



NEWSLETTER

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FIRST ANNUAL QUALITY CONGRESS FOR NEONATOLOGY ATTRACTS LARGE MULTIDISCIPLINARY AUDIENCE

The Vermont Oxford Network First Annual Quality Congress for Neonatology was held on December 3, 2000 in Washington, DC. The Congress afforded participants the opportunity to learn about how quality improvement can be applied to their daily work in the neonatal intensive care unit. The audience of over 650 health professionals from around the world included physicians, nurses, nurse practitioners, respiratory therapists, nutritionists, pharmacists, administrators, quality improvement specialists, and other allied health professionals. The Congress, chaired by Jeffrey D. Horbar, MD, Chief Executive and Scientific Officer of the Vermont Oxford Network, and moderated by Paul Plsek, an internationally recognized authority in quality improvement in health care, featured presentations by an expert faculty followed by extended discussion and audience participation.

The Congress began with an introduction to Quality Improvement in Healthcare by Mr. Plsek. He focused on recent collaborative improvement efforts using examples from the Northern New England Cardiovascular Disease Study Group, the Institute for Healthcare Improvement (IHI) Breakthrough Series, the VHA Upper Midwest Coaching and Leadership Initiative, and the Vermont Oxford Network NIC/Q Collaboratives. This was followed by an overview of the NIC/Q Collaboratives by Jeffrey Horbar who explained how Vermont Oxford members can get involved in the upcoming expanded Collaborative starting in 2002.

Next, NIC/Q participants William Edwards, MD from Dartmouth-Hitchcock Medical Center in Hanover, NH, Nathaniel R. Payne, MD from Children's Health Care in Minneapolis, MN, and John McDonald, MD and Mara Zabari, MD from the Providence St. Vincent Medical Center in Portland, OR described their personal experiences in the Network's NIC/Q 2000 Collaborative, explaining how their units had

benefited from being part of the Collaborative, the barriers they encountered and the lessons they have learned.

The morning session was completed with a presentation, Cost and Quality: Win-Win, by Jeannette Rogowski, PhD, senior health economist at the Rand Corporation, who discussed her findings based on a financial analysis of the hospitals that participated in the first Network NIC/Q Collaborative. Dr. Rogowski estimated that every dollar invested in quality improvement can result in up to \$15 dollars in savings related to lower costs for patient care! She concluded that collaborative quality improvement is a sound investment resulting not only in better care but lower costs as well.

The afternoon session began with a presentation on Medical Errors by William Rupp, MD, President and CEO of the Luther Middlefort Clinic of the Mayo Health System in Eau Claire, WI. Dr. Rupp's presentation, clearly one of the highlights of the Congress, reviewed common patient injuries and adverse drug events, described the concept of "triggers" as a method for identifying adverse events through chart review, outlined the importance of systems thinking linked to a reliable reporting system and stressed the critical importance of a non-punitive error reporting policy. It was apparent that as a senior executive Dr. Rupp practices what he preaches! He has successfully created a "blame free" environment in his own institution through strong leadership and programs such as a Senior Executive Medication Safety Walk Around. Included in the meeting handouts were examples of the tools and surveys that Dr. Rupp has used at Luther Middlefort Hospital. His fine presentation and important message provided a terrific kick-off to the Vermont Oxford Network's focus on enhancing patient safety as a major component of the NIC/Q Collaborative.

The afternoon session continued with a presentation, Lessons from the IHI Breakthrough Series, by Thomas G. Rainey, MD, an adult intensivist and Chairman of the IHI Breakthrough

Series on Cost Reduction and Outcome Improvement in Adult Intensive Care. Dr. Rainey reviewed specific examples of how collaborative improvement was successful in adult critical care including reduction of inappropriate ICU days, decreasing time on assisted ventilation, better medication and sedation management. G. Ross Baker, PhD, from the Department of Health Administration at the University of Toronto, discussed Organizational Culture and Quality Improvement, explaining how the structure and function of organizations influences the effectiveness of improvement efforts. He reviewed the literature and presented findings based on a unique survey that he developed for measuring organizational factors in NICU care.

The final session of the day was an Expert Panel: Knowledge into Action in which participants in the Vermont Oxford Network's NIC/Q 2000 Collaborative described their personal experiences with quality improvement. Howard S. Cohen, MD from the Children's Hospital of IL at OSF, Peoria, IL, Maria L. Duenas, MD from the Saint John Hospital and Medical Center in Detroit, MI, Patrick K. Lewallen, MD from the Legacy Emanuel Children's Hospital in Portland, OR, Judy Ohlinger, RNC, BSN from the Children's Hospital Medical Center of Akron, OH, and Richard J. Powers, MD from the Children's Hospital Oakland, CA shared their insights into the strengths and challenges of collaborative quality improvement from the perspectives of experienced neonatal clinicians. The panel was joined by all of the afternoon speakers for a spirited discussion with the audience.

The First Annual Quality Congress was a major success. We would like to thank the faculty and all of you who attended for making it possible. We are now planning the agenda for the Second Annual Quality Congress for Neonatology that will be held on Sunday, December 9, 2001 in Washington, DC. Please reserve the date. We look forward to seeing you there!

The Congress was sponsored by an unrestricted educational grant from Ross Products Division of Abbott Laboratories.

ANNUAL MEETING 2000

The Vermont Oxford Network Annual Meeting was held on December 2, 2000 in Washington, DC. The meeting, attended by over 500 individuals, included presentations and extended discussion of a number of topics of interest to Network members. Jeffrey D. Horbar, MD welcomed the group and provided his annual update of Network activities.

This year's update included information from the Database on trends in practices and outcomes from 1991 to 1999 for very low birth weight infants.

William Edwards, MD, principal investigator of the Network Skin Care Trial, gave the first public presentation of the Trial results (see article in this Newsletter).

