

Perinatal Regionalization Breakout Session

Background and History of Regionalized Perinatal Programs

Regionalization of perinatal care can be traced to the development of premature infant centers in the United States during the 1930's and 1940's. While the premature infant centers spread throughout the country during this period, there was little in the way of standards of perinatal practice as we know it and the impact of the centers on infant mortality in the U.S. was modest (*Butterfield, 1980*).

Many of the past efforts to establish regional programs to improve access to care, to increase the number of physicians or to relocate professionals, etc. have been federally funded. Regional perinatal care programs attracted some demonstration funds; public, private and voluntary funds flowed through a pluralistic network of agencies, institutions and organizations in a disjointed and uneven approach. The diversification of program funding and direction seems to be a strength that carried regional perinatal programs forward.

There have been positive consequences of regionalization on neonatal outcomes. At the national level, the U.S. infant mortality rate (IMR) among industrialized nations had been a source of concern. From 1950 to 1965 the IMR remained almost static at 25/1000. In the next 15 years, as regional perinatal care developed in most regions of the country, the IMR fell by 50% to a record low of 13/1000 in 1979. Most of that improvement has been for newborns in the first month of life as all but 15 states reported neonatal mortality rates (NMR) less than 10/1000 in 1978. In the following years, infant mortality has never recorded such a significant decrease but the perinatal regionalization hasn't been evolving much either and in some states has not even been functioning in the last two decades (i.e., Michigan). Today the infant mortality rate is 6.8/1000 in the U.S., with a more than doubled rate in Blacks population (14/1000) compared to Whites (5.7/1000) (NCHS).

While the improvement of the pregnancy outcomes is the major goal, regional perinatal education, expanded role of nursing, inter-hospital care, shared services and systems development can be identified as well as benefiting from the macro concept of regionalization (*Butterfield, 1980*).

Evolution of Perinatal Care in the United States

As a reminder, from the Children's Bureau to today's federal state partnership in MCH programs, quality improvement has been used as a tool aimed at improving health outcomes (Table 1). The history of efforts to reduce mortality and morbidity illustrate the long tradition of quality improvement efforts in perinatal care. Maternal mortality is one such example.

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TABLE 1. Chronology of the Evolution of MCH and Perinatal Care Policy and Guidelines

1912	Children's Bureau established by Congress as first US public health "grant-in-aid" program
1921	Sheppard-Towner Act passed; provided grants to states with enabling legislation to improve access to MCH services
1929	Sheppard-Towner Act repealed
1935	Social Security Act with Title V signed; plan and provision of an infrastructure for MCH services distinguishes that population. Title V requires state MCH programs to be located in state health agencies
1946	Hospital Survey and Construction Act (Hill-Burton) Grants to states to build hospitals
1964	Medicare and Medicaid programs enacted into law to increase access to care for elderly and poor
1976	<i>Toward Improving the Outcome of Pregnancy: Recommendations for the Regional Development of Maternal and Perinatal Health Services</i> (TIOP I)
1981	Title V funds combined with other programs as an MCH block grant as a result of OBRA
1983	First edition <i>Guidelines for Perinatal Care</i> published by American Academy of Pediatrics and American College of Obstetricians and Gynecologists.
1984	First Medicaid expansion to extend coverage beyond AFDC income levels, with a series of expansions continuing through 1990
1988	Institute of Medicine report on <i>The Future of Public Health</i>
1989	OBRA '89 (Omnibus Budget Reconciliation Act of 1989) provided amendments to Title V including reporting requirements
1991	Federal MCH program unit changed (elevated) from Office to a Bureau.
1993	<i>Toward Improving the Outcome of Pregnancy: The 90s and Beyond</i> (TIOP II)
1995	GRPA, P.L. 103-62 (Government Performance and Results Act) created additional accountability requirements for Title V and other programs

1998 Maternal and Child Health Bureau National Performance Guidelines Measures

(Johnson KA and Little GA. *State Health Agencies and Quality Improvement in Perinatal Care*. In Horbar JD and Gould JB Eds. *Evidence-Based Quality Improvement in Neonatal and Perinatal Medicine Pediatrics*, 1999; 103(s):233-247.)

