How our community has attempted to characterize and address

opioid addiction in pregnancy: March 15, 2017

Recognition of a problem;

In March of 2013 a substance exposed neonatal task force was created. Stakeholders who were part of the SATF (Substance Abuse Task Force) but recognized the unique needs of the pregnant population convened. Early recognition of this pending epidemic is credited to Dixie Morgese of Healthy Start, and prenatal care providers at the VCHD, who began seeing an upturn in the numbers of pregnant women and mothers who were opioid addicted.

Move and expansion of Project WARM

At the same time, SMA Behavioral Services moved Project WARM from the 18 bed facility on Michigan Avenue in Daytona Beach, to the Vince Carter Sanctuary. Project WARM was created by the Volusia County Junior League in 1992, as a residential treatment center for pregnant women in recovery from substance abuse. The predominant substance at the time was cocaine. Women who had stopped using, but had no social support and were at risk of relapse, live on the campus and received therapy and life skills training. They either resided their voluntarily or were court ordered. The facility had resources for 18 women and their children under five. In 2013, WARM was moved to the Vince Carter Sanctuary in Bunnell, FL. The VCS was a rehabilitation center created by Vince Carter and Michelle Carter Scott. It provided state of the art facilities and therapy for adults with substance use disorders. A decision among state, local and private stake holders allowed the campus to be repurposed for WARM, using a combination of government funding, grants and private funds. Since then, Project Warm at the Vince Carter Sanctuary has been caring for women in recovery who are pregnant, mothers of young children or both. They have capacity for over 80 women and their children, with a substantial waiting list. Pregnant women who have recently stopped opioid use have highest priority

The women are provided extensive counseling, skill building, obstetrical and mental health care. Their infants are born drug free and they have better skills for being mothers and entering the work force. But success after graduation from WARM requires a greater focus on after care programs, involving other services organizations and the community at large. Success after graduation is not guaranteed and there is a significant relapse rate. Many women at WARM have been there with prior pregnancies, underscoring the need for more aftercare services. And WARM's model cannot accommodate those women who are being maintained on opioids during their pregnancy—a larger population, with more complicated social and medical circumstances. Currently, there does not exist any residential treatment programs for pregnant women who are being maintained on legal opioids-- methadone or buprenorphine. This is still the national standard of care and remains a much larger population of women, than those who have been weaned off the opioids and are eligible to reside at WARM.

Opioids are different from other drugs in pregnancy

Opioids are unique from other illicit substances used during pregnancy. For cocaine, methamphetamines and designer drugs, cessation of use is the best option for the developing fetus. However, the national medical standard of care for opioid dependence is to provide pregnant women with safe, legal and accessible opioids until after birth, and then have the mother and baby both wean together. This standard of care is based on several older and low powered studies, suggesting that

abrupt withdrawal from opioids caused fetal distress and poor outcomes. Especially in the third trimester, women who abruptly withdraw or lose their source of opioids were felt to be at high risk for preterm labor, placental abruption, preterm delivery and fetal death. But many recent studies have determined that monitored detoxification, followed by intensive rehabilitation is a safe option. It may be the only option when legal, affordable and accessible MAT is not available in the community, or when the woman refuses MAT. But detoxification requires intensive and ideally residential support to avoid relapse. This is the unique and valuable asset our community has with WARM. But again many women are not candidates or chose not to detox, and are on legal or illegal opioids to avoid withdrawal. This population also needs residential options to promote the optimal outcomes.

The scope of this problem has changed dramatically

Historically, the population of pregnant addicts in our nation was not large. The standard of care, which is not evidence based, but more a standard developed from lack of better options, was to transition women from "street" opioids or opiates—typically heroin—to legal and accessible methadone. It was believed that this was the safest risk reduction option for the mother, reducing high risk behaviors and allowing a more normal life. It was felt to have the greatest risk reduction for the fetus, avoiding the wide variation in exposure that occurs with repeated withdrawal episodes. Chronic maintenance in pregnancy results in a neonate with a variable degree of opioid addiction and who most often requires a time of opioid mediated withdrawal under NICU supervision. It was hoped that mom and infant would detox at the same time, and it was felt this was the best option for a small population of women.

