

**Study Protocol for IRB Submission
Member Institutions of the Vermont Oxford Network (VON)**

**Evaluating the Utility of Illness Severity Scoring
in Neonatal Intensive Care**

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Purpose of the Study: Participating Neonatal Intensive Care Units (NICUs) will implement the SNAP-II illness severity score as part of their ongoing quality assurance data collection during CY 2002. For this study, researchers will:

1. Evaluate the feasibility of implementing SNAP-II data collection at VON member sites.
2. Assess the overall score performance and potential scoring distortions in selected subgroups that may affect interpretation.
3. Develop selected severity-adjusted quality reports.
4. Publish a joint research paper on some aspect of severity scoring.

Type of Study: This is a MEDICAL RECORDS ONLY study. It requires approval by the IRB at each participating institution. This study presents exceedingly low risk of harm or disclosure (see below).

Background: Benchmarking, in conjunction with quality improvement efforts, holds great promise for incremental improvements in the outcomes of neonatal intensive care (1). Effective benchmarking requires risk adjustment to permit accurate and fair comparisons among hospitals (2). SNAP-II is an extensively validated illness severity index developed specifically for neonatal intensive care (3). The Vermont Oxford Network (VON) is a voluntary consortium of more than 300 hospitals that have an interest in quality improvement (4,5). Member institutions submit to a central database anonymized case abstracts of all discharges that weighed <1500g at birth. Some institutions have recently expanded data collection to all NICU admissions.

Data to be Collected: The data for this study consist of two parts; 1) the VON Database records routinely collected by members, and 2) the supplemental study data for evaluation of SNAP-II. The data forms for both are attached. A few additional data items are added to enrich the analyses for quality improvement.

Data handling: Data forms are completed by direct medical records abstraction. The only identifiers on the forms are the coded Center Number and Network Patient ID Number. VON forms are photocopied to retain a local copy, and either mailed to Burlington VT where they are keypunched into the master database or submitted electronically. The SNAP-II forms will also be abstracted locally, then keypunched into a secure website by local researchers.

HIPAA compliance: All potential Personal Identifying Information (PID) has been removed from the VON and the SNAP-II data forms. Specifically, all names, medical record numbers, dates and institutional identifiers have been removed.

Protection of Confidentiality: VON infant records rely on a confidential Center Number plus a Network Patient ID Number assigned by the originating institution. These numbers create the unique and completely arbitrary identifier used to link the separate case forms submitted to VON. All data are then maintained on a secure, password protected computer. There have been no known breaches of confidentiality of patients or sites in the 11 years of operation of the VON. The SNAP-II data will follow this effective and successful protocol.

Risks and Benefits: There are no benefits to individual patients. The only risk to patients is disclosure of confidential information. The extensive efforts to fully anonymize the data make this risk virtually nil. The risk to the hospital is that its confidential performance reports may be leaked into the public domain, risking institutional embarrassment and penalties from payors or governmental agencies. Anonymized site codes make this risk minimal, and it has never occurred in the 11 years of the VON. The potential benefits relate to identifying areas of poor performance that each hospital can correct through quality improvement efforts.

Study Description

Data items: See the attached SNAP-II data form and abstractors manual. The items in boxes are SNAP-II variables. Several additional items are needed to ensure eligibility and accurate classification.

Data input: We will use web-based data entry for the SNAP-II items. The web site is under construction. It will be reached at www.vtoxford.org by selecting the (future) [SNAP-II project](#) URL. *Please note that VON members will continue to submit their standard Vermont Oxford Network data in either paper or electronic form as they are currently doing.*

Availability of SNAP-II scores: We will compute and return the SNAP-II scores to your center for local use.

Workload: We estimate the time to collect SNAP-II data at about 2-4 minutes per case. Each site will decide whether to collect SNAP-II for all NICU admissions (as part of the expanded data collection) or only for infants <1500g. Because selection bias can distort findings, we may not be able to use data at sites achieving <80% completion rates (for full or at least partial year of participation).

Training and definitions: Attached is a brief codebook. In addition we plan to maintain a FAQ (frequently asked questions) and e-mail inquiry at the SNAP-II website.

Confidentiality and HIPAA: The data used in this study will not include protected health care information. The only identifiers will be the VON Center Number and Network Patient ID. We have structured the two eligibility questions that contain time-stamps (date-time of NICU entry and date-time of death if it occurs in the 12 hours scoring period) to include time only.

IRB Approval: Since this is a research project it will require the approval of your local Institutional Review Board. In addition the project will be reviewed by the IRBs at Beth Israel Deaconess Hospital, Boston and the University of Vermont, Burlington.

Proposed Analyses:

1. Evaluate the feasibility of implementing SNAP-II data collection at VON member sites.

This will be carried out in a variety of ways, including logs of telephone and e-mail inquiries, hits on the FAQs page of the website, surveys of participating users, timing of a sample of data collection and data entry, and review of submitted data.

2. Assess the overall score performance and potential scoring distortions. SNAP-II has been validated across birth weight groups, and shown not to differ by race, gender, or multiple birth. However, scoring may be distorted by certain diagnoses, specifically congenital anomalies and early onset sepsis. For example, two patients with the same severity score, one with sepsis, the other with RDS, may not carry the same mortality risk. For our analyses, we will compare observed and expected mortality for selected subgroups. The expected mortality will be estimated using logistic regression including the SNAP II score along with other covariates such as birth weight, gestational age, gender, race, multiple birth, Apgar score, size for gestational age, location of birth, early onset sepsis, and major birth defects available in the VON Database. A null result would suggest that severity alone captures the mortality risk, and that SNAP-II is well calibrated in the VON population. A significant difference would suggest the need to add a diagnosis-adjustment in computing mortality risk.

3. Develop selected severity-adjusted quality reports. VON currently prepares an extensive series of analyses of outcomes. It currently uses a VON-derived risk-adjustment tool. We will add SNAP-II to the risk adjustment procedures to identify which reports can be further improved. We will then prepare a supplemental set of quality reports for those analyses that appear to benefit from such further adjustment. The goal is to introduce SNAP-II enhanced reporting for members in 2003 based on the results of the pilot project.

4. Publish a joint research paper on severity scoring. The analyses in #2 above represent a substantive contribution to the literature on neonatal illness severity scoring, and should be publishable. Analyses of SNAP-II components (such as admission temperature) provide the opportunity to compare pre-NICU stabilization among hospitals, paving the way for subsequent quality improvement efforts.

Attachments:

1. VON Data forms for CY 2002
2. SNAP-II data form and supplemental study data

References:

1. Horbar JD, Rogowski J, Plsek PE, Delmore P, Edwards WH, Hocker J, et al. Collaborative quality improvement for neonatal intensive care. *Pediatrics* 2001;107 (1):14-22.
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3. Richardson DK, Corcoran JD, Escobar GJ, Lee SK. SNAP-II and SNAPPE-II: Simplified newborn illness severity and mortality risk scores. *J Pediatr* 2001; 138 (1): 92-100.
4. Horbar JD. The Vermont-Oxford Neonatal Network: integrating research and clinical practice to improve the quality of medical care. *Semin Perinatol* 1995; 19 (2): 124-31.
5. Horbar JD. The Vermont Oxford Network: evidence-based quality improvement for neonatology. *Pediatrics* 1999; 103 (1 Suppl E): 350-9.