The 1976 publication of *Toward Improving the Outcome of Pregnancy: Recommendations for the Regional Development of Maternal and Perinatal Health Services* (TIOP I) is recognized as an historical marker of formal acceptance of the concept of regional allocation of resources according to need (Committee on Perinatal Health. (TIOP I) *Toward Improving the Outcome of Pregnancy: Recommendations for the Regional Development of Maternal and Perinatal Health Services*, White Plains, NY: March of Dimes Birth Defects Foundation, 1978), and as a stimulus for the rapid diffusion of regionalization across the country. The federal and state government maternal and child health agencies structured under Title V of the Social Security Act were proactively involved in advancing policies and implementing programs to support these regional system structures.

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Between the mid-1970s and mid-1980s, perinatal care activities such as risk identification, transport of patients, application of technologically sophisticated equipment, and use of the levels of care concept became the nationwide standard of care (*Gilstrap LC and Ho W. (Ed.) Guidelines for Perinatal Care (5th edition). Washington, DC: American Academy of Pediatrics and American College of Obstetricians and Gynecologists. 2002*).

The increasing number of neonatologists more than four-fold at the same time that NICUs proliferated, often into low-volume units in smaller and smaller community hospitals, generated concern about the impact of so-called “deregionalization.” Subsequently the Committee on Perinatal Health was reconstituted leading to the publication in 1993 of *Toward Improving the Outcome of Pregnancy: the Nineties and Beyond* (TIOPII) (Committee on Perinatal Health (TIOPII) *Toward Improving the Outcome of Pregnancy: The 90s and Beyond*. White Plains, NY: March of Dimes Birth Defects Foundation, 1993). TIOPII included recommendations for: a) expanding the TIOPI I primary emphasis on hospital care around the time of birth to include a more comprehensive spectrum including prenatal and preconception care, b) expanded use of data systems for quality improvement and improved accountability, and c) stronger roles for local/regional centers.

As a result, some concluded that over the past three decades, perinatal outcomes have improved significantly, but improving outcomes in a changing health care system is an ongoing challenge. (*Kliegman RM. Neonatal Technology, Perinatal Survival, Social Consequences, and the Perinatal Paradox. AJPH, 1995;85:909-913*).

The consensus framework for public MCH functions states that **one of the top 10 essential services to be performed by MCH agencies is to “evaluate the effectiveness, accessibility, and quality of perinatal health and population-based maternal and child health services.”** (Grason HA, Guyer B. *Public MCH Program Functions Framework: Essential Public Health Services to Promote Maternal and Child Health in America*, Baltimore, MD: Johns Hopkins University; 1995).

Some would say that states don’t have to do this, but a majority of observers would say it is an increasingly important role in today’s public health agencies and MCH programs. Whether benefits coverage is through private insurance, a new State Children Health Insurance Program, or Medicaid and whether services are delivered in the public or private sector, state MCH programs have a role to play and have been assigned responsibility for the policy framework and structure that undergirds quality improvement efforts for the total cohort of perinatal patients in the state.

A 50-state telephone survey of MCH programs was undertaken in May and June of 1998 to clarify their operational and perceived role in promoting quality improvement in perinatal care. The survey suggested that with the exception of a few states, overall state health agency involvement with perinatal regionalization tended to be less active and regulatory and more passive or collaborative (G. A. Little and K. A. Johnson. A

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survey of state policies and practices related to quality improvement in perinatal care. Unpublished data, June 1998). The state specific results of this survey conducted in 1998 are not available at this time but based on the current picture one could assume that Michigan is among the less active and less regulatory states.

