Managing High-Risk Obstetric Cases and Analyzing Neonatal Outcome: The KP Northern California Regional Perinatal Service Center

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Located in Santa Clara, California, the Kaiser Permanente (KP) Northern California Regional Perinatal Service Center provides obstetric care to high-risk women throughout Northern California. Services designed to prevent preterm birth began in 1991, and the center has expanded to include home hypertension management, home diabetes management, hyperemesis support, and home nonstress testing programs. The goals of the center are to provide clinical services, to coordinate and maximize resources via telecommunications, to emphasize patient education, to empower patients in self-assessment and lifestyle change, and to support clinicians in the delivery of care. The center also conducts perinatal outcome studies and clinical trials.

Donald Dyson, MD, a maternal-fetal medicine specialist who was then at KP Santa Clara, identified a causal connection between preterm birth and perinatal mortality and morbidity in our Health Plan members. From 1986 through 1989, Dr Dyson conducted a study[1] that evaluated care of patients at risk for preterm labor or delivery. Results of the study suggested that patient outcomes were improved through use of an organized education and prevention program and, for twins, through use of home uterine activity monitoring. However, the efficacy of management schemes and technology in the care of mothers at risk for preterm labor remained surrounded by controversy.[2-4] Consistent risk criteria and a Health Plan policy for benefit coverage were not defined at the regional level at KP, so the care of patients at risk for preterm labor varied by medical center. In response to these issues, Dr Dyson submitted a proposal to the TPMG Associate Executive Director and to the Perinatal Council to establish a regional program that would provide this intervention for Health Plan members at risk for preterm delivery. Dr Dyson then created the Regional Perinatal Service Center in 1991 to support the preterm birth prevention program and to meet the following objectives:

- Develop a system for identifying pregnant women at risk for preterm labor;
- Develop patient and clinician education tools and guidelines; and
- Create a perinatal database to analyze utilization and effectiveness of interventions designed to decrease preterm delivery.

These three components support KP's commitment to disease prevention and self-care promotion, continuity of care, identification of at-risk populations, and analysis of outcomes.

The center began with a census of 20 patients at risk for preterm delivery. Along with Karen Danbe, RN; Jenny Ching, RN; Judy Bamber, RN; and others, Dr Dyson conducted a new study to determine the best preventive care for women at risk for preterm delivery. The study, approved by the KP Northern California (KPNC) Institutional Review Board (IRB), began in May 1992 and was completed in August 1996. This randomized clinical trial compared delivery outcome for three methods of management. Shortly after the study was initiated, a risk assessment tool was developed in collaboration with other KP Regions and was implemented in the KPNC Region to track incidence of risk factors for preterm delivery in the Northern California KP member population. In addition, guidelines for managing high-risk patients were distributed to every provider of obstetric care.

As a result of our research conclusions and validation of our risk assessment tool, the KPNC Perinatologists

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Peer Group provided prevention recommendations for regional management of at-risk perinatal patients. These recommendations included risk screening of the perinatal population and education about preventive self-care techniques.

This research was presented at the 1997 meeting of the Society of Perinatal Obstetricians and was given the award for Best Outcome Study. The study showed no difference in outcome (preterm delivery) between daily nursing contact (with or without home monitoring of uterine activity) and weekly nursing contact. This study was published in the *New England Journal of Medicine* in January 1998.[5]

In 1998, Dr Dyson; Karen Danbe, RN; Jenny Ching, RN; Judy Bamber, RN; and the Perinatal Service Center staff received KP's prestigious James A Vohs Award for providing high-quality care. The award citation stated that the Preterm Birth Prevention Program serves as a model for other areas of medical practice by combining patient education and teams of health care professionals with a strong focus on preventive care.

The Preterm Birth Prevention Program primarily addressed two quality issues: 1) use of a Regionwide screening tool with a screening rate of 88% to 90% and 2) ongoing outcome research and education.

