Abstract
Neonatal Outcomes Improvement Project

The goal of this project is to increase the value, quality, and transparency of health care services paid for through Medicaid (and SCHIP) via a transformative commitment to the establishment of a state and national collaborative learning network. In North Carolina this collaboration will begin in the area of neonatal care as a partnership between Medicaid, the Perinatal Quality Collaborative of North Carolina (PQCNC), and the National Initiative for Child Healthcare Quality (NICHQ). PQCNC is a statewide network of perinatal providers, NICUs, hospital administrators, government officials (including state Title V and Healthy Start Initiatives), health care payers (including state Medicaid) and families whose mission is to execute quality improvement initiatives. The goal of these initiatives is to promote perinatal care practices that minimize the burden of diseases of mothers and infants in an economical and family-centered manner. The Neonatal Care Outcomes Improvement Project will allow North Carolina to continue this work in concert with parallel programs in other states. While North Carolina has been an innovator in implementing quality measures into primary care practice through Community Care of North Carolina (CCNC), neonatal care remains an untapped well of opportunity.

Premature birth is the major contributor to U.S. infant mortality. Of the roughly four million babies born in the U.S., approximately 500,000 are born at a gestational age less than 37 weeks; 9,000 of these babies will die and many will suffer high rates of medical disorders. The national annual medical cost for premature babies is $16.9 billion, with 40% of these annual medical costs being paid by Medicaid. Despite the risk of premature birth, infant mortality has declined dramatically over the past three decades, primarily a result of a reduction in mortality among premature infants. However, the decline in infant mortality has ceased and no obvious breakthroughs are on the horizon. Future improvements in outcomes will depend upon more effective applications of current knowledge and technologies.

Evidence-based clinical guidelines have been established which should improve perinatal outcomes and reduce morbidity and mortality. However, research has shown that established best practices are not implemented consistently. PQCNC 2005 data reports demonstrate wide variability in neonatal outcomes across North Carolina. However, North Carolina is fortunate to have health care professionals with great expertise and enthusiasm for improving the survival and health of infants and mothers. One of the barriers to maximal effectiveness is the lack of mechanisms to coordinate their efforts to enhance both policy and practice. We have begun to remedy this situation through PCQNC. With additional support from NICHQ, we will introduce evidence based changes developed through a national consensus process, provide further training in quality improvement methods and ongoing support for making substantive improvements in care, and establish common performance measures and an infrastructure for reporting and sharing results.

North Carolina's participation in this project will lead to development of local and state level quality infrastructures that support improvements in perinatal care and catalyze quality transformation in a manner that is synergistic with other initiatives in this state. The proposed budget for this 18 month project is $1,715,000. This will cover personnel, technology enhancements, educational needs and essential quality support from NICHQ. By enhancing our current infrastructure for quality improvement and facilitating information exchange, these initiatives will render sustainable results that will benefit current and future Medicaid recipients.

I. Statement of Need/Project

Need: There are two compelling reasons for this project. First, there are significant levels of preventable morbidity, mortality and costs associated with prematurity that permeate perinatal and neonatal care. Second, there exist substantial barriers which impair the systematic implementation of transparent best practices and diffusion of technical improvement capability for Medicaid beneficiaries. North Carolina is fortunate to have stakeholders who are committed to improving the quality of care delivered in the state; however, this willingness is hindered by difficulty in tracking and sharing data. For instance, there is no efficient means to identify which high risk prenatal patients received appropriate interventions to minimize the occurrence of preterm birth. This project will allow us to develop a database and system to improve health information exchange across the state.

The United States has one of the highest infant mortality rates among industrialized countries. This is particularly true among black infants, whose mortality rates are 2.5 times higher than those in white infants. (1) The infant mortality rate in North Carolina has declined from 17.8 infant deaths per 1,000 live births in 1976 to 8.8 in 2005. This is a reduction of 51%. Yet, despite this progress, North Carolina's infant mortality rate remains one of the highest in the country. North Carolina ranks among the ten worst states in the nation in infant mortality; despite relatively steady declines over the last few decades, North Carolina's infant mortality appears to be on the rise in recent years. In 2004, the state's infant mortality rate rose more than 7% to 8.8 infant deaths per 1,000 live births and this rate remained unchanged in 2005. In addition, the gap between minority and white infant mortality persists in North Carolina, with whites having an infant mortality rate of 6.4 per 1,000 live births, compared with a minority rate of 14.9 in 2005. Some birth-related measures appear to be improving as a result of several state programs. During 1987-1991, 24 % of women received late or no prenatal care. By 2001-2005, this rate decreased to 16%. The percentage of women who reported smoking during pregnancy has also declined. During 1988-1991, 21% of live births in North Carolina involved a mother who had smoked during pregnancy, compared with 12.9% during 2001-2005. Despite some progress in this area, other birth outcome measures have deteriorated in recent years. In 2001-2005, the percentage of North Carolina births classified as low birth weight was 9.0 compared with 8.1 in 1987-1991.