But opioid addiction in young women of reproductive age has reached epidemic proportions throughout the country and our community is no different. Well intended state legislation to reduce the number of pill mills did reduce the number of new addicts. It did not address the issues of current addicts, and the population of women who are pregnant on opioids is not small. Local, state and national data indicate a large increase in the last five years. Our NICU data for 2015 showed a doubling of NAS cases and we average one to three infants with NAS at any time. In many areas, and most especially Volusia and Flagler Counties, there exists a misalignment between what is medical standard of care, state administrative policy, and legal options and what is realistic access to drug maintenance and prenatal care. The American Congress of ObGyn (ACOG) and the American Society of Addiction Medicine (ASAM) define standard of care in pregnant addicts to be maintenance of opioid use during pregnancy. But maintenance of treatment (MAT) is simply not possible for many women in our area. There are no opioids available legally, logistically or affordably for the many of addicted pregnant women in the 7th Judicial Circuit.

Florida does not guarantee free methadone for MAT in pregnant women

The State of Florida limits methadone distribution to specific clinics and prohibits individual physicians from prescribing for addiction maintenance. The only current source of methadone in East Volusia is the Daytona Methadone Treatment Center—a subsidiary of Colonial Management (DMTC). Historically the DMTC has operated independently of other stakeholders, communicating inconsistently with medical providers for addicted pregnant women. The DMTC requires that women dependent on methadone present daily to the clinic, with $17 dollars in cash for single 24 dosing. The DMTC is required to give counseling to methadone users, who line up around the building each morning. There are pregnant women, women with strollers and multiple children in this line daily. Recently, the latest medical director, Robert Walker, has been open to communicating about individual patients and has initiated

split dosing for a few patients. But the counselors at DMTC strongly encourage rapid escalation of dosing in pregnancy. Placental hormones accelerate opioid metabolism, but this clinic begins this rapid escalation of doses even in the first trimester (before significant placental metabolism exists) in essence, treating morning sickness with methadone.

This rapid escalation is intended to avoid maternal symptoms of withdrawal that are experienced later in the day. Symptoms of withdrawal or cravings increase the risk of using IV drugs and placing the fetus in harm's way. Dividing the dose throughout the day works better than increasing the amount of a single dose in the morning. Large single daily dosing results in women experiencing nodding and lethargy in the morning, and then experiencing withdrawal symptoms hours before the next morning dose. This is the worst case scenario for the fetus. But split dosing but would require women to take methadone off the DMTC premises. which is prohibited except for a few long term clients.

In order to reduce this cyclic withdrawal, the DMTC providers rapidly increase the single morning dose, in amounts that can exceed 180-200mg daily before 20 weeks. These doses are far beyond those prescribed for the non-pregnant addict. They are much harder for the woman to wean from after delivery and they often result in the somnolent state for several hours post dosing—not ideal for women who may have other children. The DMTC quotes literature stating the adverse effects for mom and baby are not dose dependent and plateau after the first 30mg dose. But these doses impair the ability of these women to function in the first few hours after dosing. And our clinical experience suggests the negative impact on our infants can be very dose dependent. What is clear is that the adverse effects, including Neonatal Abstinence Syndrome are widely variable and impacted by the infants' genetics and concurrent exposure to nicotine and other substances. The number of NAS babies is exploding in the nation's NICUs. Their short and long term costs to society are not yet obvious or measurable.

Another logistical issue is that the DMTC is not accessible for many women in our counties without transportation. They are open from 5 am to 11am. The timing is not good for getting children to school, daycare or keeping jobs. The DMTC does not accept Medicaid or private insurance. It is cash only. The $17 daily cost results in huge resources being diverted from the family. There is no other source of Methadone in East Volusia or Flagler County. Clinics exist north and west that will accept insurance. There is River Region in St. Augustine that does take Medicaid. Some women have Medicaid that will transport them daily to Seminole county, where the methadone clinic does accept Medicaid. But far too many pregnant women who cannot afford or reach a methadone clinic resort to heroin or dilaudid on the street.

Buprenorphine is currently not the answer in our community

A newer, likely safer alternative to methadone is buprenorphine. It is being used throughout the nation as an alternative for opioid maintenance in pregnancy. Early research suggests that it is well tolerated and accepted by pregnant women, with less euphoria and less chance of respiratory depression or other maternal side effects. It may result in a less difficult withdrawal for the neonates. Prescribing physicians must complete a course to prescribe and initially must limit the number of patients to 30 in a year. Buprenorphine is expensive, and not consistently covered by Medicaid. Physicians in our community who currently prescribe buprenorphine typically charge on average $100-$250 per month, presumably to assess and counsel the patient before giving them a monthly script.

