biological effects of the aging process. PRD distribution and PRMRs by age group are shown in Figures 5a and 5b.

 In 2015, the highest percentage of maternal deaths (31.6%) occurred in women 30-34 years old. In contrast, fewer older mothers age 35 or more died in 2015 compared with 2006-2014 (26.3% vs. 31.2% respectively) as shown in Figure 5a.

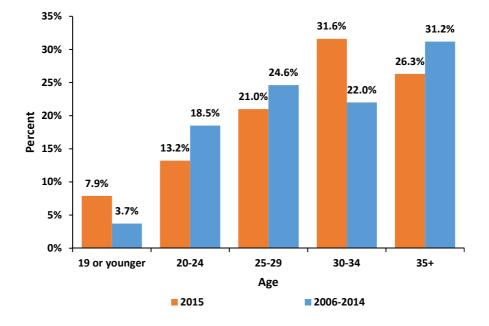


Figure 5a. Distribution of Pregnancy-Related Deaths by Age Florida, 2006-2014 (n=378) and 2015 (n=38)

 In 2015, the PRMR of mothers age 35 or more (26.8) was almost 3 times the PRMR of mothers 20-24 years old (10.4). (Figure 5b)

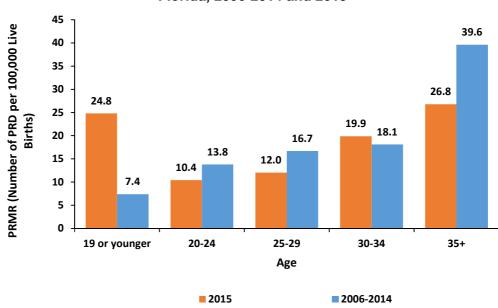


Figure 5b. Pregnancy-Related Mortality Ratios (PRMRs) by Age Florida, 2006-2014 and 2015

Pregnancy-Related Deaths by Timing of Death

The PAMR process classifies timing of death into categories defined by the three perinatal periods in which PRDs can occur: prenatal, labor and delivery, and postpartum. The postpartum period is divided into two subcategories: Postpartum not discharged from the hospital and postpartum discharged from hospital. [See Appendix 1 for detailed definitions]. PRDs by timing of death between 2006-2014 and 2015 are shown below in Figure 6.

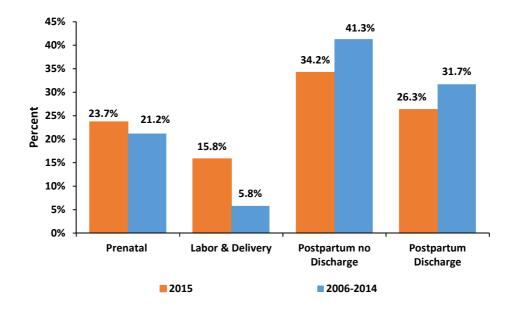


Figure 6. Distribution of Pregnancy-Related Deaths by Timing of Death Florida, 2006-2014 (n=378) and 2015 (n=38)

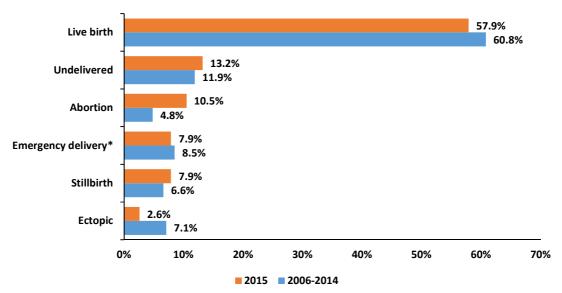
- In 2015, the majority of PRDs (60.5%) occurred during the postpartum period. There are differences between the causes of death in the postpartum period by hospital discharge status.
 - Of the postpartum PRD cases who were not discharged from the hospital, the PRD causes were: hemorrhage, other remaining causes, hypertensive disorders, and cerebrovascular accident.
 - Of the women who died after hospital discharge: the PRDs that occurred during the first six weeks postpartum were due to infection, thrombotic embolism, and cardiovascular. For women who died after six-weeks postpartum and were discharged from the hospital, the causes of deaths

were cardiomyopathy, infection, thrombotic embolism, and other remaining causes.

Pregnancy-Related Deaths by Pregnancy Outcome

In the PAMR process, pregnancy outcomes are classified as live birth, emergency delivery, undelivered, ectopic, abortion, and still birth (see Appendix 1 for detailed pregnancy outcome definitions). Figure 7 below shows PRDs by pregnancy outcome in Florida for 2015 versus 2006-2014.

Figure 7. Distribution of Pregnancy-Related Deaths by Pregnancy Outcome Florida, 2006-2014 (n=378) and 2015 (n=38)



*There were 3 emergency deliveries in 2015, all of them were live births.

- In 2015, the majority (57.9%) of PRDs occurred after a live birth and 13.2% were undelivered.
- In 2015, there were 70 surviving children of mothers who died of PRDs.

Pregnancy-Related Deaths by Type of Delivery

Type of delivery is classified by PAMR as either vaginal or C-section. C-section deliveries are further defined as planned and unplanned. [See Appendix 1 for type of delivery definitions]. Figure 8 illustrates the PRD distribution by type of delivery for the women who died during the labor/delivery or postpartum period.