Low birth weight infants constitute 7.6 % of all U.S. births but account for nearly two-thirds of all infant deaths. Very low birth weight infants constitute 1.4 % of all U.S. births but account for more than half of infant deaths. (3) In North Carolina in 2005, more than 80% of all deaths among residents under age 15 occurred in the first year of life, and 53% occurred within 28 days of birth. (2) Low birth weight infants constituted 9.3% of all North Carolina births but accounted for nearly two thirds of all infant deaths. Very low birth weight infants constituted 1.9% of all NC births but account for more than half of infant deaths. (3) Premature and low birth weight infants suffer from acute and chronic complications that not only contribute to suffering on the part of infants and children but also contribute enormously to societal costs.

Several specific prenatal interventions are likely to reduce frequency of low birth weight and potentially infant morality in North Carolina, including promotion of smoking cessation during pregnancy and identification and treatment of substance abuse. Based on NC 2004 birth certificate data, 12.5 % of pregnant women smoked during pregnancy (19.8 % of Medicaid women). Infant mortality is as much as 40 % higher among smokers compared to non-smoking

pregnant women ($p < 0.0001$). (3) The identification of high risk pregnancies and prenatal transfer of the woman to hospitals skilled in preterm delivery and newborn intensive care has been shown to reduce infant morbidity and mortality, but in an age of increasing numbers of mid size nurseries this bears further study. (4) Identification of such women may also allow for intervention with emerging preventative treatments such as 17 hydroxy-progesterone (17P). (5) Efforts to decrease prematurity rates would have significant impact on infant morbidity and mortality, but to date programs targeting reductions in low birth weight (LBW) and very low birth weight (VLBW) infants have been unsuccessful. (6) A great opportunity also exists to improve healthcare value by ensuring that the care received by medically complex infants is well developed in discharge planning, that long-term follow up in the community is coordinated and long term outcomes are tracked. There is no doubt that informed and efficient use of health information technology can be a key factor in successfully implementing these initiatives.

Newborn intensive care is clinically effective. Although incidence of low birth weight and very low birth weight newborns has not declined, the U.S. infant mortality rate has declined significantly over the past two decades from 12.6 per 1000 births in 1980 to 6.9 per 1000 in 2000. (7) Much of the decline in infant mortality in the last two decades of the twentieth century can be attributed to increases in the effectiveness of neonatal intensive care. (8-10) Despite this progress, few additional improvements in mortality or morbidity have been observed since 1995 (10) and the national infant mortality rate increased to 7.0 per 1,000 live births in 2002. As a nation, we have stalled in reducing infant mortality. No major new neonatal breakthroughs are apparent on the horizon. Effective applications of current knowledge and technologies will drive future improvement in neonatal care. By reducing variation in quality and outcomes of neonatal intensive care across hospitals, North Carolina can make further reductions in infant mortality. In one study of neonatal intensive care units, risk adjusted 28-day mortality rate was 15.1 % in high mortality rate hospitals and 6.7 % in low mortality rate hospitals. The overall mortality rate would fall by 24 % if care of infants treated in hospitals with poorer outcomes was elevated to the performance level of hospitals in top quartile.(11) Evidence based clinical processes are available but underused. Results of studies in the US and the Netherlands demonstrate that approximately 30 to 40% of patients do not receive care based on contemporary scientific evidence and that 20 to 25% of care that is provided is potentially harmful. (12) Fortunately, quality improvement activities can make a significant difference in neonatal outcomes by increasing the use of evidence based clinical practices. (13-15)

Our 2005 PQCNC collaborative report clearly demonstrates the variability that exists in North Carolina in multiple areas of NICU care. Obvious differences in bronchopulmonary dysplasia (BPD), early surfactant use and nosocomial infection rates signal an enormous opportunity to improve practice and outcomes.

When compared with other health care interventions such as coronary bypass surgery, neonatal intensive care has proven cost efficacy.(16) The application of evidence based recommendations has the potential to not only improve outcomes, but to reduce costs. Estimates performed by the Agency for Healthcare Quality and Research indicate that the implementation of three evidence based practices in neonatal intensive care has the potential to save over $175 million annually across the US. In 2005, 58,756 births occurred to NC women enrolled in Medicaid. The average cost per birth (and first year of life) ranged from $3,627 for infants weighing over 2500 grams to $65,954 per infant weighing 500 to 1499 grams. While LBW infants in North Carolina are 10.9% of the total Medicaid births, they consumed 42% of total Medicaid expenditures for all births.

Description: The Neonatal Outcomes Improvement Project centers on two innovations. First, state Medicaid Agencies will be directly engaged in facilitating the implementation of quality improvement activities related to neonatal and prenatal care. Second, a network of collaboration and learning among participating states will be built to enhance diffusion of those policies and program activities that best further healthcare value.