Douglas Staiger, PhD, an econometrician from Dartmouth College and the National Bureau of Economic Research, discussed new methods for measuring quality of medical care and showed examples of how these methods could be applied to Vermont Oxford Network reporting. This work is based on research that Dr. Staiger and Jeannette Rogowski, PhD from Rand are doing in collaboration with the Network with funding from the Agency for Healthcare Quality and Research. As part of this research, the investigators held focus group discussions with Network members attending the meeting to get their input about how the new reporting methods could be used. We thank all of you who participated in those sessions for your valuable input.

The afternoon session of the Annual Meeting included a special symposium on Bioethics. The session began with a presentation by Maureen Hack, MD, noted authority on developmental outcomes from Case Western Reserve University in Cleveland. Dr. Hack, in her extremely informative talk, Outcomes for the ELBW Infant, reviewed the current state of knowledge on this important topic. Peter Singer, PhD, DeCamp Professor of Bioethics at Princeton University discussed Ethical Issues in Treating the Extremely Low Birth Weight Infant. No stranger to controversy, Dr. Singer gave a thought provoking presentation which stimulated spirited discussion. Although a few individuals had expressed their opposition to including Dr. Singer on the program, his presentation was extremely well received and hopefully challenged us all to think more clearly about the principles that we use in making ethical decisions.

The meeting concluded with members of the Database Advisory Committee, Meena LaCorte, MD, Nathaniel R. Payne, MD, Roderic Phibbs, MD and Patricia Shiono, PhD, leading the attendees in an open discussion of Database related issues.

The next Vermont Oxford Network Annual Meeting will be held in Washington, DC on December 8, 2001. We look forward to seeing you there.

The Vermont Oxford Network Annual Meeting was supported by an unrestricted educational grant from Ross Products Division of Abbott Laboratories.

NEONATAL SKIN CARE STUDY

The Neonatal Skin Care Study was completed in March 2000 with enrollment of 1,191 infants at 53 VON centers. We found no difference in the combined outcome of nosocomial sepsis and/or death in infants treated with prophylactic Aquaphor® compared to those in the routine skin care group. There was an increased risk in the component outcome of nosocomial bacterial sepsis in the prophylactic group compared to the routine skin care group, particularly for the lowest birth weight group 501-750 grams. The results of the trial will be presented at the Society for Pediatric Research Meeting in Baltimore (during the Clinical Trials Platform Session, Tuesday, May 1st, 2:45 pm in Ballroom I/II). Thanks and congratulations to all participating centers!

EARLY SURFACTANT REPLACEMENT STUDY

The Early Surfactant Replacement Study is proceeding slowly, but well. We currently have received more than 1,000 Screening and Eligibility Forms (ESRS Form 1) on infants who are eligible to participate in the study. Of those eligible, 100 infants have met all criteria and are enrolled in the study. We have 34 centers participating in the trial. We are still looking for additional centers to participate. If your center is interested in participating, please contact Dan Morris at (802) 865-4814 x 209.

2002 TRIAL: PROPHYLACTIC SURFACTANT VS. EARLY NASAL CPAP

The next trial will be launched in early 2002. The purpose of the trial is to evaluate the effect of intubation and prophylactic surfactant administration compared to early stabilization on NCPAP with selective intubation and surfactant administration for clinical indications in premature infants at high risk of respiratory distress syndrome. Infants of extremely low birth weight will be considered as candidates for inclusion in the trial. If your center may be interested in participating in the trial, please contact us at the number above.

EXTREMELY LOW BIRTH WEIGHT INFANT FOLLOW UP PROJECT - PHASE I

We began the ELBW Follow Up Project in 2000 with the aim of assessing 18 to 24 month health and neurodevelopmental status of a cohort of infants < 1001 grams born during the later half of 1998. We currently have received data on 316 ELBW infants from 24 participating centers! This has been a remarkable project and we are so thrilled with its success, we're launching Phase II. Thanks to all of you!

EXTREMELY LOW BIRTH WEIGHT INFANT FOLLOW UP PROJECT - PHASE II

The second phase of the ELBW Follow Up Project will collect data on the cohort of ELBW infants <1001 grams born during the 1999 year. We have 56 centers interested in participating and anticipate collecting follow up data on over 1000 infants.

Where will this take us? We hope to secure funding for a third phase of the Follow Up Project in 2002! Phase III will allow us to streamline the data collection process to facilitate a more pragmatic, efficient approach to data collection for long-term follow up.

TRIALS STAFF NEWS

Dan Morris, Administrative Assistant for Clinical Trials and his wife, Julie, are expecting their first baby due in September.

Jeanette Conner, MS, MN, ARNP, Trials Administrator has completed her Ph.D. in Evaluative Clinical Sciences, Dartmouth Medical School.

Congratulations!

NIC/Q: EVIDENCE-BASED QUALITY IMPROVEMENT COLLABORATIVE

Improving the Quality, Cost and Safety of Neonatal Intensive Care

Project leaders: Jeffrey D. Horbar, MD and Paul Plsek, MS

The Vermont Oxford Network is recruiting hospitals to participate in the NIC/Q Evidence-Based Quality Improvement Collaborative for Neonatology. The Collaborative brings together multidisciplinary teams of health professionals from a broad range of NICUs. The goal is to make measurable improvements in the quality, cost, and safety of neonatal intensive care. The NIC/Q Collaborative beginning in January 2002 will be the third in a successful series of Collaboratives organized by the Vermont Oxford Network.

Participating teams will work and learn together under the guidance of a nationally recognized faculty of improvement experts. They will receive training in rapid cycle quality improvement based on 4 Key Habits of Clinical Improvement: change, collaborative learning, evidence-based practice, and systems thinking. The focus will be on action. The goal is to achieve breakthrough improvements in quality and major reductions in medical errors.