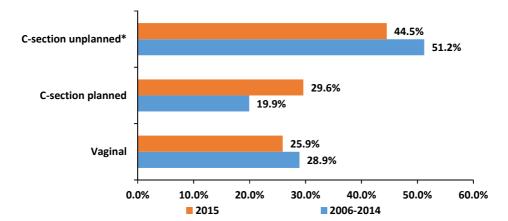


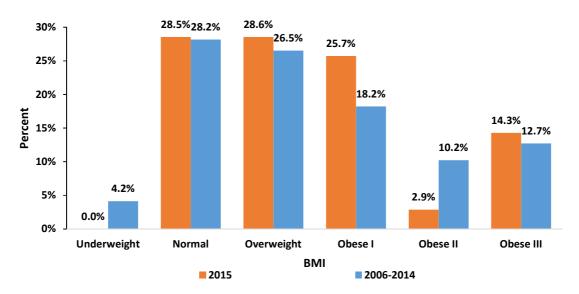
Figure 8. Distribution of Pregnancy-Related Deaths by Type of Delivery Florida, 2006-2014 (n=287), 2015 (n=27)

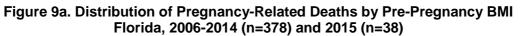
*Of 12 (44.5%) unplanned C-sections, 3 (25.0%) were emergency deliveries.

- In 2015, 71.1% of PRD cases that occurred during the labor/delivery or postpartum period were by C-section. In comparison, 37.3% of all live births in Florida were C-section deliveries in 2015 (not shown in figure 8) [1].
- Nearly 45% of the C-sections among the PRD cases that occurred in 2015 were unplanned C-section deliveries.

Pregnancy-Related Death by Pre-Pregnancy Body Mass Index

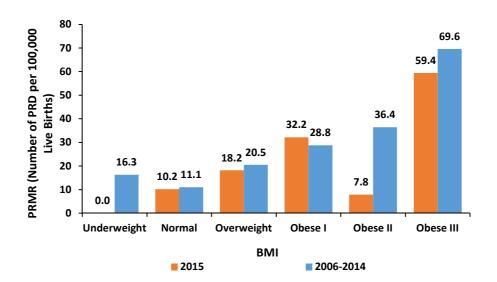
Body mass index (BMI) is a calculated measure of the relative percentage of body fat based on height and weight. PAMR uses the following six BMI categories to examine associations between weight before pregnancy and PRD: underweight, normal weight, overweight, and obese Class I, obese Class II, and obese Class III. [See Appendix 1 for detailed definitions of BMI calculations and BMI categories.] Distributions of PRDs and PRMRs by BMI category are shown in Figures 9a and 9b, respectively.





 In 2015, 71.4% of women who experienced a PRD had overweight/obese prepregnancy BMIs (Figure 9a). Comparably during the same year, a lesser percentage (49.3%) of all Florida women who had a live birth were in the overweight/obese pre-pregnancy category (not shown in figure 9a) [1].

Figure 9b. Pregnancy-Related Mortality Ratios (PRMRs) by Pre-Pregnancy BMI Florida, 2006-2014 (n=378) and 2015 (n=38)



 As shown in Figure 9b, PRD cases with higher pre-pregnancy BMIs had higher PRMRs. In 2015, the PRMR was 10.2 maternal deaths per 100,000 live births with normal weight pre-pregnancy BMIs versus 18.2 with overweight and 32.2, 7.8, and 59.4 obese Class I, Class II, and Class III pre-pregnancy BMIs, respectively.

PAMR Identified Issues and Recommendations for PRDs, 2015

After reviewing PRD cases, the PAMR committee identifies relevant issues related to each death and makes recommendations to promote system improvements. The PAMR committee places identified issues and recommendations into four prevention categories: Clinical Factors, System Factors, Individual/Community Factors, and Death Review Factors. The following narrative outlines how the PAMR committee used the four prevention categories when they identified issues and made recommendations during the 2015 review. A consistent message that has been established is that a woman's health prior to her pregnancy can greatly affect the birth outcome, as well as her health status after birth.

Clinical Factors (Health Care Services, Practice, Protocols, and Care Coordination)

Clinical factors relate to services delivered by all health care providers and include actions involving diagnosis, treatment, and communication.

<u>Issues</u>

Contributing factors identified in the review of 2015 PRDs include:

- Delay of Treatment: 25%
- Knowledge/Skills/Assessment: 20%
- Lack of Diagnosis: 20%
- Lack of Treatment: 15%
- Delay of Diagnosis: 10%
- Care Coordination-Referrals, Transfers, Follow-up: 10%

Clinical Recommendations

- It is important to reduce the C-section rate to prevent obstetric complications (e.g. abnormal placental implantation) and maternal surgical risks (e.g. adhesive disease) with subsequent pregnancies.
- It is important to have a written delivery plan for pregnant women with previous Csections and co-morbidities. A multi-disciplinary team may be needed depending on the level of risk and identified co-morbidity.
- Attention to early recognition of vital sign changes is important to trigger further clinical evaluation.
- Facilities should consider the development of a postpartum risk assessment.
- High risk pregnant women with comorbidities should be admitted to the hospital, especially if they have frequent ER visits and unresolved illness.
- Pregnant women should have a consultation with a specialist in hematology or maternal fetal medicine when their platelet count is below 20,000 per cubic millimeter (cmm) of blood to assist in accurate diagnosis and treatment.
- It is important to educate family members who have a potential genetic link to choriocarcinoma.

System Factors (Health Care Management, Reimbursement and Access)

System factors relate to system level processes involving policies, barriers to access health insurance, nursing knowledge, or infrastructure.