North Carolina and the Division of Medical Assistance (DMA) will build upon the collaborative experience and success that we have demonstrated in our primary care quality models. NICHQ, in conjunction with the state neonatal collaborative, will support the development of standard performance metrics to track and drive specific quality interventions. Our approach will be based on the Institute for Healthcare Improvement's Breakthrough Series Collaborative model. Critical components of the Neonatal Outcomes Improvement Project will include self assessment, data analysis and feedback, quality improvement training, team building, evidence reviews, and establishing networks for information sharing and peer accountability.

North Carolina is well along in the process of establishing a statewide consortium of perinatal providers, hospital administrators, government officials, health care payers and families whose mission is to execute quality improvement initiatives. This consortium is the PQCNC. The DMA is a vital member of this organization. The goal of the consortium initiatives is to promote perinatal care practices that minimize the burden of diseases of mothers and infants in an economical and family-centered manner. This will be accomplished by focusing on reducing mortality and morbidity associated with premature birth and low birth weight. DMA and PQCNC have a shared vision that North Carolina families will receive the best possible perinatal care. This will result from developing care systems based on safety, effectiveness, family-centeredness, timeliness, efficiency and equity.

It is through our collaboration and partnership with PQCNC that we expect to achieve the goals of the Neonatal Outcomes project. We will augment our current PQCNC representation with key technical staff from our Agency. PQCNC will be assisted by NICHQ on this project. PQCNC will review for endorsement the recommendations and measures developed by the national expert panels convened by CMS and NICHQ. PQCNC will facilitate performance self assessment by participating NICU's and assist in the formation of local perinatal quality improvement teams (PQITs). Participating NICUs will report on their performance monthly throughout the project period.

Key technical staff from PQCNC, including all Medicaid expert participants, regional coaches and local PQIT members will undergo training in quality improvement methods. NICHQ will support this training. Our goal is to enhance local hospital and community expertise and help train future teams in quality methods that will lead to ongoing innovations and sustainable improvements in neonatal and perinatal care delivery. Leadership from PQCNC and all local PQITs, together with our agency Medical Director and the key technical staff, will attend a national technical assistance meeting with teams from other state NICUs and agencies. Attendees will learn from clinical experts, quality improvement specialists and peers at Medicaid and other NICUs, and exchange experience, data and results. Organizational teams will plan specific changes they will make in their own units. PQCNC leadership and NICHQ will undertake regular coaching on data collection and reporting, improvement methods, spread strategies and will teleconference on a monthly basis. Eight additional NICUs will be added to the initiative in year two. During year two, deployment of pragmatic tools, which will be field

tested and refined for North Carolina through the collaborative learning process in year one, will occur. The above processes will be done in partnership with NICHQ staff and experts.

NICHQ, as an agent of the Centers for Medicare and Medicaid Services, has identified a package of required high level changes to improve neonatal care which will form the basis of the project. The required areas of investigation are:

- Identification and treatment of chronic medical conditions and high risk behaviors (smoking substance abuse, domestic violence)
- Use of antenatal steroids in pregnant women at risk of preterm delivery
- Prophylactic or early administration of the first dose of surfactant to premature infants at risk for Respiratory Distress Syndrome (RDS)
- Coordinating NICU discharge.

In addition North Carolina will target at least one of the following areas:

- Early identification of mothers at high-risk for prematurity (including those in rural areas) and prenatal transfer of these expectant mothers to facilities with tertiary care NICUs
- For those premature babies born at facilities without tertiary care neonatal intensive care units, optimal resuscitation and stabilization of the baby before transfer to the appropriate facility
- Nutrition Care Bundle in the NICU for infants at risk for poor growth and BPD
- Proper Infection Control Practices in the NICU and hospital to prevent hospital-acquired infection
- Planning and Optimizing follow-up care of high risk infants and high risk mothers.

North Carolina Medicaid is effectively poised to incorporate high quality data sources into this project. The PQCNC has contracted a data subset (NC Collaborative Data) within the Vermont Oxford Network, the leading neonatal benchmarking data system. North Carolina also has two well established database systems which provide valuable information on perinatal care: (1) Birth Certificate clinical data; (2) the Pregnancy Risk Assessment Monitoring Systems (PRAMS)-an ongoing mail/telephone survey of women who have recently given birth. Both of these systems are supported through our State Center for Health and Vital Statistics. With these rich and reliable data sources, we have a foundation for defining baseline conditions and measuring the outcomes of specific initiatives. Through this project, we will establish a consistent means for integrating such resources with the information available through the existing Medicaid database. We plan to refine interfaces between current data systems allowing queries that relate outcomes, quality and resource utilization for Medicaid patients.