Levels of Perinatal Care: Background and Definition

In 1976, the March of Dimes Committee on Perinatal Health designated three levels of perinatal care: Level I, II and III. While this typology largely remains in place, the numerical designations have been replaced with functional and descriptive designations over the years because of the complexity in providing perinatal care services. The three basic levels are summarized below and detailed in

Figure 1., as described in the latest American Academy of Pediatrics (AAP)/American College of Obstetricians and Gynecologists (ACOG) guidelines.

Level I – Basic Care

- Surveillance and care of all patients admitted to obstetric service: physical examination and interpretation of findings; routine laboratory assessment; assessment of gestational age and normal progress of pregnancy; ongoing risk identification; mechanisms for consultation and referral; psychosocial support; childbirth education; and care coordination.
- Established triage system for identifying high-risk patients who should be transferred to a higher level facility.
- Proper detection and initial care of unanticipated maternal-fetal problems that occur during labor and delivery.
- Capabilities to begin an emergency cesarean delivery within 30 minutes of the decision to do so.
- Availability of appropriate anesthesia, radiology, ultrasound, laboratory and blood bank services on a 24 hours basis.
- Care of postpartum conditions.
- Resuscitation and stabilization of all neonates born in the hospital.
- Evaluation and continuing care of healthy neonates in a nursery or with their mothers until discharge.
- Adequate nursery facilities and support for stabilization of small or ill neonates before transfer to a specialty or subspecialty facility.
- Consultation and transfer arrangements.
- Parent-sibling-neonate visitation.
- Data collection and retrieval.

Some basic care facilities may provide continuing care for neonates who have minor problems.

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Level II – Specialty Care

In addition to all of the services provided by a Level I hospital, a Level II hospital will also provide some enhanced services, such as:

- Care of appropriate high-risk women and fetuses, both admitted and transferred from other facilities.
- Stabilization of severely ill newborns before transfer.
- Treatment of moderately ill larger preterm and term newborns.

Care in a specialty level facility should be reserved for stable or moderately ill newborns that have problems that are expected to resolve rapidly and that would not be anticipated to need subspecialty level services on an urgent basis. These situations usually occur as a result of relatively uncomplicated preterm labor or preterm rupture of membranes at approximately 32 weeks of gestation or later.

Although some neonatal specialty care level hospitals also have neonatal intensive care units, the availability of perinatal subspecialty expertise often is neonatal medicine and not maternal-fetal medicine. Availability of pediatric sub specialists, such as cardiology, surgery, radiology is variable. Preterm labor and impending delivery at less than 32 weeks of gestation usually warrants maternal transfer to a subspecialty center as do gestations of less than 32 weeks.

Level III – Subspecialty Care

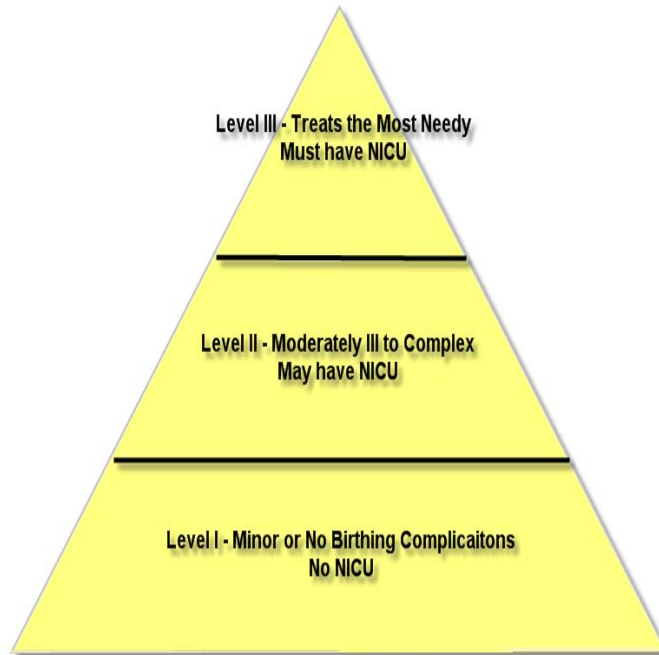
In addition to all of the services provided by a Level I and Level II hospital, a Level III hospital will also provide comprehensive services, such as:

- The provision of comprehensive perinatal care services for both admitted and transferred women and neonates of all risk categories, including basic and specialty care.
- Evaluation of new technologies and therapies.
- Where appropriate, responsibility for regional perinatal health care service organization and coordination including:
 - Maternal and neonatal transport.
 - Outreach support and regional educational programs.
 - Research support and initial evaluation of new technologies and therapies.
 - Analysis and evaluation of regional data, including those on perinatal complications and outcomes.

The services provided by a subspecialty care facility vary markedly from those at a specialty facility. Subspecialty care services include expertise in neonatal and maternal-fetal medicine. Both usually are required for management of pregnancies with threatened maternal complication at less than 32 weeks of gestation. Fetuses that may require immediate complex care should be delivered at a subspecialty care center.

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Figure 1: Regionalized Perinatal System Hierarchy



Michigan's Perinatal System of Care: brief history and current status

State roles in assuring perinatal system accountability vary widely – from passive watching on the sidelines to active regulatory power over neonatal intensive care units (NICU). (*Johnson KA and Little GA. State Health Agencies and Quality Improvement in Perinatal Care. In Horbar JD and Gould JB Eds. Evidence-Based Quality Improvement in Neonatal and Perinatal Medicine Pediatrics, 1999; 103(s):233-247.*)

Brief History: Michigan led the nation in pioneering the concept of a regionalized perinatal system in the 1970s and 80s. During that time, Nigel Paneth of Michigan State University found that mortality of low-birth weight babies was significantly higher in Level I and Level II centers than it was in Level IIIs—in some areas, mortality decreased by one third to one half when the babies were tended to in tertiary centers.

Problem: When examining a number of measures related to prenatal care access and birthing outcomes, Michigan ranks significantly lower when compared to other states and national estimates. The 2002 national infant mortality rate was 6.8/1000 births as compared to 8.2/1000 births in Michigan (MDCH website, The Annie E. Casey

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Foundation, 2006a). The percent of Michigan mothers having low birthweight babies (8.2%) (*The Annie E. Casey Foundation, 2006a*) also exceeds the national average of 7.9% (*The Annie E. Casey Foundation, 2006b*).

Michigan ranked 40th in the nation in overall infant mortality in 2005, with a rate of 7.9 per 1,000 live births. More distressingly, Michigan ranked 48th in the nation in 2005 in its black-to-white infant mortality disparity, a ratio of 3.3, based on a 2005 black infant mortality rate of 17.9 per 1,000 live births and a 2005 white infant mortality rate of 5.5 per 1,000 live births. Notably, Michigan has not seen improvement in its overall infant rate for the last ten years, although minor improvements in the white infant mortality rate have been seen over that time span.

Costs: The original cost to the State, according to those who developed the perinatal regionalization system here in the 1970's, was \$150,000-300,000 per year. These dollars were used primarily to staff masters-level perinatal nurse educators, who were trained as nurse practitioners. The educators provided technical assistance, collaborating with the birthing hospitals in their regions to develop the components of the regionalization, as noted above. Other deliverables from that era included: 1) Updating the guidelines for regional perinatal centers, 2) Surveying and reporting on the capabilities of all hospitals on the guidelines, i.e., classifying the hospitals, 3) Ensuring that non-designated hospitals did not operate at an inappropriate level of care, and 4) Conducting the perinatal effectiveness study and releasing the results publicly. In addition to these items, two others are thought to be of importance to sustaining an effort: 1) Reconstituting the Michigan Perinatal Association with at least 1 annual educational session to be the "glue" holding the system together in a voluntary manner and 2) Engaging the public in the black-white disparity issue.