<u>Issues</u>

Contributing factors mentioned in review of 2015 PRDs include:

- Lack of Standardized Policies and Procedures: 80%
- Lack of Care Coordination: 20%

System Recommendations

- It is important to institute standard guidelines for pregnancy screening in teens.
- It is important to schedule high risk deliveries when staff are at optimum levels.
- Facilities should institute protocols for management of emerging clinical issues such as the use of rapid response teams.
- High risk women with significant social factors require additional specialized care coordination.

- Facilities should consider the design of obstetric triage to include physician assessment in addition to nursing assessment.
- Policies should include the importance of conducting high risk termination of pregnancy (TOP) procedures in an inpatient setting.
- Emergency department should establish policies to consider social work assessment referrals for pregnant women with comorbidities, high risk social issues, and frequent emergency department visits.
- Transfer agreements between hospitals should be instituted to facilitate transfers to higher levels of care.
- There should be a high index of suspicion for gastrointestinal surgical complications when pregnant women who have had bariatric operative procedures present with significant abdominal symptoms (ACOG Practice Bulletin 105 June 2009), reaffirmed 2015.
- Providers should review ACOG/SMFM recommendations on safe prevention of primary C-sections.

Individual/Community Factors

Individual/Community factors relate to non-medical issues that have an underlying causal role in the PRD. For example, these can include barriers to recognizing symptoms or personal decisions about seeking care or following medical recommendations.

<u>Issues</u>

Contributing factors mentioned in review of 2015 PRDs include:

- Significant Co-Morbidity: 39%
- Personal Decisions (Example: Delayed Seeking Care): 35%
- Substance Abuse/Use: 9%
- Financial Barriers: 5%
- Lack of Social Support: 4%
- Lack of Patient Knowledge: 4%
- Cultural or Religious Belief: 4%

Individual/Community Recommendations

- It is important to avoid primary C-section, if possible, to prevent increasing risk of complications with subsequent deliveries.
- All women with comorbidities should have access to long-acting reversible contraceptives (LARCs).
- All women with health issues should seek immediate health care.
- Preconception care is important for all women, but especially important for women who are morbidly obese and women who currently use or have a history of substance use and abuse.
- Development of reproductive life plans are important particularly for women with severe comorbidities.
- Women with lung hypoplasia are at extremely high risk of death during pregnancy. They should be educated to use a highly effective method of contraception to avoid unplanned pregnancies.

Death Review Factors

The PAMR process relies on information from death certificates and autopsy reports for the identification and evaluation of PRDs.

<u>Issues</u>

- Death certificate accuracy
- PAMR abstraction process
- Lack of autopsy for sudden, unexplained, or inconclusive cause of death

Death Review Recommendations

- The PAMR medical abstraction process should include an operative report for obstetric deliveries.
- Providers should include abstraction of notes on 3rd stage of labor management.
- It is important to obtain records from providers who perform termination of pregnancy, if possible.

Committee Recommendations Related to the Leading Causes of Death

Also outlined are the PAMR committee's identified recommendations related to the five leading causes of PRD for the year 2015: hemorrhage, thrombotic embolism, infection, cardiomyopathy, hypertensive disorders, and cardiovascular problems. The PAMR committee did not make any specific recommendations for cardiovascular problems.

Hemorrhage

Clinical Recommendations

- Raise awareness on the importance of early recognition of hemorrhage and implementation of a hemorrhage protocol as outlined in the Florida Perinatal Quality Collaborative's Obstetric Hemorrhage Toolkit.
- Providers should consult a Hematologist or Maternal Fetal Medicine Specialist when there is a platelet count below 20,000 cmm to assist in diagnosis and treatment.
- Providers should be trained to develop specialized surgical skills to be utilized during high risk for hemorrhage deliveries.

System Recommendations

- Facilities should utilize the "Recommendations for Obstetric Care for Women Who Decline Transfusions" from Florida's Obstetric Hemorrhage Toolkit.
- Providers should transfer complex obstetrical cases with a high risk of hemorrhage to a higher level of obstetric care.
- Providers should promote the use of the "Checklist for Management of Pregnant Women who Decline Transfusions" from Florida's obstetric hemorrhage toolkit to plan for high risk deliveries.
- Facilities should institute protocols for early recognition and treatment for hemorrhage. The Florida Perinatal Quality Collaborative (FPQC) Obstetric Hemorrhage Tool Box contains resources, suggested protocols for risk screening, diagnosis and treatment and is available at: http://health.usf.edu/publichealth/chiles/fpqc/OHI.htm

Individual/Community Recommendations

- Pregnant women with abdominal pain should seek care promptly.
- Postpartum women should call their provider or go to the emergency room when they are having bleeding that exceeds the "normal" levels.

Thrombotic Embolism

Clinical Recommendations

- Providers should conduct a thromboembolism risk assessment and have knowledge of the guidelines for treatment in pregnancy. Conditions that contribute to risk may include C-section, obesity, and hemolytic conditions.
- Providers should take into consideration chemical thrombo-prophylaxis in patients with multiple co-morbidities and high proteinuria.

System Recommendations

 Facilities should also consider a thrombosis risk scoring system to identify high risk patients for preventative treatment for deep vein thrombosis (DVT) and a chemical prophylaxis policy which includes standards developed with the inclusion of pharmaceutical expertise. Standards should include appropriate medication dosage for weight. Conditions that contribute to risk may include C-section, obesity, and hemolytic conditions (e.g., hemoglobinopathies).

Individual/Community Recommendations

• Providers should educate morbidly obese women to seek prenatal care for chemical prophylaxis to DVT.

