WISCONSIN ASSOCIATION for Perinatal Care

POSITION statement

The Triple Aim and Risk-based Perinatal Care: Improving Care in the Era of Quality Improvement

EXECUTIVE SUMMARY

The concept of regionalized perinatal care has changed over time. From the idealization of the "hub and spoke" model of regionalized perinatal services in the 1960s-1970s to its devolution in the 1990s-2000s, the Wisconsin Association for Perinatal Care (WAPC) has been a leader in supporting equitable risk-based perinatal services commensurate with the identification and recognition of the needs of the perinatal patient. Now, with further evolution of services and models of care, often transcending state borders, there is a need to refocus on levels of care and the risk-based services provided by facilities at every level. Despite the changes, the challenges and goals have remained the same—provide appropriate care for all women and infants during the perinatal period.

Based on this history, the WAPC developed this position statement, *The Triple Aim and Risk-Based Perinatal Care: Improving Care in the Era of Quality Improvement*, to reframe the underlying assumptions related to levels of perinatal care and relationships between stakeholders: This statement is intended for providers of perinatal care, birth facilities, health systems, insurers, and policy makers.

The statement frames its approach to improving care and outcomes in the Institute for Healthcare Improvement's (IHI) Triple Aim—patient experience, population health, and cost of care.[1]

WAPC adopts the position of supporting risk-based care as a requisite condition for meeting the Triple Aim of the Institute for Healthcare Improvement (IHI). To accomplish this goal, WAPC recommends that facilities providing perinatal care services should:

- Investigate and implement technology that can be used to support families and improve their experience of care.
- Adopt evidence-based standards of care appropriate to the level of care they provide, including participation in programs to determine risk-based level of care.
- Collect, interpret, and apply data on systems and processes to improve perinatal outcomes.
- Participate in collaborative efforts with other stakeholders.
- Recommend, promote, implement, and support communication between facilities.
- Provide professional educational activities based on level of care provided.
- Adopt strategies to reduce unwarranted variations in practice.
- Use formal economic evaluations to inform decisions about development and implementation of strategies and services across the perinatal continuum of care.

WAPC will continue to monitor the ongoing evolution of perinatal health care delivery and the changing local, state, and national environment and will advocate for improving the care of women, infants, and families.

HISTORY OF REGIONALIZATION

In the 1960s and 1970s, numerous studies demonstrated that timely access to risk-appropriate neonatal and obstetrical care could reduce perinatal mortality.[2] In 1977, the Committee on Perinatal Health under the auspices of the March of Dimes, along with other partners, published *Toward Improving the Outcome of Pregnancy* (TIOP I).[3] The report articulated the value of regionalized perinatal care:

> *"Regionalization implies the development, within a geographic area, of a cooperative system of maternal and perinatal health care in which, by mutual agreements between hospitals and physicians based upon population needs, the degree of complexity of maternal and perinatal care each hospital is capable of providing is identified so as to accomplish the following objectives: quality care to all women and newborns, maximal utilization of highly trained perinatal personnel and intensive care facilities, and assurance of reasonable cost effectiveness."*[3]

The report identified three levels of perinatal care: Level I providing services to uncomplicated maternity and newborn patients, Level II providing a full range of maternal and neonatal services for uncomplicated patients as well as care for the majority of complicated obstetrical problems and certain neonatal illnesses, and Level III providing care across the continuum of care—from low-risk patients to patients with serious maternal-fetal and neonatal illnesses and abnormalities. This idea stratified maternal/fetal and neonatal care based on risk and outlined a model for the regionalization of perinatal care nationally.

In the intervening years, although there were marked improvements in neonatal survival rates, the March of Dimes Committee on Perinatal Health published a second document in 1993, *Toward Improving the Outcome of Pregnancy-The 90's and Beyond* (TIOP II)[4], building on recommendations from TIOP I and making recommendations about regionalized perinatal care that included the continuum of perinatal care, health promotion in childhood, health services before and after pregnancy, data, documentation, and financing. TIOP II also recommended replacing the numerical designations with functional, descriptive designations of basic, specialty, and subspecialty care contained in TIOP I.

