



NEWSLETTER

Winter 2006

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2005 ANNUAL MEETING AND QUALITY CONGRESS

The 2005 Vermont Oxford Network Annual Meeting and 6th Annual Quality Congress for Neonatology were held on December 3 and 4, 2005 in Washington, DC. Over 600 medical professionals representing many different disciplines attended the meetings.

At the Annual Meeting plenary presentations included an overview of Network activities and plans by Jeffrey Horbar, and an update on the Help trial and follow-up projects by Maureen Reilly and Charles Mercier.

A thought provoking and instructive session on Translating Evidence into Practice included an illuminating presentation by Jon Tyson, Critical Evaluation of Study results: When Should Evidence Affect Clinical Practice. Dr. Tyson presented a provisional definition of an “unproven intervention” and suggested an approach to deciding when an unproven therapy should be used. Robert Pfister then reviewed his observational research in which he documented and classified the actual decisions made by a NICU team during their daily rounds. Over 60% of the decisions were not supported by evidence of a high level (Systematic review or RCT with narrow confidence interval). This session raised a number of important issues regarding how decisions are made in day-to-day NICU practice.

The Annual Meeting also included a session on neonatal encephalopathy. Jeffrey Horbar described the Network’s plans for a Registry and an iNICQ Internet Collaborative on the topic of Neonatal Encephalopathy (see accompanying articles). Terrie Inder presented a state of the art lecture on neonatal encephalopathy. Her expert review addressed the diagnosis, pathophysiology, and treatment of neonatal encephalopathy.

Breakout sessions in the afternoon provided an opportunity for smaller group learning and interaction. Breakout sessions included Hot Topics in Neonatal Nursing led by Jeannette Rogowski and Thelma Patrick, Global Neonatology with Steve Ringer, Steve Wall and Gary Darmstadt, an eNICQ Users’ Group with Joe Carpenter, Dan Morris and Mike Kenny, a discussion of “unproven therapies” in the NICU with

Jon Tyson, Jerry Lucey and Andrew Wilkinson, and a discussion of neonatal encephalopathy and

hypothermia with Terrie Inder, Karin Nelson, Tonse Raju and Jeffrey Horbar. The Annual Meeting concluded with an open discussion, The Next Ten Years, in which members engaged the Network Directors in dialogue.

The 6th Annual Quality Congress began with a session, Organizational Change and Improvement: Four Perspectives, moderated by Deb Miller. Ralph Stacey opened the session with a discussion of the learning organization from the perspective of complex responsive processes. Steve Shortell addressed the evidence from observational studies of interventions designed to promote organizational change. Martin Eccles reviewed the evidence for randomized trials of organizational intervention. Richard Burton reviewed the evidence from simulation studies of organizational improvement. The four speakers gave a broad view of different approaches and ways of thinking about organizational change.

The next session of the Quality Congress, Collaborative Quality Improvement in the NICU, opened with an overview of collaborative improvement by Jim Handyside. Michele Walsh presented the results of the NICHD Neonatal Network benchmarking Study and Rob Payne presented the results from the Vermont Oxford Network NICQ Improvement Collaborative. The differing results of the two studies led to lively debate and discussion.

The final session of the day addressed New Strategies for Quality and Safety. Lou Halamek presented an excellent overview of how simulation methods can be used in clinical team training. Gautham Suresh presented the fascinating results of his study of video taped observations of central line placements. The audience clearly recognized that many of the errors noted in that study were also present in their own practices.

The Quality Congress closed with a poster session at which over 50 teams presented case studies of their local improvement work.

GLOBAL NEONATOLOGY

Following several presentations and a breakout session on global or international neonatology at the 2004 Annual Meeting, it was clear that there was considerable interest in this topic within the Network. A survey of members done during 2005 provided additional information on both the scope and magnitude of this interest. In response, a breakout session on Global Neonatology was held at the 2005 Annual Meeting, attended by 50 people. The session began with three presentations. Steven Wall, MD, from Saving Newborn Lives/Save the Children presented a discussion on Developing Priorities and Strategies to Improve Global Neonatal Health and Care. He discussed approaches to developing programs based on the type of program (e.g. community based) and on where, along the continuum of perinatal health, it is aimed. Steve also discussed a number of projects in which SNL was involved, and outlined methods for capacity building and using research as a tool in driving improvement in care. Steve highlighted the need for an organized plan for research, and some of the obstacles and difficulties in performing it well at the different sites. Gary Darmstadt, MD, from Johns Hopkins University and Save the Children then presented an Update on New Findings and Priorities for International Neonatal Health Research. Gary reviewed the recent Lancet articles describing a series of recent interventions. He outlined the key knowledge gaps in neonatal health and discussed the development and packaging of neonatal interventions. Gary finished by presenting a review of recent research projects and discussed the use of research findings and community involvement in helping to change and advance care. Finally, Steven Ringer, MD, PhD, from Brigham and Women's Hospital/Harvard Medical School presented a proposal for developing an organized scheme or "road map" for the development of neonatal care in developing countries. Based on his experience in Vietnam he highlighted the need for a stepwise method for introducing care advances, education, and research. All three speakers noted the need to involve local or community champions in the sites targeted for development.

These presentations were followed by an active discussion among all present that included ideas concerning care development and the performance of research. The group focused on the best way for VON to be involved in this area of interest, and how to partner with SNL and possible other groups. There was agreement that a **VON working group** should be formed to examine the issues in greater depth and begin to move forward. While all are welcome, it is hoped that the group will include members with

experience working in the developing world, and that each such member will identify a local champion (physician, health official or community leader) from the place they have worked who will also join the working group. The charges for the VON-international group will include planning the role for a subgroup of VON in international neonatology, consideration of a strategy or roadmap for neonatal care, developing a structure for doing research in developing countries including an IRB mechanism, establishing the academic potential of global neonatology, and developing partnerships with other entities including the Save the Children organization.