North Carolina looks forward to the opportunity to begin work in the interest areas designated by NICHQ:

- Chronic Medical Problems and High Risk Behaviors: North Carolina has significant expertise in smoking behaviors and cessation, but continues to be challenged by the impact of maternal smoking. Maternal smoking rates in North Carolina have declined, but the infant death rate in 1999 for women who smoked during pregnancy was 13.0 infant deaths per 1,000 live births, compared to a rate of 6.7 among women who did not smoke during pregnancy (for single live births only). The difference in infant mortality between women who did and did not smoke during pregnancy is even greater for some specific causes of infant death. In 1999, there were 2.8 sudden infant death syndrome (SIDS) deaths per 1,000 single live births among women who smoked, compared to 0.5 among those who did not smoke (relative risk = 5.6). The infant death rate from respiratory conditions was 1.2 per 1,000 women who smoked during pregnancy and 0.6

- Antenatal Steroid (ANS) Use: PQCNC data is available for 11/13 state tertiary centers in our 2005 report. While our median rate of administration appears to be reasonable, 82%, VON data is based on one dose of steroid administered, not a full course. It is also noteworthy that we have one referral center at 45% which may represent inadequate use of ANS in preterm births in community level facilities. We have a significant interest in developing an understanding of the rates of a complete course of ANS administration as well as assessing local rates of ANS administration to mothers progressing to delivery.
- Prophylactic Surfactant Administration: A Vermont Oxford study of neonatal intensive care units produced a 37 % improvement in the early use of surfactant in the delivery room.(17) Significant improvement in infection rate and BPD has also been achieved through use of a collaborative approach.(18) Our 2005 PQCNC report shows great variability in this practice. This suggests either a great opportunity for improvement or the movement of some centers toward less invasive ventilation practices. Further study planned for this topic includes questionnaires and site visits to determine current NICU practices, development of delivery room protocols and measurement of administration and CLD rates. Development of more refined interfaces between state data systems will allow the DMA to determine the rates for this and other measures for DMA patients.
- NICU Discharge: The goal is to optimize the NICU discharge process by focusing on discharge planning from the time of admission in a patient and family centered approach. It is currently assumed that a multitude of factors affect preparation of families and patients for discharge. These include individual provider habits, unit culture, availability of staff, distance families travel to be with their children, language, cultural and educational barriers. It is our aim to develop survey instruments to assess current discharge practices in all NICUs and use the results to determine best practices for NICU discharge. We are also attempting to develop methods to access local hospital satisfaction survey data in evaluating family perceptions of discharge planning and preparation. Just as important to this intervention is coordination of NICU follow up care. We will explore the options of enhancements to the current CCNC Case Management Information System (CMIS) and the development of a high risk database to support follow up. We will work collectively with the existing CCNC support structures to facilitate consistency in access to follow up and completion of discharge recommendations. The availability of data will provide the critical feedback for analyzing results of quality interventions in year 2 and beyond. Universal access to such data will be vital in solidifying knowledge of the best practices in North Carolina neonatal care units.

The North Carolina Medicaid Program has fervent interest in all the proposed optional areas of intervention. Our initial PQCNC Collaborative report suggests significant disparity in outcomes amongst NICUs related to chronic lung disease and nosocomial infection. These are areas of high interest to state neonatal providers with clear opportunities for standardization and improvement. It is likely that prevention of nosocomial infections will be selected as a fifth target.

Equally of interest in the state are research efforts and clinical programs designed to prevent prematurity and explore its disturbing racial disparities. Duke University is the recent recipient of a $7 million EPA award to study causes of prematurity. A state wide effort to

promote interconception care has recently been funded by the University of North Carolina. The State legislature has recently approved a vigorous 17 hydroxyprogesterone (17P) administration program designed to prevent preterm delivery in high risk mothers. PQCNC has growing obstetrical care membership and a prematurity prevention bundle that targets interconception care, 17P administration, statewide implementation of fetal fibronectin screening, an ANS enhancement program and regional analysis of deliveries of VLBW infants has been considered. Each of these factors highlights the wealth of experience available through this PQCNC partnership and illustrates the timeliness of support for these efforts through CMS.

A large number of community hospitals and outpatient practices have focused significant interest on newborn resuscitation, stabilization, and establishing a proper medical home for high risk infants after discharge. North Carolina's statewide regionalized program of perinatal and neonatal outreach educators is committed to improvements in this area.

North Carolina Medicaid and PQCNC are committed to pursuing additional projects beyond those required for the demonstration project. After careful analysis of the baseline data and consultation with the Collaborative, we will assess the potential impact and select projects which offer the greatest benefit to the NC Medicaid population.