Published in 2010, *Toward Improving the Outcome of Pregnancy III-Enhancing the Outcome of Perinatal Health Through Quality, Safety and Performance Initiatives* (TIOP III), was a call to action demonstrating that "the quality of perinatal care depends on the application of evidence-based practice and clinical guidelines throughout the course of a woman's life."[5]

Support for risk-based care was also endorsed by other organizations such as the American Academy of Pediatrics (AAP), the American College of Obstetricians and Gynecologists (ACOG), and the Society for Maternal Fetal Medicine (SMFM). In 2004, the AAP, defined three levels of neonatal care with subdivisions of level II and level III care defining specialty and subspecialty care for ill and critically ill neonates.[6] In 2012, the AAP revised the guidelines for the levels of neonatal care.[7] The updated statement included Level I (basic care), Level II (specialty care), and Level III and IV (subspecialty intensive care) designations. This expanded classification system built on the previous categories. The AAP recommended that very low birth weight (VLBW) infants and very preterm infants (<32 weeks gestation) be delivered only in level III or IV facilities, reinforcing the recommendations for risk-based care delineated in the TIOP documents.

The *Guidelines for Perinatal Care*, 7th ed. jointly published by AAP and ACOG notes, "A regionalized system that focuses on an integrated delivery of graded levels of hospital-based perinatal care has been shown to be effective and to result in improved outcomes for women and children". [8] This comprehensive guideline outlines the capabilities of hospitals and personnel across the levels of care recommended in the 2012 Levels of Care from AAP. The *Guidelines for Perinatal Care* remains a foundational document for the organization and conduct of perinatal care.

Guidelines published over the past 40 years repeatedly called for regional perinatal systems to ensure that high-risk women give birth in an appropriate facility. Since the publication of TIOP I the focus had changed almost entirely to the newborn.[3,8] In 2015, ACOG and SMFM published an obstetric care consensus, "Levels of Maternal Care," noting that, "Although there is strong evidence of more favorable neonatal beneficial effect outcomes with regionalized perinatal care, evidence of a beneficial effect on maternal outcome is limited."[9] The consensus statement focused on maternal care with four objectives:

1. To introduce uniform designations for levels of maternal care that are complementary but distinct from levels of neonatal care and that address maternal health needs, thereby reducing maternal morbidity and mortality in the United States.
2. To develop standardized definitions and nomenclature for facilities that provide each level of maternal care.
3. To provide consistent guidelines according to each level of maternal care for use in quality improvement and health promotion.
4. To foster the development and equitable geographic distribution of full-service maternal care facilities and systems that promote proactive integration of risk-based antepartum, intrapartum, and postpartum services.[9]

The consensus statement also proposed and delineated four levels of maternal care: Basic care (level I), specialty care (level II), subspecialty care (level III), and regionalized perinatal centers (level IV). According to the consensus statement, "The goal of regionalized maternal care is for pregnant women at high risk to receive care in facilities that are prepared to provide the required level of specialized care, thereby reducing maternal morbidity and mortality in the United States."[9]

THE WISCONSIN EXPERIENCE

Following the publication of TIOP I, the WAPC convened a Statewide Perinatal Task Force in October 1980. Fifty stake holders were tasked to develop guidelines to identify and categorize hospitals in Wisconsin by the level of care they provided. The Task Force published *Toward Improving the Outcome of Pregnancy in Wisconsin*[10] in 1983 identifying minimum capabilities for primary, secondary, and tertiary level care. In 1991, WAPC published *Directions in Perinatal Care*[11]--a directory containing public information and education, access to care, patient care guidelines, criteria for classification of hospitals, community heath, professional education, and communication. Unlike TIOP I, the Task Force recommended two levels of care--that provided by community hospitals and that provided by perinatal centers.

Subsequently, WAPC continued to lead improvements based on the new recommendations. In 2002, in support of the recommendations on regionalized care from national organizations, WAPC presented *To Transfer or Not to Transfer: That is the Question*- a series of regional forums on transferring newborns and pregnant women from community hospitals to perinatal centers followed in 2003 by an invitational meeting about regionalization in Wisconsin. Following the publication of the TIOP I, most states developed coordinated regionalized systems for perinatal care. Regionalized systems are typically developed and managed by state health departments in partnership with hospitals and perinatal professionals, but in some states hospital networks or non-profit groups manage the system.[12] Regionalized perinatal systems define or designate hospitals at specific risk levels. Continuing the long history of promoting healthy birth outcomes through regionalized perinatal care, WAPC initiated a self-assessment process in 2006 based on criteria adapted from the AAP[6] and patterned after a survey from Colorado.[13] WAPC adopted the levels of care guidelines set forth in 2012 by the AAP[7] and integrated the levels into the self-assessment process. Following the ACOG/SMFM consensus statement on Levels of Maternal Care[9] and with WAPC Board approval, the revised recommendations for levels of maternal care were integrated into the self-designation application as a supplemental survey.