The funding stopped in the late 1970's and the system was defunct by the 1990's. According to different MCH professionals, the State lost millions of dollars in in-kind and other contributions, e.g., the development/implementation of hospital neonatal transport teams, etc., when the funding stopped.

Michigan State activities related to Perinatal System of Care

Infant Mortality Stakeholders meeting (2004): Comprehensive state MCH data profile that included the distribution of preterm births by Hospitals with NICU

Eleven communities/counties data profiles and recommendations for actions (2005): Community/county data profiles developed, each with information related to preterm births distribution by Hospitals with NICU; Findings and recommendations presented at the Infant mortality coalitions network meetings.

Perinatal Periods of Risk (PPOR) Approach, phase 1 and 2: In the last few years (more than five), MCH Epidemiology has been providing the statewide and county specific PPOR findings with the corresponding recommendations based on the Centers for

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Disease Control and Prevention's guidelines; The continued collaboration with MCH programs staff including the infant mortality coalitions network has been very successful in promoting the PPOR findings/recommendations and thus evidence based actions (initiatives targeted to improving the preconception health stand as good examples).

Perinatal Survey (2005): designed and conducted in collaboration with Grand Valley University and with the assistance of CON staff.

Perinatal Survey findings presented at few internal meetings; Perinatal Survey Report is currently in the review process.

Learn from other states that either have a long standing perinatal system of care and state guidelines (i.e., Massachusetts, Washington State) or had no guidelines and thus reviewed and re-organized it (i.e., Louisiana just passed the law).

A coordinated perinatal system for better MCH outcomes:

The State perinatal regionalization, also known as regional perinatal centers or regional perinatal systems of care, can be briefly described as a coordinated system of care, which ensures that: 1) hospitals offering a full range of services to pregnant women and their babies exist throughout the state in accessible geographic regions, 2) the appropriate technology is present in these hospitals to serve the needs of the pregnant women and babies who give birth and are born there, 3) pregnant women and baby care is coordinated so that care needs and delivery are matched, i.e., low-risk mother-baby dyads go to hospitals without special OB units and NICUs for care, monitoring, delivery and post-partum/post-birth care, medium- risk mother-baby dyads go to hospitals with specialized OB units and NICUs for care, monitoring, delivery and post-partum/post-birth care and high- risk mother-baby dyads go to hospitals with the most specialized OB units and NICUs for care, monitoring, delivery and post-partum/post-birth care, all before the baby is born, 4) appropriate transfers take place between the different level OB units and NICUs in a region, optimally prior to the development of complications in a pregnant woman or birth of her moderate- or high-risk baby, 5) quality improvement, in the form of regular feedback among the delivery hospitals within a region is ensured, reviewing/discussing among other things the appropriateness/timeliness and outcomes of transfers, etc., and 6) different process and outcomes data are collected, analyzed and disseminated not only to improve quality but to inform the region's stakeholders as well.

The benefit of the system (perinatal regionalization) was evaluated. Having pregnant women and babies at the appropriate hospital will lead to better matching resources to their specific needs. This may eliminate the occurrence of births in inappropriate hospitals or, worse yet, while in transit to an appropriate birthing hospital. It may also stem the rising tide of pre-term and low-birth-weight babies by getting high-risk pregnant women the technology and measures sooner to stop or slow the advancement of their pregnancies.