Many buprenorphine prescribers will not prescribe in pregnancy for liability reasons. There are not established protocols on how to transition pregnant addicts from street opioids or methadone and there is a time of required abstinence during transition to buprenorphine during which fetal surveillance is ideal. Working with buprenorphine certified physicians in our counties has been difficult and requires frequent communication among providers, which does not easily occur. I become certified to provide buprenorphine in May of 2016. In the first week of my certification, I performed an induction to subutex for five patients of the 30 allowed per year. I currently have about 25 patients.

Dr. Jessika Gil Pineada is the physician providing medical services at Tomoka Correctional. To avoid having incarcerated pregnant women travel daily to the DMTC and have Prison Health Services charged $17 dollars daily per person, she has become certified to prescribe buprenorphine. This has the added benefit of keeping prescribing control among the medical team caring for the women. These women are brought to my office for prenatal care while incarcerated, and if they are released prior to delivery, I can continue their buprenorphine for continuity. The relationship between Dr. G-P, the correctional officers and myself allows optimization of care for this sub population of opioid dependent women.

Many pregnant women in the jail are in the Drug Court system. Any pregnant woman who is incarcerated will be placed on buprenorphine by the Armor prison health system. If the woman requests, she can be cleared medically by me for detoxification from her Subutex, If this request is accepted by her lawyer and granted by her Judge, she can be weaned or detoxed at SMA Pine Grove and then can enter Project WARM. Protocols at the jail specifically prohibit lowering the dose at the jail. Once released from the jail, the woman can continue prenatal care with me and I can provide buprenorphine if needed. I cannot provide methadone, and it is not appropriate to switch from methadone to Subutex during pregnancy.

Prenatal Care providers have no legal/affordable/accessible options for opioid dependent women

Many patients do not disclose their use to their doctors, or do not seek prenatal care at all. If their physicians learn of their drug addiction, many will dismiss the patient from their obstetrical care, due to the intensity of care needed, lack or reimbursement and liability. These patients need many more prenatal visits than the 8-12 historically covered by Medicaid, so the care of these patients goes largely uncompensated for the providers. Since these pregnant ladies need additional surveillance to watch for growth restriction, fetal compromise and need for early intervention, their prenatal care becomes an unacceptable economic burden for the private physician and health department alike. This attempt to maintain women on a safe and consistent amount of opioid has too many flaws when the patients remain in their social environments of use and abuse, and put both the patient and physician at risk only slightly less than continuing to purchase pills in the street. Some admit to buying the pills with sex, increasing their risk of infection with HIV or hepatitis. Sadly, IV heroin and dilaudid have become the cheaper alternatives and are used increasingly often.

Lack of prenatal care increases visits to hospitals and increases the adverse outcomes

With no or inconsistent prenatal care, these women come to the hospitals at term, or in preterm labor. They are then screened for opioid use on admission and DCF becomes involved. The babies are often in the NICU for weeks to months and then may not be reunited with the mothers, based on DCF evaluation. Our foster homes are overwhelmed with these difficult infants. Even when the mother is considered safe to take the baby home, bonding is compromised by the time spent in NICU, especially if

the mother cannot or chooses not to be there as often as possible. But worse than an extended NICU stay is that some babies may go home before signs of NAS appear, leaving an unsuspecting mother with little coping skills to deal with vomiting, uncontrollable crying, hyperactivity, inconsolability and seizures—placing the infant at risk for abuse.

The Marchman Act and how women can be court ordered to be "Detoxed"

The Marchman Act, allows family or other stakeholders to petition to the court for addiction treatment—most commonly in a residential setting. Currently there does not exist a facility with protocols or accreditation to perform medically assisted weaning (MAW) with fetal surveillance. Currently Halifax Health or Project WARM will receive moms from the 7th circuit, who are court ordered to detox. Some are sent first to Pine Grove (the SMA facility for detoxification from substances). Pine Grove does not have fetal monitoring capability and cannot assess or treat adverse fetal responses that can occur with abrupt detoxification or medication assisted withdrawal. Patients should receive medical clearance and counseling first, which is done on a case by case basis at Halifax Health or in my office. Halifax does not have a detoxification unit and cannot admit for this as a primary diagnosis. Pine Grove is a detox unit but cannot perform fetal surveillance. Our current option has been to offer Pine Grove services to pregnant women who are earlier than 22 weeks and who are on 40mg methadone daily or less. Women who are more than 22 weeks are offered this option on a case by case basis. There is risk detoxing women later in pregnancy, often with other medical issues, without fetal monitoring. Sadly, those women have on multiple occasions detoxed themselves at home, successfully or not and without prenatal care.