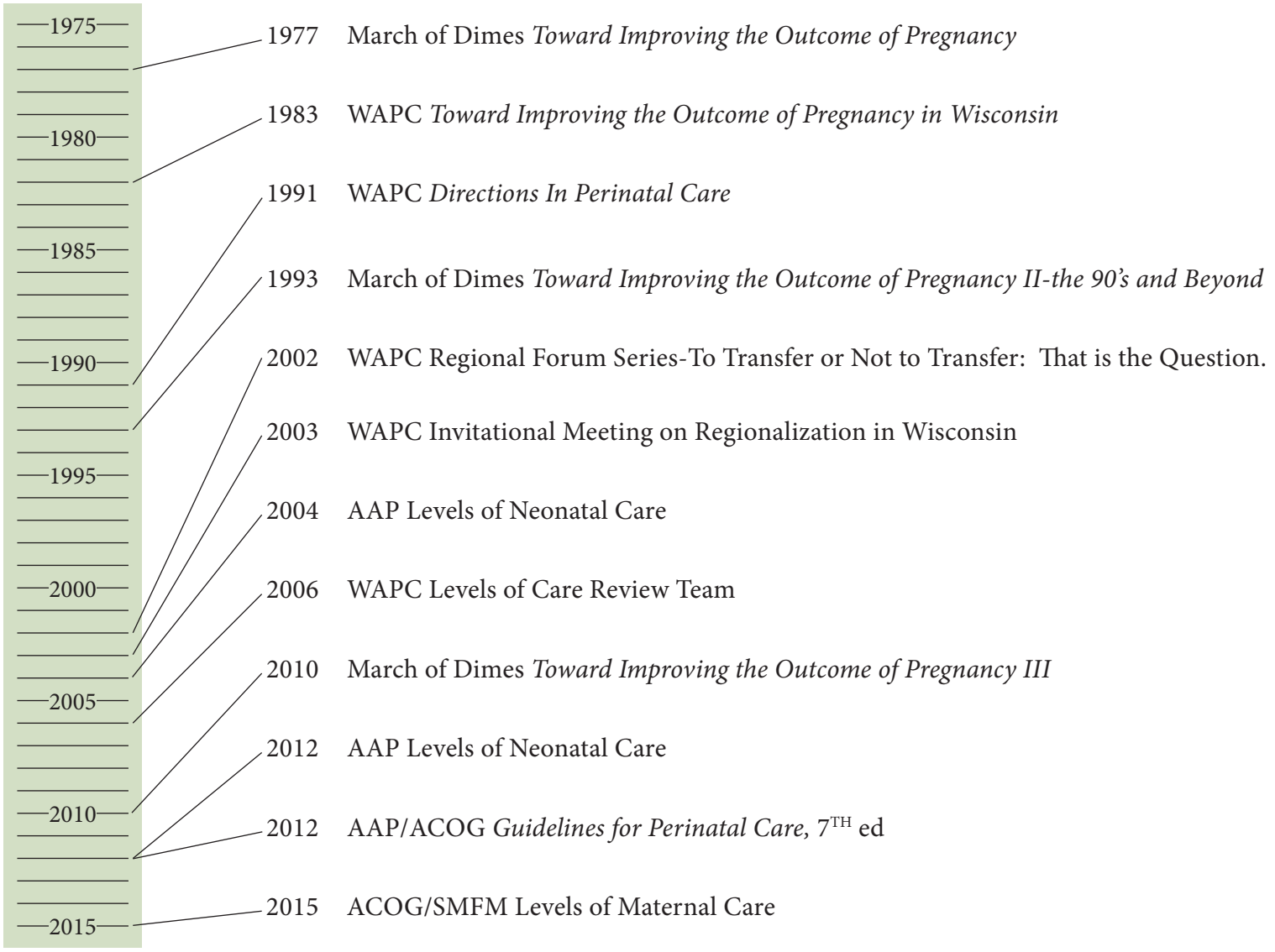
A Levels of Care Review Team, established in 2006, consisting of multi-specialty, multi-disciplinary membership from different hospital systems, reviews blinded self-designation submissions. The goals of WAPC Levels of Care Self-Assessment process are three-fold:

- Establish a consistent set of minimum expectations for each level of perinatal services.
- Enable each institution to provide consumers with a consistent level and quality of perinatal services.
- Recognize the capabilities, commitment, and resources of institutions that are beyond the minimum expectation for their level of perinatal services.