If you are interested and did not attend the session, please contact::

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STANDARDIZED DEFINITIONS ARE CRITICAL

A major strength of the Vermont Oxford Network Database is that all of the participating centers have agreed to stick to the same definitions. This is critical! If the comparative data are to be valid, then everyone must apply exactly the same eligibility criteria and adhere precisely to the definitions of the data items in the Manual of Operations. We recognize that not everyone agrees with all of the definitions. This is not surprising given the difficulty of creating definitions that cover all of the unusual situations which invariably arise. The Vermont Oxford Network Database Advisory Committee has struggled with these issues and done their best to take your comments and suggestions into account when recommending data item definitions. So, even if you don't agree with a specific definition it is your responsibility to adhere to it anyway. That is the agreement that we have made with each other as members of a large collaborative Network.

MARK YOUR CALENDAR

NETWORK ANNUAL MEETING
Saturday, 12/02/06

7th ANNUAL QUALITY CONGRESS
Sunday, 12/03/06

Omni Shoreham Hotel
Washington, DC

PLAN AND THINK AHEAD ABOUT BRAIN COOLING – IT WILL HAVE A MAJOR IMPACT ON YOUR NICU IN TEN YEARS

Jerold F. Lucey, MD

At the Hot Topics Meeting in Washington, DC, we've been discussing brain cooling for nearly a decade! The animal evidence for its effectiveness in modifying brain cell damage is pretty convincing. The clinical evidence of its effects in infants now rests on two large randomized controlled trials, one of brain cooling and one of body cooling, plus a smaller trial of body cooling. Follow up studies at two years of age are encouraging. An as of yet unpublished study of brain cooling from Shanghai, China involving 178 infants presents encouraging results. Published commentaries, a report of an NICHD workshop and an AAP statement from members of the Fetus and Newborn Committee (to appear Pediatrics March, 2006) point out that we should be cautious in adopting this new therapy. Two large randomized control trials from Europe and one in Australia are in progress. They may be completed within the next two or three years.

We are entering a long period, of at least a decade, of uncertainty and debate. What should you do and when should you do it in your unit? It's not going to be easy to answer this question. It appears that many of the NICU's that have participated in the trials may continue to use this therapy in routine care. We don't have very good figures on the current incidence of neonatal encephalopathy or a specific definition accepted by all neurologists and neonatologists. It's generally accepted that "neonatal encephalopathy" occurs in 1 or 2 infants per 1000 births. You should be able to estimate how many infants your unit might receive from your area. It's generally assumed that some (many?) births occur in smaller hospitals. All are not transported to regional NICU's.

If you decide to offer this new therapy consider the following issues:

Do you have a transport system that can handle this? A major problem is that treatment should probably be started in less than 4 hours for best effects. You can expect that future studies will try to minimize this time delay with the hope of improving outcomes.

Have you educated your obstetrical colleagues about this new therapy? You should probably start an educational program for parents, nurses and MD's in your referral area.

Do you have enough trained staff? This therapy requires a team and takes extra nursing/physician time.

What about a neurologist and neuroradiologist on call or on site? Do you need them to help with interpretation of special EEGs, brain imaging, MRI, etc.?

Debates about selection criteria, such as EEG patterns, will continue for a long, long time.

What are the malpractice risks of offering or foregoing hypothermia? Current data on long-term outcomes are minimal. It's highly unlikely that all treated infants will be "normal". This is certainly a therapy that should not be hyped, lest expectations of perfection be expected.

It's likely that a new field of therapy will emerge - the chemoprevention of brain damage. New drugs are being developed and tested in adult stroke patients, which might be helpful if given during the "window of opportunity (4 hours?)" offered by brain cooling.

What will hypothermic therapy mean for your unit? Only you can answer this question.

These questions and more will be addressed by teams in the Vermont Oxford Network iNICQ Internet Encephalopathy Collaborative and the Neonatal Encephalopathy Registry(See below article).

There are no easy answers!

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REGISTRY FOR NEONATAL ENCEPHALOPATHY

The Vermont Oxford Network has established a Registry for Neonatal Encephalopathy. The Registry will enroll newborn infants with documented encephalopathy to identify their demographic characteristics, associated perinatal factors, medical treatments, co-morbidities and outcomes. The Registry will allow us to characterize the population of infants with encephalopathy, evaluate variations in current practice, identify opportunities for improvement in the quality and safety of care for infants with encephalopathy, monitor the introduction and dissemination of new neuroprotective therapies such as hypothermia, assess selection criteria for neuroprotective therapy, define important questions for clinical research, and plan prospective research and randomized trials.

Participation in the Registry is open to all member hospitals in the Vermont Oxford Network who are participating in the Network's Expanded Database in 2006. Data will be managed and submitted using the Network's **eNICQ** user software. The Registry will be supported by an optional module in this software.

The Registry will begin collecting data for infants born in 2006. The Network is committed to operating the Registry for an initial period of two years. Subsequent operation will be contingent on a review of the initial two years.

Because the data in the Registry may be used as the basis for publications and presentations about neonatal encephalopathy, all participating units must submit the project to their local IRB for review and approval. A letter of IRB approval from your center is required before your center can participate in the Registry.

Over 50 institutions have expressed an interest in participating in the Registry.

The Registry Steering Committee includes:

Adre Duplessis, MD,
Harvard University

Terrie Inder, MD,
Washington University St. Louis

Karin Nelson,
Neuroepidemiology Branch, NIH

Tonse Raju, MD,
NICHD Liaison

We look forward to working closely with multidisciplinary teams from these sites to extend our knowledge about this important category of patient.

iNICQ INTERNET ENCEPHALOPATHY COLLABORATIVE

The Vermont Oxford Network is pleased to report that multidisciplinary teams from 65 neonatal intensive care units in North America and around the world have registered for the iNICQ Internet Encephalopathy Collaborative. This will be the fifth in a series of Internet collaboratives that have addressed a variety of topics aimed at improving the quality and safety of medical care for newborn infants and their families. The collaborative will be coordinated with the Network's Registry for Neonatal Encephalopathy under the direction of Jeffrey D. Horbar, MD.

This clinically based; action oriented series includes 5 interactive 90 minute web conferences focused on Neonatal Encephalopathy. Presented by internationally recognized experts in health care improvement and building on the learning and materials from the Network's successful NIC/Q Quality Improvement Collaborative, each web conference provides formal teaching, interactive discussion and time for teams to work together. Prior to each conference, participating teams are provided with materials and prework assignments designed to prepare the team for action.

Collaborative members have access to a dedicated e-mail listserv. Free CME and Contact Hours are available to iNICQ Collaborative participants.