Infection

Clinical Recommendations

• The sepsis protocol should be implemented for patients presenting with severe sepsis.

System Recommendations

• Facilities should institute a sepsis alert policy for early recognition and establishment of treatment of sepsis and activate the sepsis protocol for patients presenting with sepsis.

Cardiomyopathy

System Recommendations

• It is important to develop a delivery plan for pregnant women with co-morbidities such as cardiomyopathy.

Individual/Community Recommendations

• Educate women to recognize signs and symptoms of cardiomyopathy and other heart conditions they may experience during the postpartum period, such as shortness of breath, cough, dizziness, chest pain, and swelling.

Hypertensive Disorders

Clinical Recommendations

- Low-dose aspirin is recommended for the prevention of preeclampsia beginning in the first trimester for women with a history of early-onset preeclampsia and preterm delivery or women with more than one prior pregnancy complicated by preeclampsia, per ACOG Practice Advisory on Low-Dose Aspirin and Prevention of Preeclampsia: Updated Recommendations, July 11, 2016.
- Providers should ensure continuity of antihypertensive medication during the postpartum period for women with hypertension during pregnancy.
- Postpartum follow-up should include blood pressure checks at two-day and oneweek postpartum checkup as per Florida Perinatal Quality Collaborative (FPQC) Hypertension in Pregnancy (HIP) Initiative guidelines.
- Implement procedures to provide postpartum women with hypertension discharge instructions to return to their provider when they have signs and symptoms of elevated blood pressure such as headache, abdominal or stomach pain, shortness of breath, numbness, or tingling.

Assessing Preventability of Maternal Deaths in Florida in 2015

In 2014, the Florida PAMR committee initiated the assessment of preventability of PRDs. After a series of discussions with the PAMR preventability work group and mirroring the California PAMR process [2], two new columns were included in the Florida PAMR review form.

First, the PAMR committee reached consensus on whether the death appeared to have been preventable and to what degree the death was preventable by asking the following question: *If specific actions had been implemented, to what degree would these actions have changed the woman's trajectory and led to her survival?* There were three possible answers to this question:

- <u>Strong</u>: A case with a strong chance for an altered outcome would likely have one or more identified factors that definitely contributed to the death (e.g., misdiagnosis, wrong drug, or particular patient action) so that if the correct diagnosis had been made (or correct drug given or patient action had been different), the fatal course would have been reversed. For a strong chance to alter outcomes, there are often obvious deficiencies for which there are clear alternative actions that can be identified retrospectively. The alternative actions would likely target precipitating conditions or actions that either set in motion a cascade of unsuccessful 'catch-up' or 'salvage' actions, or were critical tipping points after which little could have been done.
- Possible: A case with some chance for an altered outcome would have fewer or weaker contributing factors and fewer or less specific identified quality improvement areas. These cases may parallel cases of women with similar conditions who survived; in that there may be a multitude of factors and actions that *could* have been reversed. However, in these cases, it would have required actions that were beyond what could feasibly be accomplished in that setting or required an uncommon synchronization of corrective actions to have occurred. So while there is usually *something* that could have been done to have improved care and possibly reversed the fatal trajectory, the specific actions and their impact is less clear.
- <u>None</u>: A case with no chance to alter outcome has no clear point of prevention or intervention identified. In such cases, no intervenable risks were presented and there were no instances where improved care or alternative actions might have changed the outcome.

Second, for each PRD case, the PAMR committee identifies whether health care providers, facility, or patient/community factors contributed to the death with the following question: Did the factors identified in the improvement categories contribute to the maternal death? This question has two choices to select (when the factor did not contribute to the death, the question should be left blank).

- <u>Definitely</u>: In the reviewer's best judgment, the factor was present and definitely contributed to the cause of death.
- <u>Probably</u>: In the reviewer's best judgment, the factor was present and probably contributed to the cause of death.

These assessments of preventability are based on PAMR committee review and represent the first year of collecting these factors. The Florida PAMR committee members are optimistic that this information will help to focus the PAMR committee recommendations.

Results

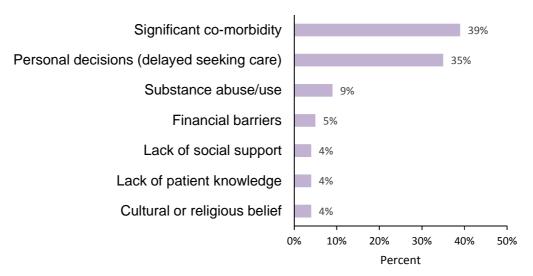
Overall, in 2015, 55.3% of PRDs had a strong chance to alter the outcome and prevent the maternal death, and 18.4% had a possible chance to alter the outcome.

	PRDs w	ith Chance to	Alter Out	tcome	Total	% Strong Chance to Alter
Cause of PRDs	Strong	Possible	None	N/I		Outcome
Hemorrhage	11	0	0	1	12	91.7%
Intrauterine	10	0	0	1	11	90.9%
Ectopic	1	0	0	0	1	100.0%
Infection	2	2	0	0	4	50.0%
Thrombotic embolism	2	1	0	1	4	50.0%
Cardiomyopathy	1	2	0	0	3	33.3%
Cardiovascular problems	1	1	0	1	3	33.3%
Hypertensive disorder	2	1	0	0	3	66.7%
Cerebrovascular accident	0	0	1	1	2	0.0%
Amniotic fluid embolism	0	0	0	1	1	0.0%
Anesthesia	1	0	0	0	1	100.0%
Other	1	0	0	4	5	20.0%
Total	21	7	1	9	38	55.3%

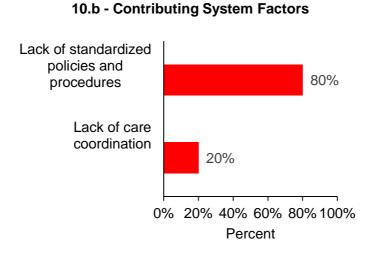
The leading causes of death showed variation (Table 2). Hemorrhage had 91.7% strong chance to alter the outcome, while hypertensive disorders had 66.7%, thrombotic embolism had 50%, infection 50%, and cardiomyopathy and cardiovascular problems both had 33.3%.