The self-assessment survey gives facilities the opportunity and tools to evaluate the breadth of perinatal services delivered and to identify strengths and weaknesses in their provision of perinatal care.

Information about the initiative and hospital designations can be found at perinatalweb.org under Major Initiatives/Perinatal Levels of Care Tab. Currently, in Wisconsin, compliance with the recommendations for each level of care is voluntary. By the end of 2014, 70 hospitals in Wisconsin had completed the self-assessment process.

Timeline



DEFINING THE CONTEXT OF RISK-BASED CARE

In the ideal world, increasingly complex care needs are met with higher levels of available services. One of the challenges facing the achievement of the ideal is that specific needs may not be known or they may, in fact, exceed the capabilities of the available services. To address this challenge, it is necessary to have a well-defined and transparent system of care that allows consumers and providers the opportunity to anticipate needs and seek or refer to higher levels of services when needed to assure optimal outcomes.

Health promotion underlies the relationship between needs and services. The World Health Organization defines health as "a state of complete physical, mental, and social well-being and not merely the absence of disease or infirmity."[14] Health promotion includes an understanding and application of both the psychological and sociological factors that can affect health and can be seen as a function of health education and health policy.[15] In the context of risk-based perinatal services, there is a need to identify and address the gaps in knowledge and practice that underlie health disparities and suboptimal health outcomes. In this manner, perinatal health stakeholders can begin to align needs and services and assure that all women and infants have access to the best care available.

There are micro- and macro- community considerations in the definition of risk-based care. Within the micro-community of an individual facility, while maintaining a strong focus on promoting and supporting health, there is also a need to consider the range of possible patient needs and the capability and capacity of the available resources. Facilities should have a thorough understanding of their capabilities and limitations. If there are conceivable needs for which services are not available, there should be a well-defined, formalized plan describing how the needs will be met. Often, this plan may involve resources available at a facility offering a higher level of services.

Macro-community considerations include the full range of services available and the relationships between facilities providing higher and lower levels of perinatal services. Within the system, facilities should work in concert to assure that the best care possible is provided, irrespective of level. To support the process, facilities providing higher levels of services should collaborate with the other facilities to evaluate their needs, strengthen areas needing additional support, and provide appropriate and timely follow-up for all referrals.

MOVING BEYOND THE CONCEPT OF REGIONALIZATION

In the 1970s, ideal distribution of perinatal services was contextualized in a regionalized system. Regionalization implied, "the development, within a geographic area, of a coordinated, cooperative system of maternal and perinatal health care."[3] With an emphasis on geography, "hubs and spokes" dominated images of how regionalization should be accomplished at the state level. The "hub and spoke" concept features a centralized regional center (the hub) and outlying referring hospitals (the spokes). The goals of regionalization focused on three primary areas—optimization of 1) care for pregnant women and newborns, 2) limited resources, and 3) cost-effectiveness and outcomes.[16] A coordinated and cooperative system of care operated under mutual agreements between providers and facilities was necessary to achieve these goals.

From the 1980s to the early 2000s, a number of supply and demand factors contributed to an erosion of the "hub and spoke" model of regionalization. First, fellowship programs trained more neonatologists who were willing to open new neonatal intensive care units and practice in smaller hospital settings. Increased availability of technology required for the units further supported the move toward newer and more numerous units. Second, economic drivers, e.g., competition between hospitals and health care systems, contributed to the demand for neonatal intensive care units.[17] These same units may now be sustained by the admission of larger and less premature newborns.[18]

The healthcare environment has continued to evolve. Where hospital systems of the recent past were constrained by state borders, it is not unusual to see smaller systems subsumed by larger systems from surrounding states, shifting administrative functions to other geopolitical centers. This evolution necessitates a paradigm shift in understanding "regionalization." While the "hub and spoke" model may still apply to administrative functions, patient care and the relationships between facilities should be reconceptualized as complementary parts of a whole. In perinatal care, the

underlying assumptions are 1) facilities will continue to provide a range of perinatal services, 2) optimal care of patients will continue to require that patient needs are matched appropriately with services at facilities, and 3) individual facilities and larger health care systems will work collaboratively and cooperatively to assure the best care possible.