The topic areas of the iNICQ Encephalopathy Collaborative are as follows:

Overview of Neonatal Encephalopathy

January 10, 2006: Assessing and caring for newborns with encephalopathy based on state of the art current evidence.

Hypothermic Therapy

February 14, 2006: Current research relating to head and body cooling, issues regarding the conduction of research on human subjects.

Electrophysiology and Seizures

April 11, 2006: Practical considerations relating to the technology of performing EEG and aEEG in the NICU.

Neuroimaging

June 6, 2006: Methods of imaging the newborn brain, discussion of the incidence, presentation and treatment of neonatal stroke.

Follow-up and Community Services

September 12, 2006: Follow-up data available on newborns with encephalopathy, Family-centered care as it relates to supporting families of newborns with encephalopathy.

Participants will be invited to prepare a case study for the 2006 Quality Congress in Neonatology using the tools and information gathered from this series.

**iNICQ Encephalopathy
Faculty and Steering Committee**

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Director of Clinical Trials, Vermont Oxford Network

**iNICQ VALUE COMPASS INTERNET COLLABORATIVE
BEGINS MAY 2006**

The Vermont Oxford Network is pleased to offer a new six part Internet collaborative, *The NICU Value Compass: Pointing the Way to Better Outcomes*, beginning in May 2005. Under the direction of William Edwards, MD and Gene Nelson, DSc, participating multidisciplinary teams will learn to assess their unit's performance across important domains of outcomes to assess/improve quality and value of care. Teams will apply Value Compass thinking to their unit using tools and methods that have been tested by teams that have participated in the Network's intensive NICQ collaboratives.

What is the clinical Value Compass?

The clinical Value Compass, named to reflect its similarity to the NSEW compass rose, has at its four cardinal points (1) functional status and well-being, (2) costs, (3) satisfaction with care, and (4) clinical outcomes. It is a tool for monitoring performance across all of these domains in support of improvement. The measures in each quadrant of the value compass are driven by key underlying processes of care. In this iNICQ series we will explore the measures that NICU teams are using for each quadrant of a NICU specific Value Compass, and will identify the key processes that drive performance for those measures.

What are the goals of the iNICQ series?

- To promote understanding of the NICU Value Compass
- To assist NICU teams in developing and using their own Value Compass
- To identify key NICU processes that drive outcomes
- To improve the quality and safety of care for newborns and their families

What will be included in the series?

The series will include six interactive, 90-minute Internet sessions. Multidisciplinary teams from participating hospitals will view the slides over the Internet using Webex technology, and listen to the presentations and participate in the discussions via a conference call over a standard phone line. Many teams choose to meet in a conference room, project the slides using a digital projector, and connect to the audio with a conference speaker phone. Each session will include a pre-work self-assessment package. A 30 minute team exercise will be scheduled following each 90 minute session. This is an opportunity for the local team to test and implement change ideas learned in the sessions. A dedicated email discussion list will support the Value Compass initiative. A provisional schedule follows.

Provisional iNICQ Value Compass Schedule:

- Session 1: Introduction and Overview
May 10, 2006
- Session 2: The Clinical Quadrant
June 21, 2006
Clinical measures
Drilling down to key processes
- Session 3: The Satisfaction Quadrant
September 13, 2006
Satisfaction Measures
HowsYourbaby, an Internet tool for families
- Session 4: The Cost Quadrant
October 25, 2006
Cost and resource measures
Drilling down to key processes
- Session 5: The Functional Quadrant
January 17, 2007
Measures of functional outcome
Vermont Oxford Network Follow Up Project
- Session 6: Case Studies
February 28, 2007
Review of progress
Case studies from the participants
Next steps

What will it cost to participate?

\$3,500 per team includes one Internet connection and one phone line, plus continuing education credits for all team members. There is no limit on the size of the team. There is a \$500 discount for early registration (prior to March 15, 2005)

For additional information or to register please contact Pam Ford, iNICQ Coordinator:
Phone: 802-865-4814, extension 204
Fax: 802-865-9613
Email: pam@vtoxford.org

NIC/Q 2005 (YIN AND YANG)

The NIC/Q 2005 Collaborative is the fourth in a series of intensive face-to-face improvement collaboratives conducted by the Network. This group has two separate arms, YIN (Your Ideal NICU) comprised of 12 veteran centers, and YANG composed of 42 new and returning centers.

The first year of the two year project has been a busy one. The two arms had back to back meetings in Portland, OR in April '05 and again in Nashville, TN in September '05.

At the first meeting, the YANG centers focused on measurement for improvement, team effectiveness, and hazard analysis and management. Under the guidance of content experts, facilitators & clinical leaders, the centers began working in their topic specific exploratory groups to establish group aims and start the process of identifying potentially better practices. The exploratory group topics include: Pharmacy, Hemodynamics, Surgery, Nutrition, Respiratory Care, Physical Environment, and OB-Perinatal Care. There was extensive sharing of ideas on implementing change and promoting safety at the two poster sessions that were incorporated into the meeting.

At the fall meeting, the YANG centers continued their exploratory group work to refine potentially better practices and devise implementation strategies. Davis Balestracci, a well known statistician and quality expert, gave presentations on the use of run charts for data display and on the foibles of human nature and their effects on organizational culture. Poster sessions centered on measuring & holding the gains in improvement, and hazard analysis & control.

Building on previous Collaborative project experience and under the expert guidance of experienced coaches, the YIN centers began to apply the methods, tools and concepts needed to develop their own "ideal" NICU. We do not believe that there is a single "ideal". Each unit must define and implement their own idea. Within the framework of Microsystems thinking, the centers conducted baseline assessments of performance and issues to identify a process at their center to "idealize". Other central themes include Family-Centered Care and the construction of a clinical Value Compass. Over the summer, each YIN center had a 2 day site visit by their coach to enhance their efforts locally.

To further incorporate family-centered care, the YIN centers included parents on their teams attending the fall meeting in Nashville. The parents brought a novel and extremely valuable perspective to the project. In addition, the centers showcased their progress on their chosen ideal process through multimedia presentations and shared posters on Family-Centered Care & the "Stop the Line" concept.