We anticipate that a two-year commitment will be needed to transform the units and make changes of the magnitude we are seeking. There will be four large group meetings of the Collaborative in 2002 and 2003. These meetings will feature in-depth learning sessions and exercises aimed at helping the teams identify improvement goals, implement changes, and monitor the results. Participants will receive ongoing support from project faculty through dedicated e-mail listservs and conference calls. A unique feature of the NIC/Q Collaborative is the web site, NICQ.org, the on-line source of improvement knowledge and tools for NICUs. The fee for participation in the Collaborative is \$15,000 per year.

There are currently 65 centers that have expressed interest in participating in the upcoming Collaborative. We hope to enroll about 25 to 30 sites. Enrollment materials have been sent to these centers. We expect the participants to commit to participation via signed agreement by April 1, 2001. The fee for the first year is due September 1, 2001, and work will begin in January of 2002. There may still be a limited number of spaces available for participation. Please refer

questions and requests for materials to Kathy Leahy, NIC/Q coordinator, Vermont Oxford Network (phone: 802-865-4814 x205. fax: 802-865-9613, e-mail: Kathy@vtoxford.org).

NICQ.ORG : WEB-BASED TOOLS AND RESOURCES FOR COLLABORATIVE QUALITY IMPROVEMENT

The Vermont Oxford Network is developing and testing a unique Internet site, NICQ.org, designed to support multidisciplinary teams of health professionals from NICUs around the world engaged in collaborative quality improvement. Features of the site include: a Resource Center with practical improvement ideas and tools for neonatal intensive care, a Classroom with presentations and tutorials by recognized quality improvement experts, private Workspaces for hospital teams that allow them to track and monitor their own improvements, a section on Medical Errors and Patient Safety that will support the anonymous and voluntary submission of errors and near miss errors and Contact Information for colleagues involved in NICU improvements.

The goal is to create an ever-expanding archive of practical improvement knowledge for neonatology. It will allow a user to find out what other NICUs have done to achieve a specific improvement. Rather than reinventing the wheel each time they set out to make an improvement, users will have instant access to a wide range of ideas and experiences. The Resource Center will include better practice ideas, evidence reviews and case studies of actual improvement projects completed by participating sites. The entire archive is searchable. Access is controlled by password and limited to computers within participating institutions. Currently available only to participants in the Network's NIC/Q 2000 Collaborative, the site already contains valuable improvement ideas developed by the 34 hospital teams participating in that Collaborative.

We plan to expand access to NICQ.org in two stages. First, it will be made available to health professionals from institutions that join the Network's expanded NIC/Q Collaborative that will begin in 2002. Second, we plan to offer subscription access to all other Vermont Oxford members beginning sometime in 2002. Each participating member site will be required to have a local site administrator and to have taken basic training in quality improvement.

The Network's long-range goal is to have all members using and contributing to NICQ.org. The Internet cannot replace the person-to-person collaborative ties between individuals that are so critical to quality improvement. However, the new tools and resources that NICQ.org provides will support collaborative learning and improvement in important new ways allowing us to more effectively work together to improve the quality and safety of medical care for newborn infants and their families.

The development and evaluation of NICQ.org are supported by grants from the David and Lucile Packard Foundation and Ross Products Division of Abbott Laboratories, Inc.

2000 DATA CLOSE-OUT

The Vermont Oxford Network Data Processing Team has begun the process of closing-out the 2000 data set in preparation for creating the 2000 NICU Quality Management Report. During the next few months, participating Centers' Data Contacts will be receiving frequent updates on the status of 2000 data itemizing records in need of completion or correction.

In order to ensure the completeness of your Center's 2000 data set, we will require confirmation of accuracy on the following:

- First and Last ID Numbers and Dates of Birth used for 2000 records.
- The number of Delivery Room Deaths reported.
- Birth months in 2000 for which no records have been received.
- Gaps in numerical ID sequencing representing numbers not used for 2000 data.

All 2000 records must be submitted complete and free of errors as of June 1, 2001. Centers that have not completed their 2000 data by this date may not be included in the 2000 NICU Quality Management Report.

Please make every effort to finalize 2000 data as soon as possible. Your Center's Account Manager is happy to assist you in this effort and can be reached at 802-865-4814 for questions and comments.

ELECTRONIC DATA SUBMISSION AND EXPANDED DATABASE FOR ALL NICU INFANTS

The Vermont Oxford Network is pleased to report that we have added two new options for members participating in the Network Database for 2001. First, data may now be submitted electronically. Second, members may now choose to submit data for all NICU admissions regardless of birth weight. Members choosing to submit data on all NICU infants must submit all of their data electronically because of the increased number of eligible infants.

Prior to beginning electronic data submission members complete a test procedure designed to check that their digital files are in the required format. The Vermont Oxford staff will work closely with you during this test period. Nineteen centers that have completed the testing procedures are now routinely submitting all of their data in electronic format. An additional twenty-one centers are completing the test procedure in preparation for electronic submission. Thirteen centers are submitting data on all NICU admissions and an additional twelve centers are preparing to do so. Many other centers have expressed interest in both electronic data submission and in the expanded database for all NICU infants.

Please remember that there are now three options for submitting data:

1. Submit data for infants 401 to 1500 grams using paper data forms,
2. Submit data for infants 401 to 1500 grams electronically, or
3. Submit data for all NICU admissions regardless of birth weight electronically (Expanded Database).

Electronic data submission for infants 401 to 1500 grams is included in the basic membership fee. There is no additional fee. There is no additional fee for submitting data on all NICU infants born in 2001. We are providing this option without fee in 2001 because of the pilot nature of this effort. However, we anticipate that beginning in 2002 there will be an additional membership fee for those centers choosing to submit data and receive reports on all of their NICU infants.

We expect that over the next several years an increasing number of members will submit data electronically and will participate in the Expanded Database for all NICU infants. However, we are committed to maintaining the option of paper data

submission for infants 401 to 1500 grams for those members who prefer it.

We would like to express our thanks to all of those members who have participated in electronic and expanded data submission during its introduction into the Network. Your suggestions and patience have been extremely helpful!