CHALLENGES TO RISK-BASED CARE

There are several challenges to risk-based care that should be addressed by comprehensive policy. First, in the absence of a system providing a structure for assessing levels of care and mandating the reporting of levels of care, there is no way to assure facilities can provide the level(s) of care self-reported. Korst et al. reported on childbirth services in California.[19] They found that despite recommendations from ACOG and AAP[8] significant numbers of hospitals providing childbirth services did not have 24-hour in-house labor and delivery physician coverage, ability to perform emergency Cesarean delivery within a specified time limit, and 24-hour blood bank availability. They concluded that recognition of the variation and linkage to outcomes was necessary to identify criteria for the provision of maternal risk-based care.

Second, economic policies, or lack of policies, may incentivize behaviors that undermine risk-based care. Okoroh et al. systematically reviewed publicly available, Web-based information on maternal and neonatal transport for each state.[20] Overall, 34 states had an established state-level policy for neonatal transport, and six additional states had recommendations to develop a policy. Of the states with policies, 31 of the policies contained language regarding financial reimbursement for neonatal transport; ten of the state policies also included language relating to maternal transport. Of note, 25 of the policies did not specifically address back-transport reimbursement. They concluded that the information presented had relevance to both allocation and redistribution of resources needed for improvement.

Third, discordant levels of maternal and neonatal services provided can adversely affect delivery of risk-based care and outcomes. Brantley et al. described the spatial relationships between women of reproductive age, individual perinatal subspecialists, and obstetric and neonatal critical care facilities to identify gaps in access.[21] In the Brantley study, 92.8% of the population of the US lives within 50 miles of a level III or IV neonatal intensive care unit and 90.5% lives within 50 miles of a facility with an obstetric critical care unit (OCCU). Despite the relative proximity to the population centers, the distribution of obstetric and neonatal facilities demonstrates a mismatch. Sixty-seven percent of OCCUs were adjacent to an NICU, but only 49% of NICUs were adjacent to an OCCU. Eighteen percent of OCCUs and 20% of NICUs did not have a complementary critical care unit within 10 miles. Finally, the critical care units appear to cluster—61% of OCCUs had one or more OCCUs within 10 miles and 77% of NICUs had one or more NICUs within 10 miles. The full impact of this evaluation is limited by the lack of uniformly applied standards for determining levels of care.

Finally, in 2015, 2.5% of all deliveries in Wisconsin occurred outside a hospital.[22] In the home and birth center environments there may be challenges with assuring the level of care provided and the existence of contingency plans for higher risk situations that may develop.

POSITION AND RECOMMENDATIONS

WAPC supports risk-based care as a requisite condition for meeting the Triple Aim of the Institute for Healthcare Improvement (IHI). "Triple Aim" refers to the simultaneous pursuit of improving the patient experience of care, improving the health of populations, and reducing the per capita cost of health care.[23] The three components are not independent of each other and at times may operate in opposition. The challenge is to optimize all three within the context in which care is delivered. Risk-based care provides a common denominator by which the three components can be understood and integrated.

Berwick et al. describe three preconditions underlying successful accomplishment of the Triple Aim.[23] First, it is necessary to identify the population of concern. For the purpose of this statement, the population of concern includes women, infants, and families in Wisconsin during the perinatal period—prior to pregnancy through the infant's first year of life. By defining the population and setting a time limit, we established the extent and limitations of patient

experiences of care, population health status, and cost of care. Second, it is necessary to define the policy constraints that affect the relationship between the components of the Triple Aim. The social, political, and economic factors that define policies affecting perinatal care continue to evolve, requiring an agile and adaptive understanding of policy implications with a commitment to the needs of the population. Finally, it is necessary to identify an "integrator"—an entity that accepts responsibility for all three components of the Triple Aim for the specified population. It is a challenge to identify an integrator at this time given the breadth of the population and the diversity of stakeholders. In the future, the Wisconsin Perinatal Quality Collaborative may be positioned to fill that role.

To this end, WAPC recommends the following:

Improving the patient experience of care:	
	Facilities providing perinatal care services should investigate and implement technology that can be used to support families and improve their experience of care.
	Families seeking care from facilities providing the highest levels of care may have direct contact with providers in a location convenient to their homes. For families for whom access to services is a problem, technology can reduce or eliminate barriers to care. For example, diagnostic procedures, like ultrasounds, can be performed locally with subspecialist providers viewing the results in real time from a remote location. Video connections with patients can allow specialists in other areas to assist local providers in consultations and the interpretation of patient clinical status to support appropriate decision-making.[24,25] The Institute of Medicine describes six aims for improvement of the health care system that are often used in surveys to evaluate the experience of care of patients.[26] Risk-based approaches play significant roles in at least four of the aims--effectiveness, patient-centeredness, timeliness, and equitability of care.
Improving the health of populations:	
	Facilities providing perinatal care services should adopt evidence-based standards of care appropriate to the level of care they provide, including participation in programs to determine risk-based level of care.
	Successful quality improvement has occurred in a broad range of environments by standardizing guidelines, policies, and/or procedures. Standardization can be applied to risk-based levels of obstetric and neonatal care, as well. In the process of defining standards, there are opportunities to fit the standards to established benchmarks, like the level of care recommendations published by the AAP and ACOG.[7,8,9] There is evidence that such standardization can improve outcomes.[27]
	Facilities providing perinatal care services should collect, interpret, and apply data on systems and processes to improve perinatal outcomes.
	Readily accessible data allow facilities and health care systems the opportunity to develop benchmarks, plan strategies for improvement, and measure progress toward ideal outcomes. Further, within a system framework, level III and IV maternal and neonatal services should support the level I and II facilities with which they have relationships by providing the expertise needed to measure, interpret, and utilize data appropriately.
	Facilities providing perinatal care services should participate in collaborative efforts with other stakeholders.
	Participation in quality collaboratives can help support a change to value-focused care.[28] Value-focused care is based on the use of evidence-based medicine. The challenge to using evidence-based medicine is often determining the quality of the evidence in question. Quality collaboratives can facilitate the identification and dissemination of high-quality evidence. In addition, quality improvement science utilizes a variety of strategies focused on implementing change strategies and evaluating results of the changes.

	Facilities providing perinatal care services should recommend, promote, implement, and support communication between facilities.
	The *Guidelines for Perinatal Care*, 7th edition, gives specific recommendations about communication between facilities.[8] For example, • Formal transfer plans for mothers and infants with receiving hospitals that are established by facilities that provide lower levels of care; • A method of risk identification and assessment of problems that are expected to benefit from consultation and transport; • Assessment of the perinatal capabilities and determination of conditions necessitating consultation, referral, transfer, and return transfer of each participating facility; • A reliable, accurate, and comprehensive communication system between participating facilities and transport teams; and • Determination of responsibility for each function.[8] Much of this communication defines the capabilities and responsibilities of the risk-based care facilities should provide at each level of care.
	Facilities providing perinatal care services should provide professional educational activities based on level of care provided.
	Level III and IV facilities have an obligation to address the educational needs of not only the providers within the institution, but also providers at referring centers. Educational activities can be more accessible and available using a range of communication technologies. One goal of the education should be to democratize knowledge by allowing subspecialists to work with community-based providers in outlying areas to provide the training required to manage patients that traditionally would have had to travel distance for care.[29,30,31,32]
Reducing cost of health care:	
	Facilities providing perinatal care services should adopt strategies to reduce unwarranted variations in practice.
	Unwarranted practice variation can increase the per capita cost of health care. For example, Schulman et al. studied antibiotic usage in 127 NICUs in California and determined that antibiotic use varied 40-fold independent of proven infection, necrotizing enterocolitis, surgical volume, or mortality.[33] They concluded that a considerable portion of antibiotic use in NICUs lacked clear indications and that antibiotics were overused. This example and others demonstrate the clear need for deliberate and informed decision-making in perinatal care, of setting evidence-based standards for care. In some situations, the evidence may be inconclusive. Involvement in quality collaboratives can provide an economy of scale and allow evaluations to occur across a larger sample to determine best practice.
	Facilities providing perinatal care services should use formal economic evaluations to inform decisions about development and implementation of strategies and services across the perinatal continuum of care.
	The adoption of any strategy or service is associated with both direct and indirect costs. Direct costs arise from implementing the strategy or service, while indirect costs consider the consequences of implementing or not implementing the strategy or service. It is necessary to balance the economic implications of services delivered by facilities and systems within the larger context of health care allocation. Risk-based approaches define the components of care that should be available at and provided by facilities at each defined level of care and can form the basis for equitable, safe, and efficient distribution of services.

Summary

Throughout the changes in the health care environment, WAPC has maintained a commitment to the care of women, infants, and families and has consistently demonstrated the value and importance of standards of care for perinatal services. Using the IHI Triple Aim framework, WAPC has now developed the rationale for risk-based perinatal services and recommendations for the future. Although the ongoing evolution of health care is unknown, WAPC will continue to collaborate with stakeholders focused on improving perinatal care.

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