For 2015 PRDs, the Florida PAMR committee identified definite and possible factors that could have contributed to the maternal deaths. The Committee identified and grouped the maternal causes of death into Individual/Community, System Facility, and Clinical Contributing Factors. Each patient may have had multiple contributing factors. By individual/community, the definite factors that contributed to the maternal deaths were significant co-morbidities, personal decisions, substance abuse, financial barriers, lack of social support, lack of patient knowledge, and cultural or religious beliefs. Systems issues were related to lack of standardized policies and procedures and lack of care coordination. Clinical factors were delay of treatment, knowledge/skill assessment, lack of diagnosis, lack of treatment, delay of diagnosis, and insufficient care coordination-referrals (Figures 10.a, 10.b and 10.c).

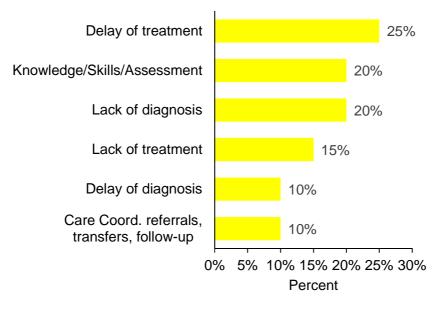
Figures 10a, 10b, and 10c. Contributing Factors among Pregnancy-Related Deaths, Individual and Community Factors (10.a), System Factors (10.b) and Clinical Factors (10.c), Florida, 2015



10.a - Contributing Individual/Community Factors



10.c - Contributing Clincal Factors



By cause of death, hemorrhage (intrauterine and ectopic) had 83.3% contributing factors, infection 75.0%, cardiomyopathy, and hypertensive disorders 66.7% each, thrombotic embolism 50%, and cardiovascular problems 33.3% (Table 3).

	Factors that Contributed			Total	% Definitely Factor Contributed	
Cause of PRDs	Definitely	Possible	N/I			
Hemorrhage	10	1	1	12	83.3%	
Intrauterine	9	1	1	11	81.8%	
Ectopic	1	0	0	1	100.0%	
Infection	3	1	0	4	75.0%	
Thrombotic embolism	2	1	1	4	50.0%	
Cardiomyopathy	2	1	0	3	66.7%	
Cardiovascular problems	1	1	1	3	33.3%	
Hypertensive disorder	2	1	0	3	66.7%	
Cerebrovascular accident	0	1	1	2	0.0%	
Amniotic fluid embolism	0	0	1	1	0.0%	
Anesthesia	1	0	0	1	100.0%	
Other	1	0	4	5	20.0%	
Total	22	7	9	38	57.9%	

Table 3. Pregnancy-Related Death by Likelihood of Factors Contributed and Cause of Death, Florida 2015 (n=38)

Conclusion

The death of a woman due to pregnancy is a loss to the family, community, state, and nation. Florida has been actively conducting ongoing surveillance of maternal mortality cases since 1996. To date, a multidisciplinary PAMR committee of maternal child specialists has reviewed over 2,400 pregnancy-associated cases. The committee carefully and respectfully considers each case before they identify issues and make recommendations.

The 2015 report shows the consistent disparity in PRDs between non-Hispanic Black and non-Hispanic White women. Non-Hispanic Black women were two times as likely to have PRDs compared to non-Hispanic White women.

The Healthy People goal for 2020 is to reduce the rate of maternal mortality to 11.4 maternal deaths per 100,000 live births [3]. Florida's pregnancy-related ratio from 2006-2015 averaged 18.7 deaths per 100,000 live births; therefore, much work is still needed to meet the Healthy People goal.

Recommendations to Action

Florida's PAMR findings and recommendations are proposed to address risk factors among individuals, communities, clinical and health care systems not only to reduce maternal deaths but to consequently improve maternal morbidity. The Department collaborates with diverse public and private organizations to pursue multifaceted approaches to moving recommendations into tangible actions.

Individual/Community, Clinical and System

Beginning in 2011, the Department, in partnership with the Florida Perinatal Quality Collaborative (FPQC) and the March of Dimes, established a perinatal health care quality initiative to reduce non-medically indicated deliveries <39 weeks gestation (NMID).

The Department, the FPQC, and the March of Dimes joined with the national Collaborative Improvement and Innovation Network (CoIIN), sponsored by the Health Resources and Services Administration (HRSA), to focus on reducing early elective deliveries (EED). Primary activities implemented to assist hospitals in reducing their NMID rates include the development of a hospital toolkit, hospital grand rounds and consultations, provider education, and data support to 55 participating Florida hospitals.

The Department, the FPQC, and the March of Dimes coordinated with the Florida Association of Healthy Start Coalitions to lead an effort in educating pregnant women in the community on NMID by offering provider education packets and e-bulletins. Data provided by the FPQC indicate Florida's NMID rate decreased by 15% between 2010 and 2013.