The next meeting of the NIC/Q 2005 project will be in Albuquerque, NM on March 31-April 3, 2006. In addition to compilation of the Project work products, the YIN and YANG groups will overlap for a collaborative sharing session AKA "Rodeo" on the afternoon of Saturday 4/1/06.

NIGHTINGALE INTERNET REPORTING SYSTEM



The Vermont Oxford Network is pleased to announce that the Nightingale Internet Reporting System is now available to all member institutions. Nightingale will allow you to access your centers data and generate customized reports in tables and figures similar to those in the Network's Annual Quality Management Report. You will have access to your own center's data and to comparative data for the Network as a whole. The data available on-line include all years in which your center has participated beginning in 1990. Access to Nightingale is secure and confidential. Only those individuals authorized by the local administrator appointed by your center can access the system.

Nightingale is provided at no additional cost to all member institutions in the Vermont Oxford Network. So far over 130 institutions have signed up. Don't miss this exciting new opportunity.

We would like to thank the following institutions that served as beta test centers for Nightingale. Their comments and suggestions were extremely valuable in developing the system:

Akron Children's Hospital, Akron, OH
Arkansas Children's Hospital, Little Rock, AR
Columbia University Medical Center, New York, NY
DeVos Children's/Spectrum Health, Grand Rapids, MI
Mercy Medical Center, Des Moines, IA
Providence St. Vincent Medical Center, Portland, OR
St. Luke's Hospital, Cedar Rapids, IA
St. John's Hospital, Springfield, IL
Wesley Medical Center, Wichita, KS
Winthrop University Hospital, Mineola, NY
Women's & Children's Hospital, Lake Charles, LA

For additional information about how to sign up, please contact Nancy Cloutier (nancy@vtoxford.org).

SURVEY AND DATA VERIFICATION PLAN

The *2005 Membership Survey*, the *Contact Information Report* and the *Data Verification Plan for 2006* for your center were mailed to all Team Leaders in January 2006.

It is essential that we obtain the *2005 Membership Survey* information from each participant in the 2005 database before we complete the Annual Quality Management Report (QMR) later this year. We need this survey information to be as complete as possible so it will provide a detailed and accurate description of the membership.

The 2006 *Data Verification Plan* is a form that each participating center is required to fill out and update each year. Its purpose is to insure that all eligible infants are included in the Database each year. Every participating center must have their plan on file before they can be included in the Annual Quality Management Report.

Also included in this mailing, the *Contact Information Report* is a list of the contact information we have in our files for your center. This information should be updated each year so we can keep all center files as current as possible.

The survey and the data verification plan are due by April 15, 2006. If you want another copy of this mailing sent to your center please call Lynn Stillman at 802-865-4814, extension 211 or email Lynn at lynn@vtoxford.org

WELCOME NEW VON STAFF MEMBERS

Vermont Oxford Network welcomes our newest staff members to our team:

Our newest programmer, **Bradley Holt**, joined the Information Technology Team in July of 2005. His initial project was building the software for the Heat Loss Prevention (HeLP) clinical trial. He is currently working on the Neonatal Encephalopathy Registry. Prior to joining Vermont Oxford Network, Bradley worked as a computer trainer. He taught software applications and software development for Daniel Webster College, The State of New Hampshire and BAE Systems among other organizations and individuals. Bradley lives in Burlington with his partner, Jason. In his spare time he and his partner run their own graphic design, marketing and web development business.

Will Robb holds a BS in computer science and a MS in Statistics. His current work at VON involves exploring issues involved in modeling standard mortality ratios, assessing trends over time in outcome measures, and report programming. He is also employed at ORC Macro, where he has been a sampling statistician and statistical programmer for over a decade. As an active divorced dad, raising two blooming adolescents, Max and Zoë, keeps Will pretty busy. In whatever time is left, Will reads an eclectic mix of science texts and junk novels, cooks, stays involved in the Intervale Community Farm, and imagines he is a writer. Traveling when he can, recent trips have included Costa Rica, San Francisco, and Grand Canyon. He currently lives, as caretaker, at the Ethan Allen Homestead, in Burlington.

CONSIDER 2006 DATABASE CHANGES CAREFULLY

There are a number of changes to the 2006 Database, and some of these modify the item definitions from previous years. The Database Advisory Committee considers new items and changes each year, and these revisions represent those for which there was consensus for change. The revisions to the Manual of Operations are described in a document on the Network web site. Go to www.vtoxford.org and click on Member Tools/Downloads (2006 Revisions).

Some of the definitions from previous years have been modified and should be considered carefully when completing the data forms for infants born in 2006. These are highlighted below. Also remember that definitions in the 2005 Manual of Operations apply to infants born in 2005, and the definitions in the 2006 Manual apply to infants born in 2006.

- Perhaps the most noteworthy definitional change applies to the surgery section on the Discharge Form (item number 25). Prior to 2006, surgery items included PDA Ligation, NEC Surgery, ROP Surgery and Other Major Surgery. In 2006 the Other Major Surgery item is no longer included on the form. Members are now requested to enter any surgery code which appears in Appendix D of the Manual. Please be sure to carefully read the new description of the surgery items on pages 75 and 76 of the 2006 Manual.
- In previous years, the 28 Day Form has included a Cranial Ultrasound item. For infants born in 2006, the item definition has been modified to include cranial MRI or CT, and the item name has been changed to "Cranial Imaging" to reflect this revision (item number 17). Please see the new definition on pages 69 and 70 of the 2006 Manual.
- The definition of the Respiratory Distress Syndrome item on the Discharge Form (item number 26) has been modified to allow pulse oximetry as a criterion. Please see the new definition on page 77 of the 2006 Manual.
- Although the definitions were not changed in 2006, the item names for Delivery Room Resuscitation on the 28 Day Form have been changed to Initial Resuscitation in 2006 (item number 13). This change was made to clarify that these interventions may be performed in the delivery room or in an initial resuscitation area immediately following birth. Please see pages 67 and 68 of the 2006 Manual.

Several new items have been added to the 2006 data forms: Head Circumference at Birth (28 Day Form, item 5), Temperature at Admission to the NICU (28 Day Form, item 14), High Flow Nasal Cannula (Discharge Form, item 19d), Nasal IMV or SIMV (Discharge Form, item 19e), the new Surgery Codes item discussed above (Discharge Form, item 25d), and Head Circumference at Initial Disposition (Discharge Form, item 39). Please see the descriptions for these new items on the applicable pages in Chapter 8 of the 2006 Manual.

