Birth Spectrum Of Care

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Back in 1977, when disease management was the wave, we asked if pregnancy could be put into disease management. The first thing that happened was people said pregnancy was not a disease, so we stopped talking about it. But it is a continuum. And you have to have had champions for new ideas. Someone had to lead. Mission St. Joseph's Health System (MSJ) was among the first to take on the challenge of health management of pregnancy. In developing our program we used the following guidelines:

Components of a Health Management Program

- Select a disease state or health state
- Use data to look at the current situation: always measure the baseline
- Research the best practices so you don't reinvent the wheel
- Develop best practice protocols, clinical guidelines and pathways using a multidisciplinary group with representation from various community providers to create total community involvement instead of a program that is imposed upon others
- Analyze program data

Disease State and Data

We started by looking at our disease/health state (high-risk pregnancy) from the business case perspective of what it cost to care for the mothers and infants at our hospital. From 1995 to 1997 we saw preterm and low birthweight admissions rising across all payor categories. It was not restricted to Medicaid. The total costs in those three years rose from $7.4 million to $10.6 million to care for women and infants there for prematurity. The other economic case we identified was that we were losing $837,000 on Medicaid patients in the NICU. What could we do to decrease that loss so we could stay in business? We set off to develop a pregnancy health management program.

Research

We knew we needed to involve all practitioners because regardless of private or public practice, prematurity rates were no different. To get physician buy-in we identified evidence-based (peer-reviewed medical journal) studies. We focused on two in particular. A study of Lovelace Health System in Albuquerque, N.M. reported a 56% reduction in NICU admissions and a 49% reduction in preterm deliveries admitted to the NICU. Locally, Wake Forest University Baptist Medical Center demonstrated a statistically significant reduction in prematurity from 15.4% to 8.7% among low-income African American women.

Best Practice Protocols and Guidelines

We devised a program with four components: 1) case management, 2) home visits, 3) telephone management, and 4) education. As soon as we mentioned one of these areas, someone would say "don't you dare invade (mess with) my program." But that controversy got them to the table and we began to build a multidisciplinary community project. Thirty-eight individuals met over six months, 18 regional organizations divided up into those four subcommittees. It cost about $250,000 to put this program together in the first year writing protocols, conducting surveys, etc. But nobody has to spend that kind of money again

This is a program that has been able to remove some of the disparity in prematurity. And we've been able to make a business case to take to employers.

because others can learn from our experience. Ours was one of the first pregnancy health management programs.

Pilot Project

In addition to clinical protocols, we also ran a pilot project that had case managers call their patients between visits. We compared a group who received calls (contacted more than three times and participated in the program) with a group with fewer calls and who did not participate. We could show there was a positive effect with participation.

MSJ's Program Components

We then incorporated the strategies with solid evidence in the research review and data analysis into our program. The program components include:

- Risk assessment
- Patient education
- Telephone management—a triage program
- Home visits
- Outpatient assessment and care
- Triage in labor and delivery
- In-patient care
- Data collection and feedback

Risk Assessment

We analyzed 20,000 deliveries at MSJ in designing our risk assessment. Through it we identified three automatic criteria that would put a woman into the program: 1) prior preterm birth, 2) multiple gestation, or 3) symptoms of preterm labor with cervical change. Other screening criteria to qualify for the program included (two or more attributes needed):

- African American race
- Age under 17 years
- Prepregnancy weight less than 100 pounds
- Bleeding during current pregnancy
- Cigarette use
- Illicit drug use
- Gonorrhea, chlamydia, syphilis or HIV
- Stress level: score of 8-10

A risk assessment was done at the first prenatal visit with the provider. Every woman in Buncombe County was assessed. We had "champions" who went around to all the obstetrical offices and found a contact person who would ensure this risk assessment was done. We have two full-time equivalents who managed 400 patients a year with an average caseload of 40 to 50 at a time.