Starting in 2017, Florida plans to implement the Maternal Mortality Review Information Application (MMRIA). MMRIA is an electronic data system designed to support standardized data collection and help Maternal Mortality Review committees organize available data and begin the critical steps necessary to comprehensively identify, access, and abstract cases. There are currently 28 states using the system with 11 more coming aboard.

Clinical and System

In fiscal year 2014-2015, the Department contracted with the FPQC to implement the Obstetric Hemorrhage Initiative (OHI) addressing the leading causes of maternal death by providing an evidence-based toolkit to hospital participants and support for implementation of evidence-based guidelines. The hospital toolkit includes highlighted activities such as interdisciplinary simulation drills designed to improve response times and treatment approaches in an obstetric hemorrhage event. Participating hospitals seek to improve their risk assessment rates, as well as diagnostic and treatment approaches. The FPQC continues to offer technical support and self-assessment tools to hospitals pursuing this ongoing OHI quality improvement initiative. The OHI's first round successfully contributed to hospitals improving quality practices. Round two of the OHI began February 2016 and consists of hospitals leading their own internal initiative with the FPQC providing online tools, resources, and assistance.

Individual/Community, Clinical and System

The Department is currently contracting with the FPQC to implement a Hypertension in Pregnancy (HIP) initiative. The HIP initiative is a quality improvement effort to address the second leading cause of maternal mortality and morbidity in the state from 2005-2013. For this initiative, the FPQC will primarily focus on developing a toolkit to guide hospital participants in implementation and evaluation of quality improvement processes related to prevention, diagnosis, and treatment of hypertensive disorders in pregnancy.

The Department is currently contracting with the FPQC to implement a Postpartum Long-Acting Reversible Contraceptives (LARC) quality improvement initiative. The purpose of the initiative is to work collaboratively with maternal health care providers and hospitals to develop and implement policies to improve the use of LARC methods at delivery among postpartum women to reduce the number of unintended pregnancies. Unintended or closely spaced pregnancies can result in delayed initiation of prenatal care and poor pregnancy outcomes for mother and baby. LARCs include copper or hormonal intrauterine devices (IUDs), and the progestin arm implant; they are safe and highly effective in preventing unintended pregnancies and can be given to women immediately after delivery.

Individual/Community

A recurring recommendation from Florida's PAMR committee is the importance of women achieving optimal health and control of chronic diseases prior to pregnancy. Florida's Healthy Start Program, administered by the Department statewide, provides support services for pregnant women, infants, and children to age three. In 2014, the Department added interconception care services (ICC) as a core component to the Healthy Start program. ICC services are provided to women who have had a pregnancy and are at high risk of having a poor birth outcome for a subsequent pregnancy. Reasons for a high-risk determination may be a previous fetal or infant loss; a low birth weight or pre-term baby; a chronic maternal disease such as hypertension, obesity or diabetes, previous pre-eclampsia or eclampsia, previous gestational diabetes; substance use or abuse; depression; or any other condition that could result in a poor birth outcome.

In August 2014, the Department, in partnership with the national Association of Maternal and Child Health Programs (AMCHP), was selected as a participant in the Every Mother Initiative Action Learning Collaborative (ALC). This collaborative is designed to support and improve maternal mortality reviews and translate recommendations into actions by facilitating peer-to-peer maternal mortality site visits between selected states and implementing a community-driven project while applying sustainable approaches to screening, prevention, treatment, and promotion of healthy behaviors. The Department worked in partnership with REACHUP, INC., a community based non-profit, to raise awareness of preconception health and to expand the Preconception Peer Educator (PPE) program in historically black colleges and universities. The PPE program trains students to educate their peers and raise awareness of infant mortality, maternal mortality, health disparities, healthy behaviors, and encourages participants to engage in community awareness events.

<u>Clinical</u>

The PAMR committee formed an Action Subcommittee in September 2015 to focus on fine tuning and rapidly and widely distributing its recommended messaging for professional, clinical, and community organizations through multiple communication venues. The Action Subcommittee centered its first Urgent Maternal Mortality Message (UMM) on hemorrhage and its second one pertained to peripartum cardiomyopathy (Appendix 4.) The latest UMM will focus on reviewing cases that demonstrated the most severe complications of pregnancy, generally referred to as SMM, to help prevent maternal mortality and is currently being developed and reviewed by the PAMR Action subcommittee. SMM affects more than 65,000 women in the United States every year [9] and includes acute renal failure, cardiac events, thromboembolism, and hemorrhage— some of the leading causes of maternal mortality.

The mixture of these efforts highlight the PAMR committee's emphasis on actively improving maternal outcomes through the evaluation of maternal mortality cases, the development of expert recommendations, and the innovative translation of recommendations into effective actions.