If you have any questions about the revisions for 2006, please contact your VON Account Manager.

eNICQ UPDATE

The **eNICQ** software, provided at no charge to Vermont Oxford Network members, is a useful tool for submitting data to the Network. Along with detailed documentation and installation support, the Network provides a help desk for members needing assistance.

Of the 584 members of the Vermont Oxford Network, 395 hospitals are currently submitting data electronically to the Network and, of these, 263 use the **eNICQ** software to enter and submit data. This includes 44 international members. There are 162 hospitals submitting data with **eNICQ** for VLBW infants and 131 centers for all eligible NICU infants to the Expanded Database.

A number of **eNICQ** resources are available on the Network web site. Go to www.vtoxford.org and click on Member Tools/eNICQ Information. These include documents describing the software capabilities, installation considerations and the **eNICQ** Users Guide. For current **eNICQ** users, the web site also includes the **eNICQ** Upgrade Center, with information about current releases, version history, upgrade instructions and a link to download the latest version.

The **eNICQ** On Line Help page is also available by clicking on Member Tools/eNICQ Information/eNICQ Online Help. This site is very helpful in answering data entry and export questions and gives instructions for resolving the most common problems experienced by **eNICQ** users.

In April of this year, a neonatal encephalopathy registry module is planned for release as an optional **eNICQ** module for members participating in the Expanded Database.

For additional information about **eNICQ** or to request the software, please contact your VON Account Manager or Nancy Cloutier (nancy@vtoxford.org).

CLINICAL TRIALS AND FOLLOW-UP PROJECTS

We have a lot of news to report as we begin 2006! There has been a great deal of activity, both in clinical trials and in our follow-up projects. The Delivery Room Management Trial continues to actively enroll infants, the Heat Loss Prevention Trial is in full swing, The Extremely Low Birth Weight Follow-up Project begins the seventh year of data collection, and the Parental Interview and Reporting Questionnaire survey was piloted on over 300 patients and the new revised form is being tested. A short summary of each of these projects follows:

Delivery Room Management (DRM) Trial

The Delivery Room Management (DRM) Trial is perhaps our most ambitious effort ever. The DRM Trial evaluates three distinct approaches to stabilization and support of premature infants at high risk of respiratory distress syndrome: intubation and surfactant treatment, intubation, surfactant treatment and rapid extubation to nasal continuous positive airway pressure (NCPAP), or NCPAP alone. Centers received extensive training in NCPAP and trials methodology via web conference prior to beginning the trial. Currently, we have 25 centers actively participating; 397 infants have been enrolled.

Enrollment has been difficult for this trial, but there is a firm commitment both from VON and the participating centers to continue with enrollment. Several centers with experience in NCPAP have stepped forward and asked if they could join these efforts. We welcome new centers and are arranging for appropriate educational materials and support for those interested in joining.

With these new centers and a strong commitment from our existing centers, we anticipate the DRM Trial to continue through 2007. Any center that is interested in joining this trial and has experience in Bubble CPAP please contact Karla Ferrelli at karla@vtoxford.org. Congratulations and many thanks to all the centers that have progressed and are participating in this trial – this is an important but difficult and challenging study and we appreciate your efforts and continued commitment!

Heat Loss Prevention Trial (HeLP)

Prevention of hypothermia is thought to be critical to survival of the smallest premature infants. The Heat Loss Prevention Trial (HeLP) is an international randomized control trial that evaluates whether polyethylene occlusive wrap applied immediately after delivery has an impact on mortality and morbidity in infants born between 24+0 and 27+6 weeks gestation. Interested participating centers are also enrolling

infants born at less than 24 weeks gestation as part of a separate pilot study. The HeLP Trial is a collaborative project led by two VON member centers, Sunnybrook and Women's College Hospital in Toronto and the University of Alberta (Co-Principal Investigators, Maureen Reilly and Sunita Vohra) and coordinated by the Vermont Oxford Network. Study enrollment began in November 2004.

Twenty eight centers have enrolled 161 infants in the main trial; in addition, we have 13 centers that are ready to begin their enrollment and 5 more that are waiting for approval by their Institutional Review Board. A trial update was presented at the Annual General Meeting 2005 and 7 new sites expressed interest in participating in the HeLP trial. We are still actively recruiting new sites; if you know of an interested VON center, please contact Luba Slatkovska by email at Lubomira.slatkovska@sw.ca or by telephone at 416-323-6400 ext. 3033.

Again, thanks to all of our participating centers for their efforts and hard work! We welcome any inquiries regarding joining the trial. A more detailed description of the study can be accessed on the VON website (<http://www.vtoxford.org/home.aspx?p=research/help/index.htm>).

Institutional Consent for the HeLP Trial

The principal investigators of the Heat Loss Prevention Trial (HeLP Trial), Sunita Vohra and Maureen Reilly, are interested in introducing the option of institutional consent in the HeLP Trial, in addition to the currently used parental consent. As such, the concept of institutional consent was discussed with the HeLP Trial participating sites that attended the last principal investigators' session at the VON Annual Meeting (December 3, 2005).

Institutional consent, or waiver of informed consent, is where the individual IRB grants consent for study participation rather than the parent or guardian, and it is only appropriate in research involving emergency situations, if the following specific criteria, outlined in the Helsinki Declaration, are met:

- a. a serious threat to the prospective participant requires immediate intervention; and
- b. either no standard efficacious care exists or the research offers a real possibility of direct benefit to the participant in comparison with standard care; and
- c. either the risk of harm is not greater than that involved in standard efficacious care, or it is clearly justified by the direct benefits to the participant; and

- d. the prospective participant is unconscious or lacks the capacity to understand risks, methods, and purposes of the research; and
- e. third party authorization cannot be secured in sufficient time, despite diligent and documented efforts to do so; and
- f. no relevant prior directive by the participant is known to exist.

The advantages of using institutional consent in the HeLP Trial and neonatal research in general include patients not being denied the opportunity to participate, results are more generalizable, and research can be completed more expediently. Conversely, potential disadvantages include parents' distress with trial enrollment that was initiated without consent and/or with the infant being exposed to an unproven therapy.