Based on the results of the individual assessment, women were referred to the Preterm Prevention Program (PPP) using the following process:

- Consent for program's health manager to contact woman was forward to PPP managers
- Woman then assigned to a PPP manager
- PPP manager contacted woman by phone to assess woman and provide education and support
- PPP manager facilitated home visit if client desired

Patient Education

We reviewed the core curriculum of our prenatal education classes. We made sure there was information about how to prevent and prepare for a premature delivery—the signs, symptoms and causes—and how to be part of the program.

Telephone Management

Calls were placed every other week prior to 20 weeks gestation and then weekly. We used existing research (from a Wake Forest University study) that demonstrated we would not get a better outcome by calling more often unless the woman wanted it. That saved a lot of time and money. We had guidelines for these calls to empower the client to become an active participant in her care, and to help with referrals to community resources such as transportation. While the community offered many services, they first had to be organized in a logical sequence as to which one to access.

Follow-up reports were sent to providers at 20, 28 and 34 weeks of gestation. If there was an intervention for emergency reasons, we had a protocol in place to fax information to as many as six different sites so there was an ongoing file for everyone in the program.

When a woman in the program called the Preterm Prevention Program, a special indicator flashed on the screen to inform the nurse that the caller was part of the program. This automatically directed the nurse to discuss specific protocols for prematurity prevention no matter why the woman was calling.

Home Visits

The first visit occurred between 12 and 16 weeks of the pregnancy, followed by a second visit between 26 and 30 weeks. The county health department funded some of the visits and a grant was obtained to reach private pay participants.

Outcomes

- Enrollment: In the first year 371 eligible women took the risk assessment and 334 enrolled. It is estimated that 800 women would have been eligible for the program.

- Birth Outcomes: We saw significant declines in preterm and low birthweight deliveries for program participants. Because these are high-risk pregnancies, we expected women to deliver prematurely 33% to 50% of the time. Excluding medical inductions:
  - 11% of those who completed the program had a low birthweight baby (8% if also excluding multiple births)
  - 37% of those who did not complete the program had a low birthweight baby (25% if also excluding multiple births)

- Racial Parity: From 1995-1997, African American women had double the low birthweight rates of white women. Starting in 1999, we saw a change.
  - African American women who participated in the program had a reduced rate of prematurity compared to whites every year. The numbers are still high however because these are high-risk pregnancies.
  - Prematurity rates in Buncombe and Madison Counties dropped from 9.7% to 7.1% which is the Healthy People 2000 goal. We have been able to sustain 7% to 8%. We have been frustrated that we have not been able to get it down lower.

- Preterm Admissions: Instead of continuing to increase as in 1996-1997 the number of hospital admissions for premature labor was reduced by nearly 20% (from ~50% to 40%).

- NICU Beds: When we started this program our NICU had 35 beds with a 55-bed NICU under development. We argued that this was wrong and the hospital should put money into prevention instead; ultimately this was reduced to 51 beds. But that was still a significant savings in the facility when one stops to think about how much each NICU bay costs.

- Gestation: In the first year we had no babies born below 28 weeks gestation for the women in the program.

- Length of Stay: We reduced length of stay in the NICU by two days per baby due to their increased gestation. While we did not reach our goal of getting our prematurity rate down to 7% for everyone on a consistent basis, we increased the gestational weight and age for those babies born in western North Carolina. In turn, this lowered the number of NICU Medicaid babies which helped us reduce some of our financial loss.

The Next Step

We then talked to MSJ to convince them that the Preterm Prevention Program would be good for our employees. We requested MSJ provide a $25 incentive per woman to join the program. We also proposed a plan to compare those who accessed the program and those who did not. (We recognized the employee group may differ from the other participants in the Preterm Prevention Program because they all were employed and may have had different lifestyles.) This is the outcome:

- Direct Cost for Hospital Care of Infant:

Participants	$530
Non-participants	$1,293
Savings	$763

Do the arithmetic: Invest $25 in an employee and save $763 in direct costs per infant care.

- Employer Health Costs:
  We also decreased the charge to MSJ's health care plan (we pay 80% of charges) by $2,112 per case.