II. Project Justification

The missions of PQCNC and the Neonatal Care Outcomes Improvement Project are analogous. We both seek to close the gaps that exist between care that is currently delivered and the care that could be delivered. National and PQCNC data clearly delineate the quality chasm that exists in neonatal care. AHRQ data suggests that coordinated quality programs to reduce nosocomial infection and maximize employment of antenatal steroid use and early surfactant therapy would lead to $175,000,000 in national gross cost savings. Implementation of effective maternal smoking cessation programs have the potential to save 338 neonatal lives per year.(19) Furthermore, it is estimated, in 1995 dollars, that an annual national drop of 1 percentage point in smoking prevalence would prevent 1300 low birth weight live births and save $21 million in direct medical costs in the first year of the program; it would prevent 57,200 low birth weight infants and save $572 million in direct medical costs in 7 years.(20) North Carolina PRAMS data indicates that the percentage of women counseled regarding the effects of smoking in pregnancy declined from 2000 to 2002. North Carolina citizens, as well as the nation at large, are in dire need of the rewards that can be reaped through this Neonatal Outcomes Improvement Project. North Carolina Medicaid anticipates significant cost reductions in direct and indirect care with resultant benefit to CMS. The improvements in care that occur in the neonatal period for these individuals will potentiate savings for the future by decreasing the morbidities and care disparities that ultimately lead to increased ongoing expenditures.

Despite the high cost of providing care to premature infants, estimates of return approaching 500% for neonatal care have been reported. This estimate was made based on the estimated economic value to society of length and quality of survival of newborn infants receiving NICU care. Such a return makes neonatal care more cost effective than interventions including treatment of severe hypertension or routine pap smears for women age 20-74.(16)

North Carolina offers CMS a unique environment for implementation of this project. The DMA has significant experience in executing quality programs that have been very successful in the primary care environment. In PQCNC, DMA is part of an established and maturing connsortium of the statewide stakeholders in perinatal care. This group is committed to a quality

agenda, has an established and growing dataset for neonatal outcomes, has begun the process of identifying leaders for local PQITs, and is in the process of identifying quality initiatives, which include resource consumption and all the areas proposed by the Neonatal Outcomes Improvement Project. PQCNC enjoys great support and enthusiasm statewide; funding for organizational and development costs and a more modest scope of quality interventions than CMS has proposed include a UNC Investment for the Future grant and NC legislative funding. In addition to funding received this year, legislation (S474) is currently pending that will support recurring funds for PQCNC. In short North Carolina offers a very worthy Medicaid population, a DMA group committed to transformation via quality and an established stakeholder group committed to this effort with clear evidence of support for the sustainability of these efforts beyond the term of the Neonatal Outcomes grant. This project will have great impact on a high volume, high risk and high cost of care, but as importantly the Neonatal Outcomes Project will add innovation to a state quality infrastructure which DMA will readily apply to additional challenging areas of care.

In addition to previous experience, the DMA has supported the deployment of master's level clinical nurse specialists (Perinatal/Neonatal Outreach Educators), located at tertiary perinatal hospitals in each of the seven NC Perinatal Health Regions. These CNSs, have worked to improve the quality of perinatal care provided by local health departments, tertiary and community hospitals, community health centers, and private health providers within their regions to Medicaid recipients through implementation of evidence-based practices, clinical education, training, skills development, preceptorship and evaluation. NICHQ will build on this foundation and work with these educators to enhance the ability of local PQITs to implement best practices and evaluate outcomes to effect sustainable improvement in local care. NICHQ will assist PQCNC in designing regional and state wide quality projects and will serve as a change agent by optimizing stakeholder buy-in and assisting in the implementation of the initiatives. A component of change that is vital to success of the project is the movement toward family centered care. NICHQ's experience in this area will be a tremendous asset to the collaborative. We will use NICHQ's expertise in educational planning and evaluation to provide high-quality education to physicians, nurses, and other health care professionals to enhance knowledge of effective measures to improve neonatal outcomes. While the education and skills developed locally will be readily adaptable to future quality endeavors, the skills and expertise developed by the state Medicaid office during the Neonatal Project will ensure the success of new quality projects.

III. <u>Project Goals and Outcomes</u>

The statewide goals, strategies and intended anticipated outcomes are as follows:

- Reduce infant morbidity and mortality by implementing practices targeting high risk areas of perinatal care. PQCNC and NICHQ will identify critical process and outcome metrics for quality improvement initiatives aimed at reducing the variability of practice and enhancing outcome improvement. Our goals at minimum include reduction in the rates of maternal smoking, serious neonatal sequellae (including BPD, neurodevelopmental disability, and nosocomial infection) and reductions in overall and unplanned use of healthcare resources for infants after NICU discharge.
- Using data from a variety of sources, we will monitor the consumption of health care resources and conduct initiatives aimed at reducing resource consumption while

maintaining quality of care. We expect reductions in resource use to manifest in areas which include decreased clinical interventions, length of stay and hospital cost.