Sunita Vohra and Maureen Reilly feel that the HeLP Trial fulfills the Helsinki Declaration criteria for institutional consent. With present parental consent, infants who experience an emergent delivery are excluded from this trial enrollment due to time constraints. In contrast, with institutional consent, all infants would be enrolled, which will ensure that our results are generalizable to the entire population, as well as offer all eligible infants the opportunity to participate in the trial.

Because of individual state, province or country legislation, institutional consent will not be an option for all of HeLP Trial participating centers. For those centers that are interested in pursuing institutional consent, we are preparing documents necessary for an IRB application at their site.

If you have any questions and comments regarding institutional consent, please contact Sunita Vohra (svohra@ualberta.ca) or Maureen Reilly (maureen.reilly@sw.ca). For any other inquiries regarding the HeLP Trial, please contact Luba Slatkovska (lubomira.slatkovska@sw.ca), HeLP Trial coordinator.

Extremely Low Birth Weight (ELBW) Infant Follow-up

The Extremely Low Birth Weight (ELBW) Follow-up project has been collecting data on ELBW infants over the past seven years! Data collection is currently being completed on infants born during 2003 with birth weight between 400 and 1001 grams. There are 30 centers currently participating in this project. The database now contains the survival status at two years adjusted age on 4235 infants born between 1998 and 2002. The five year cohort was presented at the Annual Meeting in December and has been selected for presentation at the Pediatric Academic Societies'

Annual Meeting in San Francisco, CA on Monday, May 1st at the 5:15 PM Poster Symposium Session.

A brief snapshot of the survival status at two years adjusted age on 4,235 infants born during 1998 through 2002 is noted below. Here's what our ELBW infants look like.

Of the 4,235 surviving infants, 3,190 had neurodevelopmental evaluations conducted of which:

- o 75% came from two-parent households
- o 63% of parents had some college education
- o 41% were rehospitalized after discharge
- o 30% required support after discharge
- o 31% required surgery
- o 33% had poor weight gain
- o 12% had microcephaly
- o 1% had bilateral blindness
- o 2% had hearing impairment requiring amplification
- o 8% had cerebral palsy.
- o 30% had severe disability: defined as having one of the following: cerebral palsy, inability to walk, cognitive delay, hearing loss requiring amplification, or visual impairment of bilateral blindness.

Centers with high reporting rates of follow-up (>=60%) had slightly more infants with severe disabilities 30.4% vs. 29.6% compared to centers with low reporting follow-up rates (<60%).

Parental Interview and Reporting Questionnaire (PIRQ)

Though clearly important, current neurodevelopmental follow up of all high risk infants is difficult, incomplete and expensive. The Parental Interview and Reporting Questionnaire (PIRQ) represents an effort to create a simple questionnaire that could identify infants with serious disability. In order to test the validity of this tool, we are comparing parental perception of their child's health and developmental status (as reflected in the PIRQ) with information gained from formal medical evaluation. The current interview tool has 18 structured questions and one open ended question. The PIRQ does not require a health care provider to administer. To date, we have over 400 completed PIRQs to compare to formal neurodevelopmental evaluation. Hopefully, this tool will allow for large scale, inexpensive follow up of high risk infants that will identify the major medical and developmental issues these children encounter.

CONTACT US: For more information on Clinical Trials, the Extremely Low Birth Weight Follow Up Project, the DRM Trial or the PIRQ, please contact Karla Ferrelli at 802 865 4814, ext 212 or email karla@vtoxford.org.

PROBIOTICS SUPPLEMENTED FEEDING IN EXTREMELY LOW BIRTH WEIGHT INFANTS

Necrotizing enterocolitis (NEC) is the most common serious, acquired gastrointestinal disease in the newborn infants, affecting 2.6% to 28% of the Very Low Birth Weight (VLBW) infants.

The precise pathogenesis of NEC is unknown but is widely considered as a multifactorial disease. Based on clinical observation in infants and studies in experimental animals, three factors are felt to be necessary for the NEC to occur: 1) altered enteric mucosal integrity; 2) enteral feeding; and 3) presence of pathogenic bacteria. These factors may coalesce to produce bowel injury and the subsequent NEC. Although mortality rates among infants with NEC have decreased as a result of improved supportive and surgical care, effective preventive strategies are still limited.

It has been postulated that the overgrowth of pathogenic organisms might be prevented by inducing the colonization of the bowel with nonpathogenic bacteria (probiotics) of species that normally reside in the gut of term infants. Probiotics (*Lactobacillus* sp, and *Bifidobacterium* sp.) potentially compete with other organisms for binding sites and substrates in the bowel, increase the production of anti-inflammatory cytokines, and reduce intestinal permeability.

We plan to test the hypotheses that ELBW infants who receive supplemental probiotics enteral feedings, compared to placebo, will have:

1. Reduced incidence of NEC.
2. Reduced incidence of bacterial sepsis and urinary tract infection.
3. Reduced days of antimicrobial treatment.

Secondarily, we will test the hypotheses the ELBW infants who receive supplemental probiotics enteral feedings, compared to placebo, will have:

1. Shortened time to achieve full feeding.
2. Improved weight gain (measured by average daily weight gain in grams)

We are seeking centers interested in the trial. Please contact Karla Ferrelli at karla@vtxford.org.

Roger F. Soll, Vermont Oxford Network
Mohamad Al-Hosni, Saint Louis University

The Newborn Brain – From Foundations to New Frontiers September 7 – 9, 2006

Washington University in St. Louis, St. Louis Children's Hospital is planning a 2 1/2 day symposium focused on the newborn brain – from the basics to clinical applications that would be attended by neonatologists, neonatal nurses, general pediatricians with an interest in the newborn, neurologists and intensivists.

This unique symposium is designed to update clinicians on the fundamentals of neurology, technology, and pathology in the newborn brain. A cutting edge program of keynotes and workshops with superb faculty will be directed for clinical utility at all levels in newborn care. Lectures include the fundamentals of neuroanatomy, neurochemistry, EEG, neuroimaging, mechanisms of diseases in the preterm and term brain and neuroprotection. The workshops include how to put a baby in the MRI machine without sedation; interpretation of MRI in the newborn; improving the application of cranial US in the NICU; Clinical cases of interpretation of EEG/aEEG in the newborn; and Hypothermia workshop and glucose and the developing brain. The faculty include prestigious speakers such as Drs Joseph Volpe, Donna Ferriero, Linda deVries, Faye Silverstein, Laura Ment, and Susan Vannucci. Registration and details are found on www.peds.wustl.edu.