If you are interested in hearing more about electronic data submission or the Expanded Database for all NICU infants, please contact Nancy Morse, Electronic Data Coordinator (phone: 802 865 4814, ext. 208 or e-mail: nancy@vtoxford.org).

HIPAA Privacy Rules

The Health Insurance Portability and Accountability Act (HIPAA) was enacted by Congress in 1996. The law gave Congress three years to pass comprehensive health privacy legislation and gave the Department of Health and Human Services authority to craft privacy regulations in the event that Congress failed to act. Congress did not act. Therefore, prior to leaving office, the Clinton administration issued HIPAA privacy rules described by Mr. Clinton as "the most sweeping privacy protections ever written." The privacy rules would affect virtually every doctor, patient, hospital, pharmacy and insurance plan in the country. They will apply to both paper and electronic medical information. These rules could have major implications for the Vermont Oxford Network Database. The rules were initially planned to go into effect in 2 years, but there is now a possibility of further delay.

Although the Vermont Oxford Network does not collect information that contains the names, medical record numbers or other personal information about patients, we do collect certain data items considered under the proposed HIPAA rules to be potential personal identifiers. These items are date of birth, date of admission, date of discharge and maternal zip code. Because we use our data for research, if the privacy rules go into effect as currently written, our understanding based on discussion with the Network's legal counsel, is that we would have two basic options. The first option would be to remove the date items and zip code from the database in the future. The data would then be considered "de-identified" and would therefore not be subject to the consent requirements outlined in the rules. If we removed these items the major implication for the Database would be that members would have to calculate and submit length-of-stay rather than having the

Network calculate it based on submitted dates. Alternatively, we could keep the date and zip code items. However, then we would either have to obtain individual consent for each patient on whom data are submitted or obtain a waiver from the IRB at each member institution. We would qualify for the waivers, but obtaining waivers from several hundred IRBs, many of whom may be unclear about the complicated regulations, would at the very least be a considerable undertaking for the Network and its members.

The future of the HIPAA privacy rules is currently uncertain. As reported on February 27 in the New York Times in an article by Robert Pear:

Tommy G. Thompson, the new Secretary of Health and Human Services, said today that he would delay and reconsider rules that President Bill Clinton issued in late December to protect the privacy of people's medical records.

Mr. Thompson said today that the Bush administration was "absolutely committed" to protecting the privacy of medical records. But he said he would invite public comment on the final rules issued by Mr. Clinton.

The purpose, Mr. Thompson said, is to make sure the rules "will work as intended throughout the complex field of health care, without creating unanticipated consequences that might harm patients, access to care or the quality of care."

Mr. Thompson described his plans in a speech to the American Association of Health Plans, a trade group for health maintenance organizations.

The Vermont Oxford Network is closely monitoring developments regarding the proposed HIPAA privacy rules. As soon as it is clear what form the final rules will take and when they will be implemented, the Network will inform the membership about its plans for HIPAA compliance. If you have ideas or suggestions on this important issue, please let us know.

NEWSLETTER ARTICLES

Vermont Oxford Network welcomes Network members to contribute articles for publication in the Vermont Oxford Network Newsletter. Submission of articles for consideration should be sent via email to Nancy Morse as an attachment to nancy@vtoxford.org or faxed to 802-865-9613.

CONGRATULATIONS JEANETTE!

Jeanette Conner, MS, MN, ARNP, Vermont Oxford Network Coordinator of Clinical Trials, recently completed her Ph.D. in Evaluative Clinical Sciences from Dartmouth Medical School. Her thesis titled EVIDENCE BASED PRACTICE IN NEONATAL INTENSIVE CARE: The Effect of Prophylactic Topical Emollient Ointment Therapy and Systemic Antibiotic Administration Practice on Nosocomial Sepsis Rates and Mortality In Extremely Low Birth Weight Infants 501- To 1000 Grams was based on her preplanned analysis of the Aquaphor® study, "The Effect of Aquaphor® Original Emollient Ointment on Nosocomial Sepsis Rates and Skin Integrity in Infants of Birth Weight 501 to 1000 Grams."

Congratulations to Jeanette for this very significant accomplishment! We are so pleased to have Dr. Conner at Vermont Oxford.

NETWORK MISSION TO INCLUDE PATIENT SAFETY

The recent Institute of Medicine, IOM, report, *To Err is Human: Building a Safer Health Care System*, has raised both public and professional awareness of the impact of medical errors on patient outcomes in the United States. Although little is known about medical errors in newborn medicine, there is reason to believe that adverse events related to NICU care are both frequent and serious. The Vermont Oxford Network is ideally suited to address this problem. In fact, the IOM report specifically mentions the Network and indicates that:

"Organizations can also collaborate with other facilities, even within their market areas, to understand patterns of error and new approaches to prevention. For example, The Northern New England Cardiovascular Project, the Vermont Oxford Neonatal Network, and multisite research on the organization and delivery of care in intensive care units have demonstrated the gains that are possible from such collaborative work (*To Err is Human*, page 182)."

We heartily agree! Medical Errors and Patient Safety are an important focus of the Network's NIC/Q Quality Improvement Collaborative. Multidisciplinary teams from participating hospitals are now working together to identify hazards in the NICU and to share new ideas for reducing errors and improving safety. The Internet site, NICQ.org, provides participants in the Collaborative with a

unique tool for the voluntary and anonymous reporting of medical errors, adverse events and near miss errors in their NICUs. In addition to reporting on errors so as to alert others to the dangers, users can comment on the submitted errors, documenting and sharing the solutions they have discovered for preventing these errors. It is our hope that in the future, NICQ.org will become a national voluntary reporting system for medical errors in neonatology similar to the voluntary system in use by the airline industry. We believe that NICQ.org can play an important role in improving patient safety for newborn infants and their families.