Appendix 1 - Definitions

- Body mass index (BMI) a calculated measure of the relative percentage of body fat based on height and weight.
 - Formula for BMI calculation: $BMI = (weight (pounds)/height (inches)^2) \times 703$
 - o BMI Classifications and Value Ranges for Adults (ages 20 or older)
 - Underweight: BMI <18.5
 - Normal Weight: BMI 18.5 24.9
 - Overweight: BMI 25.0 29.9
 - Obese Class I: BMI 30.0 34.9
 - Obese Class II: BMI 35.0 39.9
 - Obese Class III: BMI 40.0 or more
- *Pregnancy-associated death (PAD)* a death of a woman from any cause, while she is pregnant or within one year of termination of pregnancy, regardless of the duration and site of pregnancy.
- *Pregnancy-related mortality ratio (PRMR)* number of pregnancy-related deaths per 100,000 live births; a measure of maternal mortality.
- *Pregnancy-related death (PRD)* a death of a woman that is directly attributed to pregnancy and/or childbirth.
- Pregnancy outcome
 - *Abortion* A procedure to end a pregnancy. Medicinal and surgical methods are used to remove an embryo or fetus and placenta from the uterus [2].
 - *Ectopic* Occurs when the fertilized egg grows in an abnormal place outside the uterus, usually in the fallopian tubes [4].
 - *Emergency delivery* An unplanned, emergency C-section delivery due to deteriorating maternal or fetal status. The outcome could be a live birth or fetal death/stillbirth [5].
 - Postmortem/perimortem C-section: An unplanned, emergency C-section delivery that is conducted shortly after a maternal death or during the maternal death process [6].
 - Live birth The complete expulsion or extraction from the mother of a product of human conception that shows evidence of life after expulsion/extraction [5].
 - Molar (also known as hydatidiform mole) A noncancerous (benign) tumor that develops in the uterus. A molar pregnancy starts when an egg is

fertilized, but instead of continuing to the stages of a viable pregnancy, the placenta develops into an abnormal mass of cysts [7].

- Stillbirth Death of a fetus before the complete expulsion or extraction from the mother irrespective of the duration of pregnancy; the death is indicated by the fact that after expulsion or extraction, the fetus does not show any evidence of life [5].
- Undelivered A woman that dies before delivering or the extraction of her fetus [5].
- Timing of death perinatal period in which PRDs occur; three main classifications
 - Prenatal PRD occurs between conception and birth.
 - *Labor and Delivery PRD* occurs between the start of the delivery process and ends when the mother leaves the delivery room.
 - Postpartum PRD occurs during the period after labor and delivery and up to one year after delivery or termination of pregnancy. The Postpartum PRD classification has two sub classifications:
 - Postpartum Not discharged from the Hospital/Health Facility PRD occurs in the postpartum period after delivery or termination of pregnancy and before discharge from the hospital/birth facility.
 - Postpartum Discharged from Hospital/Health Facility PRD occurs in the postpartum period after delivery/termination of pregnancy and after discharge from a hospital or health facility up to one year after the delivery/termination event.
- Type of delivery
 - C-section An assisted delivery procedure where an infant or fetus is delivered through surgical incisions made in the abdomen and the uterus [8].
 - Vaginal Delivery of an infant or fetus through the vaginal canal.

Appendix 2 - PAMR Case Selection Process for Committee Review

The PAMR process begins with collecting data for all Florida resident deaths associated with pregnancy. A pregnancy-associated death (PAD) is defined as a death to a woman during pregnancy or up to one year after the pregnancy ends, regardless of the cause of death. The Florida Department of Health Bureau of Family Health Services has implemented a process of data linkages to maximize the identification of PADs. This enhanced surveillance system fosters improved case identification when compared with a more limited process utilized by the Bureau of Vital Statistics also at FDOH. Cases are included in the listing of PADs if any of the following four criteria are met:

- 1) The response on the death certificate is "yes" to the question: "If female, was she pregnant in the past year?"
- 2) The cause of death International Classification of Diseases (ICD) diagnosis code indicates a death classified as being due to "Pregnancy, Childbirth, and the Puerperium."
- 3) There is a matching birth or fetal death record within 365 days prior to the woman's death.
- 4) There is a matching Florida universal prenatal screening tool, which is used to identify and assess pregnant women at risk for adverse birth outcomes within 365 days prior to the woman's death.

A pregnancy-related death (PRD) is a PAD which resulted from 1) complications of the pregnancy itself, 2) the chain of events initiated by the pregnancy that led to death, or 3) aggravation of an unrelated condition by the physiologic or pharmacologic effects of the pregnancy that subsequently caused death. A possible PRD is a PAD where determination of the death could not be conclusively classified as either related or not related to the pregnancy. PADs due to a cause deemed unrelated to pregnancy are classified as not pregnancy-related.

Quarterly, the PAMR case selection committee composed of PAMR committee members (an obstetrician, a nurse, PAMR data manager, and a PAMR coordinator) reviews ascertained pregnancy-associated cases by cause and time of death to categorize the cases as pregnancy-related, possibly pregnancy-related, or not pregnancy-related. The pregnancy-associated cases determined to be either pregnancy-related or possibly pregnancy-related are submitted for record abstraction and subsequent review by the full PAMR committee. Abstraction and review preference is given death cases categorized as pregnancy-related. If there are fewer than 15 PRDs in a given quarter to review, case abstraction and review of "possibly pregnancy-related" and "not pregnancy-related" cases may occur.

For additional details of the PAMR case ascertainment process, see the following: Burch D, Noell D, Hill WC, Delke I. <u>Pregnancy-associated mortality review: the Florida</u> <u>experience.</u> Semin Perinatol. 2012; 36: 31-6.

Appendix 3 – Florida Pregnancy Associated Mortality Review Members, 2015

PAMR committee Co-Chairs

- Shay Chapman, BSN, MBA Chief, Bureau of Family Health Services, Title V MCH Director, DOH
- Anthony Gregg, MD Professor & Chief, Division of Maternal-Fetal Medicine/Department of Obstetrics and Gynecology/University of Florida

PAMR Coordinator Rhonda Brown, RN, BSN - Program Administrator, Maternal & Child Health Section, DOH

PAMR Lead Abstractor Dani Noell, ARNP, NNP, BC, MSN - PAMR Facilitator & Abstractor, DOH

PAMR committee Review Members

Estrellita "Lo" Berry, MA, LTFP - President, REACHUP Inc.