Hospital care savings	$763
Employer healthcare savings	+ $2,112
Incentive (now $100)	- $25
Total savings per participant	**$2,850**

We are taking this information to other self-insured employers now. While some may argue that the $763 can't be deducted because it is the cost of health care, we can show the difference in charges between those who participate and those who don't. This program has removed some of the disparity in prematurity. And we had a business case to take to employers.

What was the secret ingredient? There is no one answer. Prematurity is multifactorial. But we did give participants knowledge. Knowledge of causes, signs and symptoms,

and community resources. We also gave them access to those resources and transportation to those resources. Then we made sure they used them.

What If ... ?

The success of the MSJ program raises some interesting questions: In the future should we make these kinds of programs mandatory instead of voluntary? How do we encourage private obstetrical practices to manage at-risk women? Should we manage all pregnancies rather than just the at-risk ones? (That's another way to get at the other half of women who will deliver prematurely but are not identified in programs.) Then there is the challenge of how to finance all of this.

Finally, perhaps we should do what the French did in addressing stress in the labor force. They decreased their prematurity rate from 8% to 4% by just making sure that no pregnant woman had to work in the last three months of pregnancy.

The TeleHomecare Program

Julius Q. Mallette, MD, FACOG
Senior Associate Dean, The Brody School of Medicine, Eastern Carolina University

The TeleHomecare Program provides care, monitoring and education to patients in their place of residence using telecommunications technologies. The Eastern Carolina University Health System had a TeleHomecare program that was first used in 1977. In 1998, we moved forward to use it for pregnancy.

We used what may now be considered low tech—a telephone line—and a device that would give us information about a patient through the phone line. It created a tremendous partnership between the local home health system and tertiary care system.

Those who know Eastern North Carolina understand the hurdles we faced. The participants were apt to have little understanding about the importance of regular health care—and were just as likely to be caught in a challenging economic system. We had patients who lived 60 miles from healthcare services and with limited resources to obtain care. That's where gentle touch and ability to reach people can make a big difference.

We thought one way to help women at high risk for preterm delivery maintain their pregnancies and self-esteem was to consider a project that would allow a woman to stay at home with her support systems. For this pilot project, we focused specifically on pregnancy-induced hypertension. Stress plays a major factor in pregnancy and if we can keep a person at home, that reduces stress.

Preeclampsia is a condition where hypertension, proteinuria and edema are present. It can be a deadly and it is the number one cause of maternal mortality. It is the number two cause of prematurity in our area. What is interesting about preeclampsia is that it can be diagnosed very easily. However, its management is often very complicated. It is hard to determine when a mild case will become severe and lead to the deadly consequences. We take preeclampsia very seriously—to make certain that the patients we were monitoring did not become severely ill and require a prolonged hospitalization or deliver prematurely. Almost 12% to 22% of the pregnancies we see in our area are affected by some type of hypertensive disorder.

Our pregnancy TeleHomecare program involved the University Home Care, Pitt County Memorial Hospital and East Carolina University School of Medicine, Department of Obstetrics. We had to convince a lot of people in the medical community that we wanted to keep these high-risk women at home. We went through the University's Internal Review Board protocol which provided protection for the patient. As a result, all of the providers participated, and we didn't even have to fund an administrative position to do it. Everyone was happy to be on board.

Program Components

Personal contact was one of the most significant factors. Participants had two home visits and two TeleHomecare visits per week. There also could be one clinic visit per week. A lot happened at those skilled nursing home visits ... it's amazing what nurses can do. They assessed vital signs, headaches, vision changes, reflexes/clonus, epigastric pain, heart rate/rhythm, respirations, uterine activity, fetal activity, renal function, edema, weight, emotional status, compliance and even home safety. We recognized that there were

Yes we saved money with this project, but most important we saved lives and that's where it really counts. We helped women be with their families at home, getting the best of care.

differences in the amenities providers might have in the hospital versus the home but we found options. For example, the patient put her eye up to a telemonitor—a small camera—to assess periorbital edema. At the visits the nurses were also able to get 24-hour urine to determine protein clearance. They also did other interventions such as non-stress test, patient education, urine dipstick, weight and fetal kick counts. We found we could do fetal monitoring, no matter how far away the patient was. In fact we did a spin-off pregnancy TeleMedicine project with babies at a military site in Hawaii. This shows that one can use this technology no matter how far away.