Medical Errors and reporting through NICQ.org will be an important topic for the 2nd Annual Quality Congress in Neonatology planned for Washington, DC on December 9, 2001. We hope to see you there.

To Err is Human: Building a Safer Health Care System, Kohn LT, Corrigan JM, Donaldson MS, editors. Committee on Quality of Health Care in America, Institute of Medicine. 2000. Available online at:

<http://www.nap.edu/books/0309068371/html/>.

VERMONT OXFORD NETWORK MISSION

To improve the quality and safety of medical care for newborn infants and their families through a coordinated program of research, education and quality improvement.

Note that we have added "safety" to our mission. The Network has the potential to make a major contribution in reducing medical errors and enhancing patient safety.

IMPORTANT DEADLINES TO REMEMBER

- FIRST QUARTER 2001 DATA SUBMISSIONS deadline for 2001 First Quarter Report: **April 9, 2001**
- 2000 YEAR-END CLOSE-OUT. All 2000 data must be complete and corrected by **June 1, 2001**. Please contact your Center's Account Manager at 802 - 865 - 4814 for a detailed status of your Center's 2000 data.
- ELBW FOLLOW UP PROJECT data forms for 1998 cohort of infants are due by: **June 1, 2001**.
- SECOND QUARTER SUBMISSIONS deadline for 2001 Second Quarter Report: **July 9, 2001**.

DATABASE ADVISORY COMMITTEE

The Vermont Oxford Network Database Advisory Committee is currently working on a number of projects of importance to the Network and its Database. These include:

1. Preparing manuscripts describing the trends in practices and outcomes at Network centers from 1991 to 1999 and describing the Network's experience with infants 401 to 500 grams.
2. Developing recommendations for an audit of the quality of data submitted by members to the Database.
3. Reviewing the results of the recent member survey about changes to the Database.
4. Advising the Directors on changes to the Database for 2002 including the HIPAA privacy rules.
5. Selecting a new member for the Committee from among the names submitted by the membership.

The Database Advisory Committee meets twice each year. The next meeting is on April 27, 2001. If you have suggestions or ideas related to any of the issues listed above or to other questions of importance to the Database, please send your comments to the Vermont Oxford Network and we will forward them to the Committee.

The current members of the Database Advisory Committee are:

Avroy Fanaroff, MB, BCh
Rainbow Babies and Children's Hospital
Cleveland, Ohio

Sarah Kilpatrick, MD, PhD
University of Illinois at Chicago
Chicago, IL

Meena LaCorte, MD
The Brooklyn Hospital
Brooklyn, NY

Nathaniel R. Payne, MD
Children's Health Care
Minneapolis, MN

Roderic Phibbs, MD
UCSF Medical Center
San Francisco, CA

Jeannette Rogowski, PhD
Rand Corporation
Washington, DC

Patricia Shiono, PhD
Epidemiologist
San Francisco, CA

Andrew Wilkinson, MD
John Radcliffe Hospital
Oxford, United Kingdom

POSTNATAL DEXAMETHASONE IN TINY BABIES: DOES IT DO MORE GOOD THAN HARM?

The DART (Dexamethasone – A Randomised Trial) Study

If you are interested in participating or would like additional information contact: Associate Professor Lex W. Doyle, Department of Obstetrics and Gynaecology, The Royal Women's Hospital, 132 Grattan St, Carlton, Victoria, Australia. Tele: (61 3) 9344 2151; Fax: (61 3) 9347 1761. Email: uwd@unimelb.edu.au

Corticosteroids have been prescribed increasingly frequently in neonatal intensive care nurseries, particularly to reduce ventilator-dependence and the rate of chronic lung disease in preterm infants. To date, there appears to be no survival advantage of postnatal corticosteroids and they may be causing adverse sensorineural outcome. However, most of the babies in the reported randomized controlled trials (RCTs) have been from the prophylactic use of corticosteroids in the first week of life, rather than the more common therapeutic use after the first week of life in babies with established lung disease. What is not clear is the effect of therapeutic corticosteroids on the rate of survival free of disability.

The aim of the DART study is to determine if low-dose dexamethasone given to extremely low birthweight (<1000 g) or very preterm (<28 weeks) infants who are ventilator-dependent after 7 days of age reduces the rates of ventilator dependence and chronic lung disease, without adversely affecting either mortality or sensorineural impairments or disabilities at 2 years of age.

The active treatment regimen will be a 10-day course of dexamethasone at 0.15 mg/kg/day every 12 hours for treatment days 1-3, followed by 0.10 mg/kg/day on days 4-6, 0.05 mg/kg/day on days 7-8, and 0.02 mg/kg/day on days 9-10. Repeat courses, still blinded to treatment group, will be allowed if the infant requires ongoing assisted ventilation via an endotracheal tube, is in at least 40% oxygen for at least 24 hours continuously with no treatable cause, and is deteriorating. Open treatment with corticosteroids will be actively discouraged, but will be allowed if the infant requires ongoing assisted ventilation via an endotracheal tube, is in at least 70% oxygen for at least 24 hours continuously with no treatable cause, has been chronically ventilated up to this time and the attending paediatrician considers that

the child is otherwise likely to die. The major outcome will be determined at 2 years of age corrected for prematurity. Survival free of major sensorineural disability will comprise the major endpoint of the study. Major sensorineural disability will comprise any of legal blindness, deafness requiring amplification, cerebral palsy in a child who is not walking at 2 years of age, or a developmental quotient < 70 (more than 2 SD below the mean) on the Mental Developmental Index of the Bayley Scales. A sample size of 407 infants in each group is calculated to be able to detect an absolute 10% increase or decrease in the rate of survival free of major disability at 2 years of age, from an expected rate of 60%, with type - I error of 5% and power of 80%.

The Vermont Oxford Network is pleased to bring this trial organized by Dr. Doyle to the attention of our members.