- We will attempt to enhance the benefits of quality interventions by developing and implementing strategies that integrate families into project execution. The intent of these interventions will also be to enhance family satisfaction with care processes. We will analyze the effect families have on the delivery of care with regard to clinical outcomes and resource utilization.
- Transparency and validation of data to stakeholders across the Collaborative is vital. It is our intent to develop a pathway for transparency amongst participating centers over the first year. In the second year it is our expectation that a successful collaboration will lead to a willingness and desire for all participants to allow all PQCNC stakeholders, families and payers to have access to statewide outcomes data.
- In collaboration with other state participants, we will develop a model of care that disseminates learning to other NICUs, states, regions and Medicaid Offices. This collaboration will allow for the development of case mixed, risk adjusted data that can be applied across states and nationally.
- We will enhance potential effectiveness and efficiency for all services insured through Medicaid by improving the capacity to promote quality improvement locally. Support of this project will further our expertise in the development and application of quality measures. Community Care North Carolina provides our framework for future Medicaid quality transformation in other multidisciplinary areas of care in North Carolina. With additional integration of functional health information technology, the transformation should be dramatic in scope.
- Through collaborative development of metrics and standards with Medicaid agencies from other states, we will intensify national transformation in the area of perinatal care.

IV. Estimate of Impact to Beneficiaries

In 2005, Medicaid paid for 58,756 births in the state of North Carolina. This accounted for 48% of all North Carolina births. Of Medicaid births, 10.9% of were classified as LBW. This accounted for 57% of all LBW infants in the state. Medical costs for the LBW infant population were $137 million, 42% of Medicaid infant payments. Literature supports that implementation of successful quality initiatives that reduce nosocomial infection rates in LBW infants could lead to an annual savings of $5 million in 2005 dollars. The authors also propose that if one assumes that nosocomial infection impacts other neonatal morbidities that a successful infection prevention effort in LBW infants could result in much greater savings.(21) This reasonable assumption translates into a potential annual savings of $15.5 million in 2005 dollars for the state of North Carolina.

The positive impact of this project on North Carolina beneficiaries includes partnership in determining the future direction of neonatal care in the state, the opportunity to inform care providers and payers in developing methods of care which promote family involvement at the NICU level, assisting in further exploring the role of families in improving outcomes, and the reduction in morbidity and mortality that will accompany successful interventions. Significant enhancement of full courses of antenatal steroids, reductions in CLD and infections, and even modest reductions in LBW rates would have enormous impact for North Carolina beneficiaries. Length of stays would be reduced, less neonatal resources would be required, and children would

be discharged home with less long term medical complications. The sequellae of prematurity are long term and in many cases lifelong. The Institute of Medicine report describes longitudinal costs that average $31,000/year for the first seven years for infants born less than 28 weeks. Based on the IOM estimate, annual costs for all such infants less than seven years in North Carolina is approximately $63 million. A combination of interventions which reduced the number of less than 28 week infants with significant complications by 10% would save the state an additional $6.3 million in annual costs beyond initial NICU hospitalization.(22)

The impact to beneficiaries would include reduction in needs for medical care, reduced pain and suffering from complications related to prematurity and neonatal care, and an increase in quality life years. The enhancements to the care process during and beyond NICU care will translate into more coordinated and efficient care delivery as these infants enter the primary care system through CCNC. Lessons learned through data coordination and sharing will facilitate maintenance of better health records as they transition from Medicaid to SCHIP to private coverage throughout their lives.

V. Description of Magnitude of the Transformation/System Change

This project is a national effort which will initially impact four states, but will ultimately spread to all fifty states after year two. This project offers an unprecedented opportunity for states to function as learning laboratories, allowing collaborative learning that will enhance spread of best perinatal practices throughout the Medicaid system. The sad reality is that more than two-thirds of all deaths among Americans under age 15 occur in the first year of life, and nearly half occur within 28 days of birth.(23) Complications of prematurity and low birth weight are the greatest contributors to mortality among children and youth. This project has the potential to significantly reduce the number of children dying early in life. In addition, the caring for premature and low birth weight infants is the largest source of Medicaid expenditures for children. This project has the potential for enormous impact on both health outcomes and cost.

We will work with 12 NICUs in year one. This represents 40% of the state's current NICU's. We will expand to 20 NICU's in year two, this expansion will encompass 75% of the state's current NICUs. In addition, this project is part of a national effort. In the first phase, we anticipate working in concert with 4-12 additional states, creating greater transformative impact than a single state initiative would on its own. NICHQ's intent is to spread the successful approaches and measures defined in this initial project period to all fifty states after the 2 year proposed project period through a national neonatal outcomes quality improvement campaign.