Gene Burkett, M.D - Professor, University of Miami, Division of Maternal-Fetal Medicine, Department of Obstetrics and Gynecology

Anthony Clark, MD - Medical Examiner, KWB Pathology Associates; Medical Examiner's Commission

Mary Kaye Collins, CNM, MN, JD, FACNM - Assistant Professor, Nursing, Indian River State College; American College of Nurse-Midwives

Carol Cox, MD – University of Florida, Department of Obstetrics and Gynecology

Isaac Delke, MD - Professor and Medical Director, University of Florida, College of Medicine; ACOG

Christine Hackshaw, CNM, ARNP - American College of Nursing-Midwives

Karen Harris, MD, **MPH -** Chair, Florida District XII/ACOG (Since May 2015); President, North Florida Women's Physicians, PA

Leticia Hernandez, PhD, MS – MCH Epidemiologist, Maternal & Child Health Section, DOH

Washington Hill, MD - Emeritus

Ashlee Morgan, RN, BSN - Nursing Consultant, Maternal & Child Health Section, DOH

Jane Murphy, MPA - Executive Director, Healthy Start Coalition of Hillsborough County

William Sappenfield, MD, MPH - Professor & Chair, College of Public Health, Chair Lawton and Rhea Chiles Center/University of South Florida

Robert Yelverton, MD – Chair, Florida District XII/ACOG

ACOG = American Congress of Obstetricians and Gynecologists; DOH = Florida Department of Health

Appendix 4 Urgent Maternal Mortality Message to Providers

During Pregnancy or Postpartum: Women should go to the hospital if they cannot breathe or have severe shortness of breath because they could have Peripartum Cardiomyopathy (PPCM).

Urgent Maternal Mortality Message to Providers

Consider echocardiogram in pregnant or postplartum patients with persistent moderate or severe respiratory symptoms. Initial presentation of PPCM can be mistaken for upper respiratory illnesses. Pregnancy Associated Mortality Review (PAMR) findings.

Florida PAMR Findings:

1999-2012: 11.1% of pregnancy-related deaths in Florida were due to cardiomy opathy.¹

1999-2011:78% of pregnan cy-related deaths occurred during the postpartum period.²

From 2009-2013:

- The percent of pregnan cy-related deaths due to cardiomyopathy for non-Hispanic black women was 55% versus 25% for non-Hispanic white women.
- 80% of women who died from pregnancy-related cardiomyopathy were either overweight or obese (BMI > 25).3

Providers:

Peripartum cardiomyopathy is the development of heart failure in the last month of pregnancy or within 5 months postpartum in the absence of prior heart failure with no identifiable cause and echocardiogram indicative of left ventricular (LV) dysfunction.⁴

SIGNS/SYMPTOMS—ONSET CAN BE EASILY MISSED⁶

- Marked limitation of physical activity. Comfortable at rest. Less than ordinary activity causes fatigue, palpitation or dyspnea⁶
- Unable to carry on any physical activity with out discomfort, symptoms of heart failure at rest; if any physical activity is undertaken, discomfort increases⁶
- Arrhythmia/Cardiac Arrest

Wom en with PPCM most commonly have dyspnea, dizziness, chest pain, cough, neckvein distention, fatigue and peripheral edema⁵

PPCM CRITERIA

- Idiopathic(no other cause)heart failure characterized by left ventricular(LV)systolic dysfunction
- At the end of pregnancy or during the postpartum period (spectrum of timing)
- Diagnosis of exclusion
- Ejection fraction (EF) generally below 45%
- Left ventricular (LV) dilation not required

RISK FACTORS^{7,3}

Social: Advanced maternal age, smoking, malnutrition, African American race

Medical: Hypertension, Diabetes, family history, sleep apnea, obesity

Obstetric: Gravidity and parity, number of children, labor inducing medications, multiple gestation, family history

continued

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Urgent Maternal Mortality Message to Providers

DIAGNOSIS

- Early diagnosis is essential—watch for early signs and symptoms and a decline in function
- Echocardiogram, the primary diagnostic test, to identify left ventricular systolic dysfunction
- Differential Diagnosis: myocardial infarction, amniotic fluid embolism, severe preeclampsia, pericarditis, pulmonary thromboembolism, myocarditis, sepsis, drug toxicity, metabolic disorders, and aortic dissection®
- When a postpartum patient presents with a cough and shortness of breath a careful physical examination should follow. If hypoxemia is identified or risk factors raise suspicion an echocardiogram should be considered

PAMR Recommendations (2015):

Importance of identifying barriers for participation in treatment for non-compliant patients.

MANAGEMENT

Similar to standard treatment for other forms of heart failure

Avoid routine use of ACE-in hibitors or angiotensin receptor blockers (ARBS) during pregnancy

- Collaboration between cardiologists, obstetricians, perinatologists, neonatologists and anesthesiologists is . essential
- Consider transfer to high risk perinatal center and potential for early delivery

PAMR Recommendations (2015):

Important to provide preconception and interconception care for patients with co-morbidities.

DISCHARGE

- Ensure follow-up appointment in one week and consider more frequent follow-up care if history of cardiac symptoms.
- Patient and family should be counseled to return immediately to emergency room or L&D triage if showing any signs or symptoms
- Educate on the importance of long-acting reversible contraceptives (LARCs), interconception care and risks offuture pregnancies
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