UPCOMING VERMONT OXFORD NETWORK PRESENTATIONS AT THE PEDIATRIC ACADEMIC SOCIETIES

The Effect of Aquaphor® Original Emollient Ointment on Nosocomial Sepsis Rates and Skin Integrity in Infants of Birth Weight 501 to 1000 Grams. Edwards W, Soll RF, Conner, JM for the Vermont Oxford Network. To be presented at Neonatal Clinical Trials Platform, Ballroom I-II (Baltimore Convention Center). Tuesday, May 1, 2001 at 2:45 PM.

Trends in Mortality and Morbidity for Very Low Birth Weight (VLBW) Infants: The Vermont Oxford Network Experience, 1991-1999. Horbar JD, Badger GJ, Carpenter JH, Fanaroff AA, LaCorte M, Phibbs Roderic, Soll RF for the members of the Vermont Oxford Network. To be presented at Neonatal Patient Oriented Research II, Ballroom I-II (Baltimore Convention Center). Sunday, April 29, 2001 at 5:15 PM.

PROJECTS TO HELP NICUs IN NEED

The Vermont Oxford Network is pleased to devote space in the Newsletter to charitable projects related to newborn medical care in the developing world. Dr. LaCorte, Dr. Stewart and their colleagues involved in the following efforts should be proud of their work!

WORLD WIDE CHILDREN'S VARIETY CLUB

Dr. Meena LaCorte is involved in a project designed to help NICU's in developing countries. She is a member of a world-wide children's charity – Variety Club – whose Lifeline Program to addresses medical needs of children in developing countries.

Meena would like to be notified of any outdated but functional NICU equipment you may like to donate. She will be able to match NICU needs in developing countries with available equipment and arrange shipping. The immediate countries in need include Trinidad and Haiti.

Meena can be reached as follows:
Telephone: 718-250-8525
e-mail: meenaksh@aol.com
FAX: 718-250-8467
Address: 121 Dekalb Ave, Brooklyn, NY 11201.

Thanks for your attention and help in this worthy cause.

ROMANIAN ASSISTANCE NEONATAL PROJECT

For more than ten years, both the Department of Pediatrics at the University of Louisville School of Medicine and the Humana Foundation have participated in humanitarian medical missions to Romania. Initiated under the direction of former President George Bush in the early 1990s as part of the Healthcare Leadership Council, this project includes a neonatology program that has been one of the most rewarding, yet frustrating experiences of our lives. Despite hopes for exponential growth in the knowledge and abilities of the Romanian physicians, the pace of improvement has been slow. While many infants that would have died before are now surviving due to both improved mechanical ventilation techniques and surfactant usage, much more needs to be done to bring Romania neonatal care into the 21st Century.

Romania has a prematurity rate of between 12-14% with an equally high perinatal and neonatal mortality. The obstetricians are just now beginning to use prenatal steroids on a routine basis and are entering into the realm of tocolysis with a great deal of reluctance. Infections, however, still remain a

major cause of neonatal mortality in Romania. For example, in Oradea, obstetricians still see mortality rates of greater than 50% in infants between 30-35 weeks. During the past six years, our team has taught the basics of neonatal medicine including intubation, placement of arterial lines, chest tube insertion, and surfactant administration under the constraints of limited resources.

One factor exacerbating this resource constraint was the maldistribution of equipment that was purchased by the Romanian government from a World Bank grant in 1995. Sixty hospitals received a single ventilator, pulse oximeter, blood gas machine, radiant warmer, and cardio-respiratory monitor without any training or technical assistance. This has created an equipment shortage in the regional perinatal centers capable of using the equipment, while in other centers the equipment is not being used due to a lack of training and expertise. Thus, many centers are having to choose which infants will live or die based on the availability of a mechanical ventilator. Despite our best efforts, the government will not "order" this equipment to be sent to the hospitals that are now capable of adequately caring for preterm infants. This has created a critical need for ventilators, pulse oximeters and CPAP generators in these perinatal centers.

We respectfully request that you consider donating used ventilators and other ancillary equipment that are still functional to neonatal units in Romania! Shipments should be labeled **Humana Shipment to Romania** and sent directly to:

A. Arnold Warehouse
12201 Westport Road
Louisville, KY 40245

Please let me know what equipment is shipped and when so that we can plan appropriate distribution. Thank you.

Dan L. Stewart, MD
Professor of Pediatrics
University of Louisville School of Medicine
571 South Floyd, Suite 342
Louisville, KY 40202
Phone: 502-852-8470
Fax: 502-852-8473
E-mail: DanStewart@louisville.edu

MEMBERSHIP SURVEY AND DATA VERIFICATION

It is essential that we have the 2000 Membership Survey information from all centers participating in the 2000 database when 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 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 center must have their plan on file before they can be included in the Annual Quality Management Report.

If your center has not submitted its 2000 Membership Survey and/or Data Verification Plan, please contact A. Lynn Stillman at 802-865-4814, extension 211 or email: lynn@vtxford.org

RECENT NETWORK RELATED PUBLICATIONS

Stewart, DL Vermont Oxford Network: Effective and efficient medical care for the neonate. *Journal of the Kentucky Medical Association*, February 2001; 99:23-25

Horbar, J.D., Rogowski, J.A., Plsek, P.E., Delmore, P., Edwards, W.H., Hocker, J., Kantak, A.D., Lewallen, P., Lewis, W., Lewit, E., McCarroll, C. J., Majsce, D., Payne, N.R., Shiono, P., Soll, R.F., Leahy, K., Carpenter, J.H., for the NIC/Q Project Investigators of the Vermont Oxford Network: Collaborative Quality Improvement for Neonatal Intensive Care. *Pediatrics* 2001; 107:14-21

Rogowski, J.A., Horbar, J.D., Plsek, P.E., Schuurmann Baker, L., Deterding, J., Edwards, W.H., Hocker, J., Kantak, A.D., Lewallen, P., Lewis, W., Lewit, E., McCarroll, C.J., Majsce, D., Payne, N.R., Shiono, P., Soll, R.F., Leahy, K.: Economic Implications of Neonatal Intensive Care Unit Collaborative Quality Improvement. *Pediatrics* 2001; 107:23-29

AD CAMPAIGN HAS PARENTS ASKING FOR COSTLY DRUG

"...Five months after Synagis gained federal approval in June 1998, a panel of doctors at the American Academy of Pediatrics recommended that doctors consider using Synagis in most children under the age of 2 who had chronic lung disease.