Initial Program Concerns

- Continuity of care between the home, clinic and hospital
- Satisfaction among the doctors and nurse
- Providing the same care as in the hospital

Results

Yes, we saved money with this project, but most important we saved lives and that's what really counts. We helped families be with their families, while at home, getting the best of care.

Participant Profile

- Average maternal age = 26.6 years
- Average gestational age at enrollment = 32.2 weeks
- Average number of clinic visits = 2.9
- Average number of home visits = 5.7
- Average number of TeleHomecare visits = 4.4 visits
- Average number emergency department visits = 0
- Average number hospital admissions = 0.3

Savings

- We averted 187 hospital days (for 10 patients)
- The charges per hospital day would have been $587
- Total charges for 187 hospital days would have been $109,769
- Total charges for program participants = $9,200
- Total savings to system = $100,569 (for 10 patients)

While all that is good, the most important outcome is what happened with the patients.

Patient Outcomes

- Identified 1 unsafe living situation that would have been missed
- NICU admissions = 1 of 11 babies
- Average gestational age at delivery = 36 weeks
- Average patient satisfaction = 3.6 on a 4.0 scale
- All 10 program participants said they would recommend the program to their friends and family

Patient Quote: *I felt that my only attribute (sic) was being put in the hospital, so I was really glad that they offered me something besides that. I wouldn't have been able to go to the hospital because I have a son ... My life didn't stop just because I got sick. And, I still needed to be somewhere where I could still do my daily functions as mother and as a wife, I need to be there (home).*

Clearing The Air

Smoking, Preterm Birth and Low Birthweight

Cathy L. Melvin, PhD, MPH
Director, Smokefree Families National Dissemination Office;
Senior Research Fellow, Cecil G. Sheps Center for Health Services Research

Smoking is the most modifiable risk factor for poor birth outcomes. Successful treatment of tobacco dependence can achieve:

- 20% reduction in low birthweight babies
- 17% decrease in preterm births
- Average increase in birthweight of 28 grams per individual

Smoking Risks in Pregnancy

- Ectopic pregnancy
- Intrauterine growth retardation
- Placenta previa
- Abruptio placentae
- Premature rupture of membrane
- Spontaneous abortion
- Preterm delivery (< 37 weeks gestation) and very preterm (< than 32 weeks gestation)
  Two-thirds of all preterm births occur spontaneously—tobacco contributes directly

Smoking Risks and Prematurity

Intervention trials have shown that among pregnant women who quit smoking during the trial, the risk of preterm birth can be reduced by as much as 17%. Smoking is more strongly associated with spontaneous preterm delivery than with induced preterm delivery. The relative risk of smoking during pregnancy (the risk of smokers compared to non-smokers) on preterm birth ranges from 1.2 to 1.6.

Smoking:

- Increases risk of preterm labor
  - Increases risk of intrauterine infection
  - Increases production of prostaglandins in the fetal membranes
- Increases risk of Preterm Premature Rupture of Membranes (PROM), the second leading cause of spontaneous preterm birth
  - Reducing elastic properties of fetal membranes due to decreases in serum copper and ascorbic acid levels
  - Increasing risk of intrauterine infection

Smoking and Low Birthweight

The relationship between smoking and low birthweight is one of the most consistent findings in the epidemiologic literature. More than 30 studies have been published in the past 35 years.

The relative risk of smoking during pregnancy and low birthweight (the risk of smokers compared to the risk of non-smokers) on low birthweight ranges from 1.4 to 2.6. Smoking

We can say with certainty that smoking intervention with pregnant women makes a difference.

accounts for as much as 20% of all low birthweight births and 45% of such births are among women who smoke during pregnancy. This is significant. Intervention trials have shown that among women who quit smoking during the trial, the risk of low birthweight can be reduced by as much as 20% and mean birthweight can be increased by 28 grams.