2005 DATA FINALIZATION DEADLINES REMINDER

APRIL 1ST – COMPLETE

MAY 15TH – CONFIRM

JUNE 1ST – CORRECT

JUNE 15TH – CLOSE

**IF ALL ITEMS ARE COMPLETE, CONFIRMED,
CORRECT AND CLOSED BY JUNE 15TH, 2006, YOUR
CENTER WILL RECEIVE THE 2005 NICU QUALITY
MANAGEMENT REPORT (QMR) IN SEPTEMBER,
2006**

**PLEASE REFER TO THE VON DATA FINALIZATION
CHECKLIST RECENTLY SENT TO DATA AND REPORT
CONTACTS AT ALL PARTICIPATING CENTERS.**

**PGPR SYMPOSIUM AND WORKSHOP:
NEONATAL INFECTIOUS DISEASES IN
DEVELOPING COUNTRIES
MAY 2 & 3, 2006**

On May 2, 2006, The Programme for Global Paediatric Research will hold a symposium within the annual Pediatric Academic Societies' Meeting in San Francisco. The symposium is entitled "Neonatal Infectious Diseases in Developing Countries".

Presentations will include:

- An overview by Barbara Stoll of Emory University; Healthcare Associated Neonatal Infections and Antimicrobial Resistance in Developing Countries by Anita Zaidi of Aga Khan University Hospital in Karachi, Pakistan
- Diagnosis and Antibiotic Therapy of Neonatal Infections by Health Care Workers by Abhay T. Bang of The Society for Education, Action and Research in Community Health ("Search"), Gadchiroli, Maharashtra, India;
- Global Partnerships for Infectious Disease Research - A Focus on Pediatric Studies of Dengue in Nicaragua by Eva Harris of the University of California at Berkeley;
- Cutaneous Innate Immunity by Steven Hoath of Children's Hospital, Cincinnati;
- Preventing Neonatal Infections Through Skin Barrier Therapy by Gary Darmstadt of Johns Hopkins University, Baltimore;
- Experiences with Neonatal Infectious Diseases in Low-Income Countries by Margaret Nakakeeto of the Mulago Hospital, Kampala, Uganda and Upton Allen of The Hospital for Sick Children, Toronto.

In addition, there will be platform presentations of abstracts selected following an international call.

At the follow-up workshop on May 3, colleagues from high-, mid- and low-income countries, who are working in fields related to neonatal infectious diseases, will meet in order to examine the critical issues and establish clear plans for collaborative study and other action. One of the expected outcomes of the workshop will be a preliminary statement on research needs related to neonatal infectious diseases in developing countries. If you wish to attend the symposium please register for the PAS Meeting at www.pas-meeting.org.

If you wish to attend the workshop and/or require further information, please contact:

Professor Alvin Zipursky, Chair and Scientific Director, The Programme for Global Paediatric Research, The Hospital for Sick Children, 555 University Ave., Toronto, ON M5G 1X8 Canada; Ph: 416-813-8762; Alvin.Zipursky@sickkids.ca

**RECENT AND UPCOMING PUBLICATIONS RELATED TO
THE VERMONT OXFORD NETWORK**

1. Leviton, L C. and Horbar, JD. Cluster Randomized Trials for the Evaluation of Strategies Designed to Promote Evidence-Based Practice in Perinatal and Neonatal Medicine. The Annals of the American Academy of Political and Social Sciences 2005; 599: 94-114.
2. Morales LS, Staiger DO, Horbar JD, Carpenter J, Kenny M, Geppert J, Rogowski J. Mortality Among Very Low Birthweight Infants in Hospitals Serving Minority Population Am J Pub Health 2005; 95: 2206-12.
3. Ursprung R, Gray JE, Edwards WH, Horbar JD, Nickerson J, Plsek P, Shiono PH, Suresh G, and Goldman DA. Real Time Patient Safety Audits: Improving Safety Every Day. Qual Saf Health Care, 2005; 14: 284 – 289.
4. Gray JE, Ursprung R, Edwards WH, Horbar JD, Nickerson J, Plsek P, Shiono PH, Suresh G, and Goldman DA. Patient Mis-identification in the NICU: Quantification of Risk. Pediatrics 2006;117: e43-e47.
5. Zupancic JAF, Richardson DK, Horbar JD, Carpenter JH, Lee SK, Escobar GJ, and the Vermont Oxford Network SNAP Pilot Project Participants Revalidation of the Score for Neonatal Acute Physiology in the Vermont Oxford Network. (Pediatrics, accepted for publication).
6. Walsh, MC, Qing Yao, Horbar JD, Carpenter JH, Shoo Lee, and Ohlsson A. for the NICHD Neonatal Network; Vermont Oxford Network (VON) and Canadian Neonatal Network (CNN) Changes in the Use of Postnatal Steroids In Three Large Neonatal Networks. (in preparation)

Sign up for the Nightingale Internet Reporting System and have access to view your center's data and the ability to create tables and figures similar to those in the annual Quality Management Report!
Go to: www.vtoxford.org for more information and to sign up or email Nancy Cloutier at: nancy@vtoxford.org

Nightingale

MULTIDISCIPLINARY ADVISORY COUNCIL

The Vermont Oxford Network Multidisciplinary Advisory Council is a group of health professionals representing nurses, nurse practitioners, respiratory therapists, nutritionists, pharmacists and others who advise the Network regarding the inclusion of a broad range of disciplines in Vermont Oxford Network activities and programs.

If there are any specific issues you would like to see the Multidisciplinary Advisory Council address, please send your comments/suggestions to Nancy Cloutier at nancy@vtoxford.org for the Committee to consider.