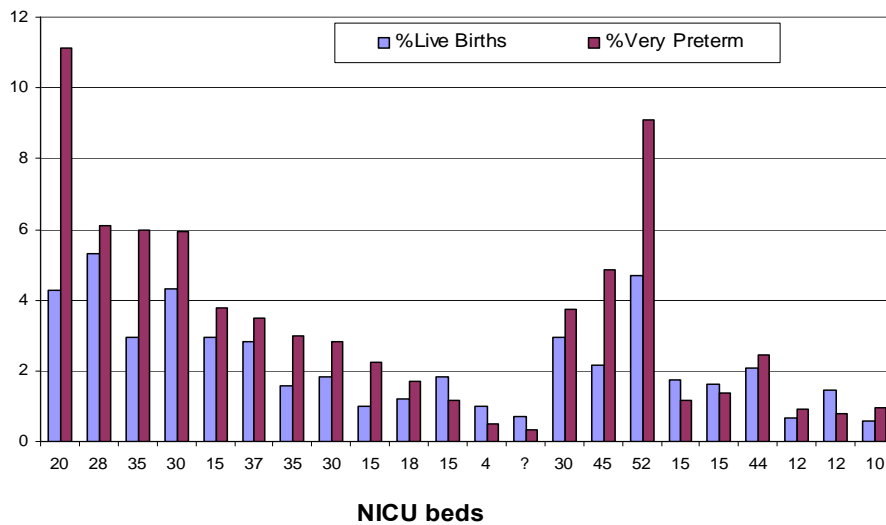
Despite the proven benefit of regionalized perinatal systems nationally and in Michigan, the state guidelines do not reflect the current practice patterns and were last updated in 1986. As a result, no formal perinatal system exists in Michigan today. The changes in the Michigan's health care system have impacted the proportion of high-risk pregnancies

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measured by birth-weight and gestational age, infant mortality rates and the risk for certain causes of death.

Without a formalized system, we identified 24 hospitals in Michigan prior to the survey as potential Level III health care centers. The identification of these hospitals as potential Level III health care centers was based on the number of licensed NICU beds (ranging from 4 to 52 beds) as reported to 2002 CON survey). What is most notable about this figure is that a number of hospitals in Michigan seem to have disproportionate share of very preterm births.

Figure 2: Distribution of Live Births and Very Preterm (≤ 31 Wks. Gestation) Among Level III Hospitals by Number of NICU Beds



Using this method, little information could be provided about the staffing and service capabilities of Michigan hospitals to provide perinatal care. Thus, we developed a perinatal survey based on the latest American Academy of Pediatrics (AAP) guidelines to assess each hospital's operational and staffing capacity in offering perinatal services.

The AAP has developed guidelines for perinatal care based on the three hospital level approach along geographic lines in a pyramid fashion. The survey was sent to each of Michigan's 98 birthing hospitals. At the conclusion of the survey, each hospital was asked to self-evaluate its capabilities as either Level I or II or III hospital. Seventy-one birthing hospitals completed the survey, which translates into a response rate of 72.4%. The full report can be found at:

http://www.michigan.gov/documents/mdch/MDCH_MCH_Epi_VG_PerinatalReportCorrectSept2007Rev_215949_7.pdf

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Suggested future key strategies

1. Engage health professionals from both medicine and public health in a collaborative effort.
2. Develop “regional” teams to advance data-driven projects and activities. Each team that would include representatives from the tertiary birthing centers, the county/urban health department, clinical care providers, and community-based programs and organizations. Teams also were required to have a mix of medical, public health, statistical/ epidemiological, and community program skills. A state team will be formed at the same time, with the expectation that it would model the collaborative, cross-sector behavior desired at the local/regional level.
3. Create a statewide consortium to promote interaction among regional teams. A statewide effort is needed to integrate regional efforts and to create a broader base for collaborative learning. The statewide consortium, with regular meetings, is the mechanism for sharing strategies, lessons, and ideas.
4. Develop the structures, requirements, and activities in the regional perinatal program.

The design will be guided by principles from the Urban MCH Data Use Institute (now known as the DaTA Institute) model developed in 1997 by CityMatCH in collaboration with Centers for Disease Control and Prevention (CDC). The four guiding principles from the Data Use Institute were: 1) focus on data use, 2) emphasis on teams, 3) anchor leadership in a core organization (the RPC in this situation), and 4) use a mix of technological methods and adult learning principles.