The association between low birthweight and maternal smoking is independent of: maternal age, alcohol and drug use, education, employment, parity, prenatal care, socioeconomic status and weight. This means that smoking increases the likelihood of having a low birthweight birth even when taking into account these other variables.

One of the more interesting recent discoveries about birthweight is the relation between birthweight and smoking. We knew for a long time that there was a dose-response relationship between the number of cigarettes smoked and the decline of birthweight. That holds true. But we had assumed this relationship to be linear: that as the number of cigarettes smoked went up, so would the likelihood of birthweight being lower. What we have seen in some recent studies is that reducing the number of cigarettes smoked does not result in increases in birthweight unless pregnant women smoke five or fewer cigarettes per day. While pregnant smokers may significantly reduce their smoking levels, unless they reduce their smoking to five cigarettes per day or fewer, we are not likely to see improvement in birthweight. That is why it is so important for pregnant women to quit smoking.

Implications to Healthcare Costs in the U.S.

- The cost effectiveness of smoking cessation intervention is very high compared to mammography and treatment of high cholesterol. Not only are the savings higher with smoking cessation but the program costs are lower
- The cost of complicated births (hemorrhage from placenta previa, maternal infections, fetal distress, malposition of the fetus) is $10,894 for smokers versus $6,544 for non-smokers
- Between 354,000 and 1.2 million episodes of otis media in children every year is due to smoking
- 13 million physician visits for coughs by infants is due to smoke exposure
- 1 million children suffer more severe and frequent asthma attacks as a result of being exposed to secondhand smoke
- Exposure to secondhand smoke can create major health problems for mother and child
- Fire from cigarette smoking causes death and injury

Bringing The Issues Home

A woman is more likely to quit smoking during pregnancy than at any other time in her life because she is very motivated to have a healthy baby (10% to 40% of women will quit on their own as soon as know they are pregnant or if they are trying to become pregnant).

Intervening with pregnant women makes a difference. Intervention works best for moderate (less than 20 cigarettes/day) smokers. Smoking cessation intervention by trained clinicians improves quit rates.

Brief counseling (5 to 15 minutes total) is all that is needed to help many pregnant smokers quit and improve cessation rates by 30% to 70%.

Oral Health And Pregnancy

Relationship of periodontal disease and preterm/low birthweight

Rosemary McKaig, MPH, PhD
Assistant Professor, UNC School of Dentistry

On the known list of risk factors for prematurity and low birthweight, there is a relatively new one to consider: infection of oral origin (mouth). We know that in the presence of bacteria our bodies try to fight infection and the resultant enzymes are inflammatory mediators (cytokines). An overabundance of cytokines causes destruction of periodontal tissue and development of more destructive disease which may cause gums to bleed during brushing, flossing or eating. That bleeding can start the infection/infection-fighting cycle over again.

In 1988 the *New England Journal of Medicine* published an article that stated "Bacterial-induced activation of cell-mediated immune response leading to cytokine production may trigger preterm labor." More recently, the first-ever *Oral Health in America: A Report of the Surgeons General* (Department of Health and Human Services, 2000) made it very clear that the mouth serves as a portal for infection. Included among the major findings is that oral diseases and conditions are associated with many health problems: diabetes, heart disease, respiratory infections, osteoporosis, HIV infection and ... adverse pregnancy outcomes.

UNC Research

The University of North Carolina, Chapel Hill, is now home to Dr. Steven Offenbacher's preterm periodontal research. Earlier in his dental career in Atlanta he had referrals from young pregnant women with severe periodontal disease, unusual in child-bearing years. He noticed at their three-month follow-up visits that many of these women had delivered a preterm low birthweight baby. Curious about what was going on, Offenbacher developed a case-control pilot study to determine if women who deliver a preterm low birthweight baby have more severe periodontitis than women who have normal deliveries. Sixty-two women who had delivered premature low birthweight babies and 62 who had not were given dental exams. Their medical charts were also reviewed for other risk factors (e.g., alcohol use and parity) but none of the women were interviewed so other risk factors may have been missed. The results showed an odds ratio (an estimate of probability, not causality) of seven, meaning that women who delivered preterm, low birthweight had seven times the risk of having severe periodontal disease than women who didn't deliver a preterm, low birthweight baby.