The collaborative methodology described, including the formation of a broad based coalition, the establishment of collaborative relationships aimed at improving the quality of health care, the establishment of common metrics and creation of an infrastructure to report and share performance data will lead to the development of an expanded quality infrastructure across the state. The potential direct quality benefit and cost savings of this project to the DMA and Medicaid perinatal patients are enormous. Proper execution of this initiative will require the spread of a quality infrastructure to inpatient facilities offering perinatal care. We propose to construct a quality training and education system which will not only carry out this project, but will leave in place at community and tertiary centers a cadre of experts capable of supporting and training participants in future DMA collaborative work. Successful implementation of the Neonatal Outcomes project means that DMA will have developed a self-sustaining statewide quality collaborative infrastructure capable of being deployed in other high cost/high impact

Medicaid populations and conditions. We anticipate expansion of current work in primary care areas, including diabetes and cardiovascular disease, to include inpatient care delivered across the state. The Northern New England Cardiovascular Disease Study Group has shown reductions in inpatient mortality of 24% for coronary bypass patients via collaborative learning and quality implementation. Developing an infrastructure that sustains such efforts would relieve the DMA and North Carolinians of a tremendous physical, emotional and fiscal burden.(24)

VI. Description of Sustainability of the Project

Using quality improvement strategies to change systems of care is key to the sustainability of the improved clinical practices. This effort will have key components of success; buy-in from key stakeholders, effective use of data, establishment of effective local PQITs, sensitivity to privacy concerns, clear communications of core knowledge to PQCNC, partnering with national organizations, financial support for infrastructure development, establishing a business case that stresses a return on investment, and provider incentives to participate. A key component of the Neonatal Care Outcomes Improvement Project is to build improvements into the fabric of normal practice at the bedside.

PQCNC has been in development for several years and formally began the organizational process this year using seed funding from legislation approved by the State of North Carolina. North Carolina DMA and Public Health have actively participated since inception. This year PQCNC was awarded a UNC School of Medicine Investments for the Future Grant. This three year award allows us to further refine our organizational structure, solidify collaborative data relationships with VON and the State, construct and develop a timeline for realistic implementation of two statewide multidisciplinary collaborative projects. Current projects being considered by PQCNC are all contained within the perinatal interest areas established by CMS. We have received legislative funding on an annual basis. Currently recurring funding for PQCNC is being considered. Given the significant legislative interest that has been generated, we believe that future funding will follow our demonstration of effectiveness.

PQCNC will work in partnership with NICHQ to solicit funds from private foundations, including the March of Dimes, Duke Endowment and the Kate B Reynolds Fund, to sustain the project beyond the two years of this grant. We view this as a requisite as we intend to remain a force in the national campaign to spread and support adoption of best perinatal practices across all fifty states. It is also anticipated that with improved clinical outcomes that Medicaid will realize costs savings; this may potentially provide North Carolina with resources to sustain this project and spread the improvement model to other areas.

VII. Evaluation Plan

The Neonatal Care Outcomes Improvement Project design is suffused with extensive data that allows for programmatic evaluation. The data are of two fundamental types:

1. Team derived data: This is the most fundamental component of evaluation data. Specific measures for our state to track throughout participation in the collaborative process have been identified by national experts. These measures will include: process, outcome, global outcome and cost outcome measures specific for each intervention package. These measures will be tracked using registries (databases) of babies born prematurely and encounter based measures. Our NICU sites will report monthly on the key

collaborative required measures as well as additional measures specific to our state's individualized aims. Data will be collected in such a manner that it can be aggregated across multiple participating sites. Because these data are used to drive improvement, we anticipate that they will be openly reported within the collaborative (on a password protected "extranet").

2. Participant evaluation data: In addition to using these performance based evaluations of team and overall project performance, NICHQ conducts systematic evaluation of the experience of project participants through surveys, and interviews of faculty, parents, and other stakeholders involved in the project. Such experiential data provide specific insights into the continuous improvement of the collaborative process. With its linked birth and infant death file, the State Center for Health Statistics will provide support in tracking birth weight specific neonatal and infant death rates for the hospitals targeted by this project. These rates could be risk-adjusted for maternal age, race, education, or other variables collected on the North Carolina birth certificate. Also, comparisons to similar hospitals not targeted by the project could be made.
3. Medicaid claims data: The claims data warehouse maintained by North Carolina's Division of Medical Assistance is available for evaluating the cost and length-of-stay impact of the specific interventions relating to BPD, surfactant administration, and nonsocomial infections as well as overall LBW cost-per-case comparisons.