The panel also said that infants born 12 or more weeks prematurely might benefit from Synagis up to the age of 1, and infants born 8 weeks to 11 weeks prematurely might benefit up to the age of 6 months.

But it recommended that because of the high cost of the drug, infants born 5 to 8 weeks prematurely should receive Synagis only if they had additional risk factors- staying in day care, a parent who smokes, many siblings who could spread the virus, among others.

MedImmune's ads, critics say, make it harder for doctors to draw these distinctions when dealing with the parents of any premature baby. In September, the company began running ads aimed at parents of all premature babies in magazines like American Baby and on television during shows like "The Young and The Restless" and the "Today Show."

The print advertisement shows a photograph of a doctor putting an infant on oxygen. The main caption reads, "If you knew what RSV could do to your precious baby, it would take your breath away."

The ad ends with: "If your baby was born early, call your pediatrician now-before it's too late."

Mr. Anido, MedImmune's Senior Vice President for Sales, agreed that the ads carried a powerful emotional force. "It is a picture that really stops the parent," he said. The intention, he said, is to encourage parents to call their pediatrician.

The company is also sponsoring evening teleconferences for pediatricians. During the 45-minute calls, doctors that the company considers experts on Synagis give advice on the treatment. For their time, Mr. Anido said the company offers the pediatricians textbooks or "something of value to the doctor's practice."

MedImmune executives say there is a huge untapped market for Synagis. Mr. Anido says the potential market includes all 300,000 babies who are born at least five weeks early in the United States each year. Mr. Anido said sales of Synagis could, in theory, reach \$1.5 billion.

But about 200,000 of those babies were born five to eight weeks prematurely-the lower-risk category where the American Academy of Pediatrics recommends only limited treatment. Mr. Anido said that these infants represented "one of the largest market opportunities"...Mr. Anido said that the company's sales representatives were urging the doctors to follow the academy's guidelines and were not encouraging prescriptions for all premature infants. ...The new marketing campaign appears to be working. Last year, sales of Synagis in the United States were up 46 percent over 1999."

Petersen, M; The New York Times,
Wednesday, January 31, 2001

Noted by Jerold F. Lucey, MD

INCREASE IN PRETERM BIRTHS

"...In the United States in the last 2 decades, despite increasing availability of prenatal care, nutrition supplementation programs, and drugs to stop preterm contractions, the preterm birth rate has increased from 9.5% in 1980 to 11% in 1998. Part of this increase is due to multiple births associated with infertility treatments, but many preterm births occur spontaneously. None of the medical or public health strategies used to reduce preterm birth have succeeded. One of the major unsolved issues is the very high occurrence of preterm births among black women in the United State, who have twice the rate of preterm birth of other women, along with a 3- to 4-fold increase in the earliest preterm births which account for most of the neonate deaths and long-term morbidity. The increased rate of preterm birth accounts for much of the black-white difference in infant mortality (estimated at 6.3 deaths per 1,000 live births for white women vs 15.1 per 1,000 live births for black women in 1995.)"

Goldenberg RL, Jobe AH; JAMA 2001;285:633-639

Noted by Jerold F. Lucey, MD

PHARMACEUTICAL FIRMS WIN BIG ON PLAN TO TEST ADULT DRUGS ON KIDS

By Doing Inexpensive Trials, They Gain
6 More Months Free From Generic Rivals

FDA: Law Does Some Good

By Rachel Zimmerman
Staff Reporter of the Wall Street Journal

Mary Robinson, a Philadelphia X-Ray technologist, received \$300 and a \$50 gift certificate to Toys "R" Us as an incentive to enroll her seven-month-old daughter in a drug trial to treat a form of indigestion babies can get.

Merck & Co., the maker of the medicine, also received an incentive: about \$290 million. That's the estimated revenue Merck will pocket from six months of additional marketing exclusivity it won.

Its drug, Pepcid, was slated to lose its patent protection last October, opening the way to low-priced generic competition. But, as a reward for conducting the first formal studies of Pepcid in infants, the federal government has given Merck a half year of extra protection from generics. And the gains are even greater for some of the other companies rushing to take advantage of a 1997 law meant to encourage pediatric trials of adult medicines.

That law, by giving drug makers an incentive to test on children, is producing important new prescribing information for pediatricians, the Food and Drug Administration says. Labels have been changed on 14 drugs to reflect new data. Some pediatricians are delighted with the results and are lobbying to extend the law past its scheduled expiration at year end.

But a close look at the law shows that it is also producing an unintended consequence: a drug-industry financial bonanza.

Stronger Sales

The studies required to gain six more months of marketing exclusivity are relatively small and inexpensive, costing anywhere from \$200,000 to \$3 million. But the extended exclusivity that results can be very valuable. It will boost drug-company sales by more than \$4 billion, by Journal's calculations...

Excerpt from The Wall Street Journal,
January 5, 2001

When I first heard about this new bill it sounded great; at last drugs would be tested for safety. Infants and children would no longer be "therapeutic orphans."

Now look what's happened! The drugs being tested are of little, if any, benefit to infants, and the drug companies are making hundreds of millions of dollars. Have we been duped?

Jerold F. Lucey, MD

FATE OF THE VERY, VERY, VERY LOW BIRTH WEIGHT INFANT 1996-1998 IN THE USA

According to the CDC- National Center for Health Statistics, between 51-54 thousand very low birth weight infants <1500 grams are born each year (1996-98) in the USA. About 3,000 of these infants (5-6%) weigh between 401-500 grams at birth. The national infant mortality rate for these infants is approximately 84%.