Based on this study:

- 18% of all low birthweight births may be attributable to periodontal disease
- In the United States that could be the equivalent of 45,000 births and $1 billion in neonatal intensive care unit costs each year

Oral Conditions and Pregnancy Cohort Study

Next, Dr. Offenbacher was funded by the National Institutes of Health to do a cohort study at Duke University. In the Oral Conditions and Pregnancy Study, women were enrolled, given an oral exam around their 20th week of pregnancy and then followed up after delivery. The women also were interviewed to collect information about possible risk factors.

Women who deliver preterm are seven times more likely to have periodontal disease.

Some of the questions the study addressed included:

- What was the periodontal disease status at early pregnancy?
- To what extent was there change at delivery?
- What was the pregnancy outcome?
- Were those who had more severe periodontal disease more likely to have an adverse outcome?

Participants

- Screened = 5,775 women at Duke clinics
- Eligible = 1,655 at first Ob visit (exclusions included HIV, drug abuse, diabetes, hypertension, STD (delivery not planned at Duke was later added to criteria)
- Consented = 1,102
- Completed initial oral exam and known birth outcome = 1,020
- Had post-partum exam = 891

The majority of women enrolled (58%) had mild periodontal disease. A smaller number (27%) had a healthy mouth. The balance (15%) had moderate-severe disease. Progression of periodontal disease occurred in about one-fourth (26%) of the women. Some of the women who did not have disease at baseline did at delivery. Some who had disease at baseline got worse; some who had disease at baseline stayed the same.

Study Conclusions

- Women with moderate to severe periodontal disease at their first prenatal visit were two times more likely to deliver a baby earlier than 37 weeks than women with normal periodontal health (95% CI = 1.1, 3.6)
- When periodontitis progressed significantly during pregnancy, women were four times more likely to deliver earlier than 30 weeks (95% CI = 1.3, 9.7)

Clinical Implications

- Moderate-severe periodontal disease before delivery appears to increase the risk for prematurity and low birthweight
- The magnitude of periodontal disease is significant with odds ratios of 2-to-10 depending on baseline status and worsening of condition during pregnancy
- Associations may not be causal in nature, yet prevention would appear to be a prudent clinical management strategy
- Having teeth cleaned before and during pregnancy would be prudent

Follow-up note : At the time of this presentation, the study had moved into a randomized clinic trial (at Wake Medical Center in Raleigh). The study question is: If the source of oral infection (periodontitis) is removed, will the risk of a preterm low birthweight event decrease?: A large trial was expected to begin in the fall 2003 at Duke University, the University of Alabama and University of San Antonio in Texas.

Oral Care During Pregnancy

Dental care is both recommended and safe during pregnancy. Studies have indicated that pregnancy-related changes are most frequently seen as inflammation in gingival tissue. With good oral hygiene, pregnancy gingivitis will likely resolve within a few months of delivery (however periodontitis is not reversible but is preventable and treatable).

Here are some guidelines for pregnant women:

- See the dentist during the second trimester when morning sickness typically has subsided and you are still comfortable sitting in the dental chair
- Only have radiographs (X-rays) under a lead apron
- Postpone major dental work (crown or bridge) but get fillings done
- Eliminate Strep Mutant bacteria which cause dental caries; the bacteria can be passed on to the baby after delivery by either parent
- Avoid taking tetracycline during pregnancy to prevent staining of baby's teeth

At the Community Level

- Promote referrals: ask pregnant women when they had their teeth cleaned last
- Provide access: if they don't have a dentist, help them identify where they can get dental care, especially if they are on Medicaid
- Address cost: even when there is dental insurance, cost can be a big barrier; help them become empowered to ask for discounts and payment plans
- Reduce fear: help women be better educated about the need for good oral care and what happens at a dental visit