Table 1. Kaiser Permanente Northern California Regional Perinatal Service Center Core Program members

Program member	Kaiser Permanente facility
Donald Dyson, MD	Santa Clara Medical Center
Colleen Hendershott, MD	Sacramento Medical Center
Darrell Edwards, MD	Hayward Medical Center
Larry Newman, MD	Oakland Medical Center
Alexander Mentakis, MD	South Sacramento Medical Center
Rosa Won, MD	Hayward Medical Center
David Walton, MD	Oakland Medical Center
Hamid Safari, MD	Fresno Medical Center
Paul Meyer, MD	Santa Clara Medical Center
Robin Field, MD	San Francisco Medical Center
Jeffrey Maier, MD	Walnut Creek Medical Center
Thomas Downs, MD	Vallejo Medical Center
Anne Regenstein, MD	San Francisco Medical Center
Jeffrey Traynor, MD	Walnut Creek Medical Center

To track important perinatal data, we implemented a perinatal operational and research database in 1991. The database supports care as well as ad hoc queries and standard reports that generate outcome data for providers of obstetric care. Reports are created to match service data to mainframe data. Standard reports describe preterm delivery at various gestational ages, by risk factor, by facility of screening, and by facility of delivery.

Patients are educated about the warning signs and symptoms of preterm labor and are instructed to perform twice-daily self-assessment for contractions.

Because 66% of our preterm deliveries before 35 weeks were in women who had no identifiable risk for preterm delivery, we developed an educational pamphlet for low-risk patients. (The pamphlet is now included in the *Healthy Beginnings Newsletter* #4.) We then studied the reliability of tests that might be more helpful or that might be useful as additional predictors for preterm labor or delivery.

The fetal fibronectin (FFN) study began in 1998 and evaluated use of the FFN test as a predictor of preterm delivery in symptomatic women. Presence of FFN in cervical-vaginal secretions is thought to be a marker for inflammation and preterm birth.[6-8] However, FFN had not been studied in a population with demographic characteristics similar to the KPNC member population. Moreover, a testing method was needed to provide test results rapidly as opposed to the 24-hour turnaround time for the ELISA test. Our study showed that a test result positive for FFN was associated with increased risk for delivery within 7 days, delivery within 14 days, and delivery before 35 weeks, particularly in patients presenting before 32 weeks. Most important, only 1% of symptomatic women with a negative FFN test result delivered within 7 days. On the basis of our study results, the FFN test was implemented in the KP Northern California Region in March 2001 with specific guidelines and protocol for its use. In 2002, after the FFN assay was implemented, a prospective cohort study compared patients who had threatened preterm labor during 2000 (before implementation of the FFN assay) and 2001 (after systemwide implementation of the FFN assay). This study found that admission rates decreased from 88% (in 2000) to 47% (in 2001) and that tocolysis use decreased from 41% (in 2000) to 27% (in 2001). On the basis of admission rates, cost analysis showed that routine use of the FFN assay could lead KP to realize savings of $1 million annually without increase in rates of preterm delivery. The center continues to collect FFN data and delivery outcome and provides data to the KPNC Regional Perinatologists Peer Group on a yearly basis.

Currently, every pregnant patient seen in a KP obstetrics/gynecology clinic in Northern California is screened with the Risk Assessment for Preterm Labor form. After the risk is identified and validated, the at-risk patient is enrolled for service. Patients are educated about the warning signs and symptoms of preterm labor and are instructed to

perform twice-daily self-assessment for contractions. Service commences ideally at 24 weeks' gestation and concludes at 36 weeks' gestation. In the KPNC Region, the preterm delivery rate is 3.1% for pregnancies shorter than 35 weeks and is 7.8% for pregnancies shorter than 37 weeks—a rate well below the statewide California rate of 10.2% and the nationwide rate of 12.1%.

In 1994, we added the Home Hypertension Program to our service line. This program assists pregnant hypertensive women who would otherwise require hospitalization or frequent outpatient visits. A two-tier surveillance service is provided. Level 1 is a high-acuity service that provides intensive surveillance for third-trimester patients with preeclampsia or who are at clinically significant risk for preeclampsia. Patients perform blood pressure monitoring two times per day, check urine protein every morning, and check for signs and symptoms of preeclampsia. These patients are contacted daily by the center. Level 2 is a lower-acuity service for patients whose chronic hypertension remains stable throughout the pregnancy. These patients are contacted weekly to report their high and low systolic and diastolic pressures. Patients can switch from intensive surveillance at or after 28 weeks' gestation (ie, they may receive daily contact calls) if medically needed. TPMG physicians support the program because it has allowed at-home case management for more patients and has decreased the number of clinic visits required to monitor for preeclampsia.