To reiterate, well intended parents and judges are enacting a Marchman Act for pregnant addicts who are greater than 22 weeks, presuming that detoxification is safe and available and once detox is performed, these women can be court ordered to Project WARM and undergo residential treatment for the duration of pregnancy and beyond. There does not exist a residential treatment center for women on MAT, so court ordered diversion from incarceration to residential treatment requires detoxification. But after 22 weeks, detoxification, if determined the appropriate risk reduction, would be ideal in a hospital environment with delivery capabilities. Halifax Health is not a certified detox center and cannot accept these patients and bill insurance for an admission diagnosis of opioid addiction and intent to provide MAW.

The cost to our community and state is unacceptable. Infants in the NICU require care that is costing thousands of dollars daily for many weeks. Infants unified to parents still addicted do not often receive stable childcare. The costs in terms of foster care, developmental delays, learning disabilities and lost potential are not calculable but they are vast.

Summary: A Community based solution is needed involving all stakeholders

WARM can only care for those women who have successfully gotten off their drugs and are willing or mandated to receive the intensive behavioral counseling that optimizes their health and maintenance of recovery. WARM has performed this task well and is to be commended. But they do not, as of yet provide prenatal care on the premises. With the closing of the VCHD prenatal care clinic, WARM has had to find hospital based or private physician practices that will see these patients. Florida Hospital Memorial created the Women Care clinic; Halifax Health created Care for Women. The FCHD still sees some of these women for prenatal care and some private obgyns do accept a small number of these

patients. These women, despite their lack of ongoing drug use remain high risk and should be delivered at a facility with a level II or III nursery.

Currently we do not have options for residential care of opioid addicted women who chose or are already maintained on opioids for the duration of their pregnancy. This is the majority of the addicted population at this time.

We do not have a formal detoxification program for women who desire to be weaned off their substances while pregnant. Many would choose this, as they want drug free newborns or cannot access their drugs consistently and the cost is ruining their families. Many would like to go into WARM, but cannot until they are drug free. Many are continuing to find their opioids on the street and currently the most common drug is dilaudid pills, which are crushed and either snorted or injected IV. Their habits cost them $30 to $150 or more, daily. They are developing heart, bone and brain infections. They are contracting HIV and Hep C. Their families are being destroyed.

The ACOG and ASAM guidelines of addiction maintenance during pregnancy are not realistic with these circumstances existing in the 7th circuit in Florida and in many communities nationwide. There exists a population of women on MAT who would benefit in a residential setting until well after delivery. There exsist others for whom MAW would deliver better outcomes for other mothers and infants if relapse could be minimized in a extended residential setting. Detoxification, if conducted in a hospital setting with continuous fetal surveillance by laborists and perinatologists could result in an abstinent pregnant woman with a fetus that tolerated this weaning. These women would then be sent to WARM at VCS for continued counseling and wrap around services—for the remainder of pregnancy and afterwards. The reduction of babies born with opioid addiction, requiring prolonged hospitalization could be reduced—with improved outcomes and decrease in cost.

Creation of additional programs to support these different populations of pregnant women require the support and agreement of all involved. Outpatient maternity care must be provided early and consistently. Hospital based services should be contracted with protocols created. At Halifax Health, the laborists, perinatologists, psychiatrists and neonatologists could create these protocols. Funding sources must be identified and secured. Liability issues for the physicians, hospital and WARM must be evaluated. And above all, metrics must be established and evaluated so that the program can be assessed for its success—medically, financially and socially.

Such a program needs the support of our medical community, our social services, law enforcement and county and state administrations. It should be presented to our State's Attorney as a potential solution for a dire problem that would improve outcome for the affected families and tax payers alike. We need to explore grant opportunities and lobby for this type of support at a state level.