Courtesy of the CDC-NCHS/OEHD; D. Dunan,
K. Schoendorf, 2001

We need to know the long-term follow-up results of this group of so called "miracle babies". It won't be great, so what can we do?

Noted by Jerold F. Lucey, MD

LACK OF EFFECT OF INDUCTION OF HYPOTHERMIA AFTER ACUTE BRAIN INJURY

Guy L. Clifton, M.D. et al
N Engl J Med, Vol. 344, No. 8 · February 22, 2001 ·
www.nejm.org

Abstract

Background Induction of hypothermia in patients with brain injury was shown to improve outcomes in small clinical studies, but the results were not definitive. To study this issue, we conducted a multicenter trial comparing the effects of hypothermia with those of normothermia in 392 patients 16 to 65 years of age with acute brain injury.

Conclusions Treatment with hypothermia, with the body temperature reaching 33°C within eight hours after injury, is not effective in improving outcomes in patients with severe brain injury. (N Engl J Med 2001;344:556-63)

Commentary on Above Study:

Raj K. Narayan, M.D. Hypothermia for Traumatic Brain Injury – A Good Idea Proved Ineffective
N Engl J Med, Vol. 344, No. 8 · February 22, 2001 ·
www.nejm.org

A little discouraging, but note that the hypothermia didn't start until 4.3 hours after the accident. That's too late, if the current reperfusion theory of brain cell injury is correct. Only time will tell whether hypothermia will be effective in the asphyxiated newborn infant.

Jerold F. Lucey, MD

END - OF- LIFE DECISIONS FOR NEONATES IN EUROPE

Rebagliato M et al. Neonatal End of Life Decision Making...in Ten European Countries.
JAMA 2000; 284:2451-2459

Physicians more likely to agree with statements consistent with preserving life at any cost were from Hungary, Estonia, Lithuania and Italy; while physicians more likely to agree with the idea that quality of life must be taken into account were from the United Kingdom, the Netherlands and Sweden.

VARIATION IN HUMANE TREATMENT OF EXTREME PREMATURETY

De Leeuw R et al. Treatment Choices for Extremely Preterm Infants: An International Perspective.
J Ped 2000;137:6080615

We compared treatment choices of neonatal physicians and nurses in 11 European countries for a hypothetical case of extreme prematurity (24 weeks gestational age, birth weight of 560 g, Apgar score of 1 at 1 minute).

Most physicians in every country but the Netherlands would resuscitate this baby and start intensive care. On subsequent deterioration of clinical conditions caused by a severe intraventricular hemorrhage, attitudes diverge: most neonatologists in Germany, Italy, Estonia, and Hungary would favor continuation of intensive care, whereas in the other countries some form of limitation of treatment would be the preferred choice. Parental wishes appear to play a role especially in Great Britain and the Netherlands. Nurses are more prone than doctors to withhold resuscitation in the delivery room and to ask parental opinion regarding subsequent treatment choices.

Noted by Jerold F. Lucey, MD

CYBER-SERFDOM

"...I am struck at how many people call my office, ask if I'm in, and, if I'm not, immediately ask to be connected to my cell phone or pager... You're never out anymore. The assumption now is that you're always in. Out is over. Now you are always in, you are always on. And when you are always on, what are you most like? A computer server....This Evernet will allow us all to be online all the time from everywhere."

Friedman T.L. New York Times, January 30, 2001
Do you recognize this feeling? Jerold F. Lucey, MD

DON'T FORGET!

HOT TOPICS IN NEONATOLOGY

December 9 – 11, 2001

**Omni Shoreham Hotel,
2500 Calvert Street, N.W.
Washington D.C. 20008
Tele: 202-234-0700**

PROGRAM WILL INCLUDE:

Cerebral White Matter Injury

- The Developing Brain vs Steroids
- Neuroimaging
- High Variation Therapies

"Green Apples"

- Protein C for Sepsis (Zovant)
- Continuous Glucose Monitoring

**Iatrogenic Multiple Pregnancies
C.P.A.P. & HiFi Trials
Fetal Origins of Adult Disease
Very, Very Low Birth Weight Infants-401-501
Gms.**

Registration will be limited!
Preliminary program to be mailed in June.

For registration information contact:
**Neonatal Research &
Technology Assessment, Inc.**
52 Overlake Park
Burlington, VT 05401
(802) 865-2283 office, (802) 865-0241 Fax
WWW.HotTopics.org
NRTA@Sover.net

RESERVE THESE DATES:

VERMONT OXFORD NETWORK ANNUAL MEETING SATURDAY, DECEMBER 8, 2001

- Database, Trials, Follow-up
- Special Session on Informatics in the NICU
- Free Registration for Vermont Oxford Network Members

2ND ANNUAL QUALITY CONGRESS FOR NEONATOLOGY SUNDAY, DECEMBER 9, 2001

- Medical Errors in the NICU
- Multi-disciplinary Quality Improvement
- Free Registration for Vermont Oxford Members

Meetings to be held at:
Omni Shoreham Hotel
2500 Calvert St. NW
Washington, DC 20008
Tele: 202-234-0700

Vermont Oxford Network Annual Meeting
and
2nd Annual Quality Congress for Neonatology
are supported by an unrestricted educational grant from
Ross Products Division of Abbott Laboratories.

Look for meeting agenda and registration materials in late Spring, 2001.
For more information on the Vermont Oxford Network meetings, please contact
Nancy Morse at 802-865-4814, ext 208 or email: nancy@vtoxford.org

These meetings will be followed on Monday and Tuesday, December 10 and 11
by the Special Ross Conference, Hot Topics in Neonatology at the same location.
For more information on Hot Topics, please contact Gail Glore at 802-865-2283
or visit the Hot Topics in Neonatology website: www.hottopics.com

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