In 1995, the Home Nonstress Testing Program was begun to assist specific high-risk patients who require antepartum fetal heart rate monitoring. This service is offered in lieu of frequent medical office visits or hospitalization. Patients are instructed to perform nonstress tests (NST) at home and then transmit the tracing for interpretation by the registered nurse at the center. Among the 88 patients enrolled in the program from 1996 through 2003, more than 1500 antepartum hospital days were saved without adverse neonatal outcome.

In 1996, the Home Diabetes Management Program began for patients with Type I, Type II, and gestational diabetes. After patients in this program receive their initial education at their local clinic, the center provides ongoing education and support regarding dietary choices, meal planning, and exercise. The center's registered dietitian assists patients with additional nutritional consultation and tips regarding special dietary needs, such as vegetarian meal planning or ethnic food exchanges. Nurses at the center reinforce lifestyle and daily exercise. Patients are contacted at least weekly by the nurse to review blood glucose levels. The center nurse can adjust patients' insulin in accordance with our insulin adjustment protocol. Service begins when the provider makes a referral, and service concludes at delivery. All patients with gestational diabetes mellitus also receive six-week postpartum follow-up testing of glucose levels and are advised of the results as well as the need for appropriate lifestyle changes and follow-up.

The center also developed a set of diabetes outcome reports that provides the rate of macrosomia and maternal and neonatal complications related to diabetes and pregnancy. Our preliminary data suggests that improved outcomes may result for babies of diabetic women who enroll in the service. The center will continue to participate with Gabriel Escobar, MD, at the Division of Research, to evaluate our data on diabetes outcomes.

Our newest service, the Hyperemesis Support program, is available for patients with electrolyte imbalance, weight loss, or who require intravenous hydration. Daily contact calls are made during the acute phase. The center nurse assesses 24-hour intake of fluids and solids, episodes of vomiting, urine color, medication times and dosages, daily weight, and possibly the need for intravenous hydration. Contact calls become less frequent when the patient's condition improves. Service is discontinued when the patient has stable weight or weight gain.

The center is open 7 days per week, 24 hours per day, and is staffed with registered nurses. The role of our nurses is as challenging as hospital nursing and requires nurses to use a variety of skills: listening, educating, counseling, triaging, and helping pregnant women to change their lifestyles during high-risk pregnancy. The nurses make every effort to make each patient's experience safer and less stressful. The nurses often provide complex teaching and education over the telephone: for example, programming an infusion device or setting up the NST equipment at home. Making critical nursing diagnoses can be quite challenging using only the telephone, telecommunication translation services, and computer. The nurses' clinical experience and listening skills are the primary tools for making decisions that directly affect pregnancy outcome.

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Since its inception, the center has applied new technology, such as a local area network (LAN); exclusive use of computers for patient man-

agement and access to a customized perinatal database; 24-hour call processing in English, Spanish, and Cantonese; and telecommunications for remote transmission of patient data 24 hours per day, 7 days per week. This improved access to care has enabled early discharge from the hospital and reinforces each patient's plan of care between medical office visits. After-hours coverage by a registered nurse (ie, 11:30 pm to 7:00 am) is provided via laptop and modem connection to our server.

Over the past 13 years, the center has grown in service options and in census. In 2003, the center enrolled 3201 patients. Currently, the center manages cases of approximately 860 patients, of whom 30% are enrolled in the Preterm Labor Program, 24% in our Home Hypertension Program, 43% in our Diabetes Management Program, and 4% in the Hyperemesis Program.

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The experience we have gained and the information we have gathered—in both research and operations—are transferable to other areas. The center has shared information with staff of the Kaiser Foundation Health Plan and Permanente Medical Groups in the Ohio, Mid-Atlantic, Hawaii, Northwest, and Colorado geographic areas. The materials most frequently provided include patient educational materials, outcome data, and the Risk Assessment for Preterm labor form. In the future, operations related to services provided by the Perinatal Service Center may be extended to patients outside our geographic area by providing broader access to the department's toll-free number. ❖

Acknowledgments

The Kaiser Permanente Northern California Perinatal Service Center programs have been the recipient of a Garfield Memorial Fund grant.

Gabriel Escobar, MD, provided data analysis support.

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Masterpiece

The great and glorious masterpiece of man is how to live with a purpose.

— Michel de Montaigne, 1533-92, French philosopher