The Council members include:

Bobby Bellflower, DNSc, NNP
Regional Medical Center at Memphis
Memphis, Tennessee

Rosanne Buck, RN, MS, CNNP
Beth Israel Deaconess Medical Center
Boston, Massachusetts

Betty Campbell, RNC, BSN
Providence St. Vincent Medical Center
Portland, Oregon

Dianne Charsha, RNC, MSN, CRNP
St. John's Mercy Medical Center
St. Louis, Missouri

Paula Delmore, RNC, MSN
Wesley Medical Center
Wichita, Kansas

Diane Eastman, ARNP, MA, CPNP
Children's Hospital of Iowa
Iowa City, Iowa

Shirley Hargreaves, RN
Al Corniche Hospital
Abu Dhabi, UAE

Stephanie Howard, MPH, RN
St. Luke's Hospital
Kansas City, Missouri

Sharon Nelson, MSN, NNP
Waukesha Memorial Hospital
Waukesha, Wisconsin

Maureen Reilly, RRT, RRCP, Co-Chair
Sunnybrook & Women's College Health Science
Toronto, Ontario, Canada

Diana Reiser, RN, MSN
St. Luke's Hospital
Kansas City, Missouri

Eliza Rinehart, Pharm D
Regional Medical Center at Memphis
Memphis, Tennessee

Catherine Sawtell, MSN, CRNP, Co-Chair
Morristown Memorial Hospital
Morristown, New Jersey

The Vermont Oxford Network thanks the Council for its important contributions!

WELCOME TO OUR NEWEST MEMBERS!

Vermont Oxford Network welcomes the following members who have joined the Network since March 1, 2005:

Aspirus Wausau Hospital, Wausau, WI
Banner Thunderbird Medical Center, Glendale, AZ
Billings Clinic, Billings, MT
CHSD, NICU @ Scripps Encinitas, Encinitas, CA
Clarion North NICU, Carmel, IN
Children's Hospital, The, Denver, CO
DuBois Regional Medical Center NICU, DuBois, PA
Exempla Good Samaritan Medical Ctr, Lafayette, CO
Franklin Square Hospital Center, Baltimore, MD
Hollywood Presbyterian Medical Ctr, Los Angeles, CA
Holy Redeemer Hospital & Med Ctr, Meadowbrook, PA
Hospital de Basurto, Bilbao, Vizcaya, Spain
Hospital Univ Central de Asturias, Oviedo, Spain
Hospitales Univer Virgen del Rocio, Sevilla, Spain
Kaiser Permanente - Honolulu, Honolulu, HI
Kimberley MediClinic, Kimberley, South Africa
Kloof MediClinic, Elarduspark, South Africa
LAC+USC Women's & Children's Hosp, Los Angeles, CA
Legacy Salmon Creek Hospital, Vancouver, WA
Meadowcrest Hospital, Gretna, LA
Memorial Hermann Children's Hospital, Houston, TX
Memorial Medical Center - Modesto, Modesto, CA
Neonatologia - A.O. Policlinico di Modena, Modena, Italy
NICU Azienda Ospedaliera Varese, Varese, Italy
North Austin Medical Center, Austin, TX
Olive View - UCLA Medical Center, Sylmar, CA
Ospedale Vittore Buzzi, Milano, Italy
Policlinico Umberto I, Roma, Italy
Presbyterian Hospital of Plano, Plano, TX
Rapid City Regional Hospital, Rapid City, SD
Rapides Women's & Children's Hosp, Alexandria, LA
San Gerardo Hospital, Monza, Italy
Santa Monica UCLA NICU, Santa Monica, CA
SCDU Neonatologia-ASO OIRM S Anna U Torino Italy
Spartanburg Reg Healthcare System, Spartanburg, SC
St. Joseph Medical Center, Towson, MD
St. Vincent Health Center, Erie, PA
Sutter Medical Center of Santa Rosa, Santa Rosa, CA
Swedish Medical Center, Seattle, WA
Texas Children's Hosp/Baylor Col. of Med, Houston, TX
UNM Sch of Med Dept of Pediatrics, Albuquerque, NM
Washington Hospital Center, Washington, DC
West Coast Neonatology Inc @ ACH, St. Petersburg, FL
West Jefferson Medical Center, Marrero, LA
Women's Center at UCH, The, Tampa, FL

Hot Topics
IN NEONATOLOGY

December 4 & 5, 2006

For information go to:

www.hottopics.org

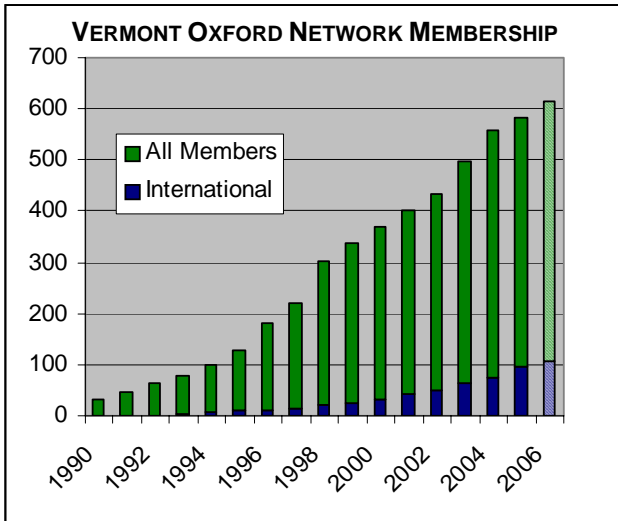
or contact

Gail Murphy at
802-865-2283

NETWORK MEMBERSHIP GROWTH

Over the past 16 years, we have experienced continued growth in membership.

In 2005, 44 new members joined. Eleven of those new members are in countries outside of the US. There are now 584 active Network members with 95 of these members in countries outside of the United States.



Vermont Oxford Network currently has members in the following countries:

Austria	New Zealand
Belgium	Northern Ireland
Brazil	Poland
Canada	Portugal
Chile	Saudi Arabia
China	Singapore
Czech Republic	South Africa
Finland	Spain
Germany	Switzerland
Ireland	Turkey
Italy	United Arab Emirates
Kuwait	United Kingdom
Malaysia	United States

We estimate our total membership will be over 600 units by the end of 2006. Our international membership will surpass 100.

We look forwards to working with all of you!



Vermont Oxford Network members and guests had the pleasure and privilege of attending a reception at the residence of the Irish Ambassador to the United States, Ambassador Noel Fahey (fourth from right) on December 5, 2005 in Washington, DC.

(Photo courtesy of Emma McCall)