VIII. Description of the Project Implementation Readiness

In Year 1 we will:

a) Hire and/or allocate PQCNC staff to lead this project in the state
b) Work within PQCNC to gain stakeholder support and identify NICUs that will participate
c) As a PQCNC stakeholder, participate in developing formal member agreements with participating sites
a) Assist in assembling state technical expertise to support the project
b) Send selected representatives from PQCNC (parents, Medicaid and other payers, consumers, administrators, providers) and all PQITs to a national meeting hosted by NICHQ
c) Facilitate and host a site visit of NICHQ-identified experts in clinical care and quality improvement to the Medicaid office and NICU sites
d) Support PQCNC and NICUs in implementing best practices in their sites through monthly calls, site visits, and technical assistance in data collection. We will work through PQCNC to identify clinical methods and individual units with the highest rates of diffusion. We will seek to identify causes for successful diffusion and develop spread plans for these discoveries to other participating centers in and out of state.
e) Incorporate quality improvement methods in our own Agency to increase our effectiveness, efficiency and ability to promote effectiveness/efficiency in providers
f) Identify and address policy and regulatory changes that could facilitate the improvement process.
g) Continually measure and report on our results

In Year 2 we will:

a) Identify additional NICU sites to work with and develop formal agreements with these additional sites
b) Send representatives from PQCNC and PQITs to a national meeting hosted by NICHQ
c) Facilitate and host a site visit of NICHQ-identified experts in clinical care and quality improvement to the Medicaid office and NICU sites
d) Support PQCNC and NICUs in implementing best practices in their sites through monthly calls, site visits, and technical assistance in data collection. We will work through PQCNC to identify clinical methods and individual units with the highest rates of diffusion. We will seek to identify causes for successful diffusion and develop spread plans for these discoveries to other participating centers in and out of state.
e) Incorporate quality improvement methods in our own offices to increase our effectiveness, efficiency and ability to promote effectiveness/efficiency in providers
f) Continually measure and report on our results
g) Develop a plan to share learning to other NICUs in our state

Grant resources will be used to support the mission of PQCNC. Pivotal in this implementation effort will be the development of local PQITs. The success of this effort will rely on the ability of PQCNC to provide communication and education support for the development of these groups. The administrative core of PQCNC will serve as the day to day contact for local quality teams. The PQCNC Executive Board will work with NICHQ to identify best evidence and sites with potential best practices. As intervention areas are adopted, intervention strategies, goals and monitoring plans will be developed using PQCNC subcommittees. Discussions will be held with PQITs to determine best approaches to project implementation. Formal education sessions for initiatives will be held regionally and statewide using a variety of mediums. Projects will likely be rolled out regionally allowing smaller group experimentation to more rapidly identify best mechanisms for change introduction, implementation, diffusion and adoption. PQCNC will work with NICHQ to ensure that all members of the PQIT have access to a basic web-based course in quality improvement and that proper methods for data collection and analysis are established.

IX. Budget

Neonatal Outcomes Improvement Project	**FFY 2007***	**FFY 2008****	**Total**
Personnel/ Fringe Benefits *(Fringe @30%)*			
Project Director (0.6 FTE) Neonatologist	$145,000	$72,500	$217,500
Education Coordinator (0.6 FTE)	$60,000	$30,000	$90,000
Statistician (0.6 FTE)	$60,000	$30,000	$90,000
Project Team Leaders (0.1 FTE/project X 5 projects)	$75,000	$37,500	$112,500
Quality Support Staff (0.6 FTE)	$60,000	$30,000	$90,000
Total Personnel	**$400,000**	**$200,000**	**$600,000**

Contractual Costs			
NICHQ Support[1]	$175,000	$87,500	$262,500
Database Support/ Modifications[2]	$265,000	$132,500	$397,500
PQCNC Website Support	$40,000	$20,000	$60,000
Total Contractual	**$480,000**	**$240,000**	**$720,000**
Supplies			
Education Materials	$2,500	$1,250	$3,750
Standardized Forms	$2,500	$1,250	$3,750
Total Supplies	**$5,000**	**$2,500**	**$7,500**
Equipment			
Computers and Supporting Quality Software	$25,000		$25,000
Total Equipment	**$25,000**	**$0**	**$25,000**
Other Costs			
Travel[3]	$115,000	$130,000	$245,000
Teleconference and Web Meetings	$25,000	$12,500	$37,500
Other Education[4]	$50,000	$30,000	$80,000
Total Other Costs	**$190,000**	**$172,500**	**$362,500**
Total Project Budget	**$1,100,000**	**$615,000**	**$1,715,000**

** FFY 07: 12 months, September 30, 2007 to September 29, 2008*
*** FFY 08: 6 months, September 30, 2008 to March 31, 2009*

Budget Notes:

1. Includes educational, change packages and quality support.
2. Enhancing interface capabilities, VON, database development.
3. Includes local, state and national meetings regarding neonatal outcomes, educational conferences. Local/regional meetings: $30,000 Year 1 & $15,000 Year 2. State neonatal outcomes quality meeting: $10,000 Year 1 & $10,000 Year 2. National neonatal outcomes meeting: $75,000 for 12 NICU quality teams to attend Year 1 & $105,000 for 20 NICU teams to attend Year 2. Higher travel cost in Year 2 due to larger number of participating sites and increased conference attendance.
4. Training PQIT staff, onsite training at participating NICUs.

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