Version

3

Pediatric Intensive Care Unit Evaluations Software Version 3

OPERATIONS MANUAL

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PICU Evaluations Software Version 3

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Table of Contents

Chapter 1

Introduction from the PICUEs Executive Director

Development of the Physiologic Stability Index (PSI), the Pediatric Risk of Mortality (PRISM) score, and the PRISM III algorithms has been aided by government funding, institutional support by Children's National Medical Center, much dedicated work by my research team, and the cooperation and collaboration of many pediatric intensive care units (PICUs) in the United States and abroad.

As the research issues related to methodology were solved, it became clear that further external funding for the support of pediatric severity-of-illness research was very unlikely. Simultaneously, individual PICUs and national organizations requested severity-of-illness-based, unit-level quality assessments. I believed the best way to maintain a pediatric severity-of-illness score calibrated for contemporary patient samples, make performance improvements in pediatric severity-of-illness, and provide relevant quality evaluations using a benchmark reference set of PICUs was to start the Pediatric Intensive Care Unit Evaluations (PICUEs) project.

In my view, the PICUEs project has five areas of focus:

- The central focus of the PICUEs project is the measurement of standardized morality rates. Dramatic improvements in PICU outcomes can occur if we identify those ICUs that could benefit by making improvements. Those units performing below a self-imposed standard should have the opportunity to improve, while those units performing at a level that meets their goals should focus on maintaining their performance.

- A second major focus of the PICUEs project is the measurement of severity and diagnosis adjusted length of stays, and efficiency rates, as well as the generation of basic administrative data. In this era of cost reductions and needed improvements in the efficient utilization of PICUs, this information has become very important.

- A third major focus of the PICUEs project is to keep PRISM III algorithms current. The PICUEs project will enable us to maintain and improve our predictors by expanding our national database, and increase the size of our national reference sample.

- A fourth major focus of the PICUEs project is to foster research. Data obtained from multiple sites will enable us to continue to perform national studies, including outcome evaluations.

- Finally, these goals will only be met if PICUEs generates sufficient funds. The seed funds for this project came from the Children's National Medical Center and the Children's Research Institute in Washington, DC. The project will only be successful if it generates sufficient interest and revenue to repay these initial investments and maintain the future operation of the project. Therefore, we need to assess a fee for the services we provide. In addition, PRISM III algorithms, PICUEs software, and other materials have been copyrighted and may be the subject of one or more patents.

The PICUEs fee structure represents our attempt to provide the data collection and entry service and fund severity of illness research, but not inhibit the use of PRISM III algorithms. PICUEs Software Version 3 puts flexibility in the hands of the users since the user can generate more than one hundred Institutional and Comparative Performance Reports without ever submitting data to the PICUEs National Data Center. For research purposes, PRISM III algorithms are available free of charge. Most users will choose to purchase our software, which is designed to allow users to enter data and generate reports that are relevant to the administration and quality assessment of their PICUs.

An important aspect of severity-of-illness based quality assessments is complete confidentiality. The PICUEs staff has maintained confidentiality in three national studies and analyses of more than 60 unique PICUs. We will maintain this unblemished record by carefully encrypting all confidential data and patient-specific identifiers, and by insuring that data formatting will not allow others to identify specific institutions.

I sincerely hope that this project meets our goals. We will only be successful if PICUEs users are satisfied. Please let me know if you are not satisfied.

Murray M Pollack, MD
PICUEs Founder and Executive Director

Chapter 2

Quality Assessment

Quality assessment is an increasingly important issue for our health care system because there is a general societal belief that all citizens have a right to quality health care. Intensive care is an important component of our health care system, not only because its sophisticated care benefits many patients, but also, because, as the most sophisticated hospital care routinely available, it demonstrates our general commitment to health care. The focus on outcomes in quality assessment is quite recent. The precise relationship between severity of illness and outcome (measured and validated in national studies) enables quality assessments of individual PICUs.

Pediatric critical care medicine may represent the single service that best characterizes tertiary, pediatric health centers, and PICU services are proliferating in all types of hospitals. The American Board of Pediatrics has only certified pediatric intensive care specialists since 1987, and many pediatric programs are just now realizing the importance of intensive care for their future, as other types of pediatric care come to require greater technology-intensive therapies.

The central goal of the PICUEs project is the provision of quality assessments in individual PICUs. The methodology used in our project is based on the validated relationship between outcome (i.e. survival or death) and severity of illness variables, including physiologic status (measured by the PRISM III score), operative status, cardiopulmonary resuscitation status, previous care location, and diagnoses. In our project, the performance of individual PICUs is compared to a reference set that is composed of PICUs from previous research projects as well as contemporary PICUs from the PICUEs project that are actively collecting and entering data and contributing it to the PICUEs Master Database.

In our project, quality assessment information comprises analyses of an ICU's observed mortality rate compared to its expected mortality rate (i.e. the ICU's standardized mortality rate), and, when indicated, analyses of observed mortality rates in defined mortality risk strata. When relevant, our analyses identify individual patients suitable for focused case reviews. Confidential institutional comparisons are provided for descriptive information. Other goals of PICUEs are the provision of measures often used for quality assessment, including

severity of illness-adjusted length of stay (i.e. standardized length of stay) and efficiency rate computations.

Chapter 3

Background Information

Pediatric Intensive Care Units

PICUs concentrate sophisticated technology and trained personnel to monitor and treat physiologic instability in infants and children with life threatening disorders, or monitor physiologic status in patients at risk for sudden, life threatening events. The characteristics of care and populations differ significantly among individual PICUs. In fact, when characteristics were compared among ICUs in three national PICU studies, essentially all ICU characteristics differed significantly. Most important, mortality rates ranged from less than 3% to greater than 15%.

According to a national survey conducted in 1989, the organizational structures associated with quality of care also differ substantially among PICUs. For example, greater than 25% of PICUs did not have a pediatric specialist in intensive care, greater than 20% did not have a full time medical director, greater than 50% did not have 24-hour/day in-house physician coverage dedicated to the PICU, greater than 20% were not affiliated with a medical school, and 40% were small (i.e. less than 6 beds). The data indicate that medical centers are realizing the value that PICUs add to an overall pediatric program, but the proliferation is associated with a diversity of traditional and nontraditional structures and organizations.

It is known that quality, assessed by severity-adjusted or standardized mortality rates (i.e. the ratio of observed to predicted mortality rates), is associated with some characteristics of PICUs, including teaching status and intensivist status. However, knowledge of quality characteristics cannot automatically be applied to individual PICUs because some PICUs with excellent quality characteristics perform poorly, and some with adverse quality characteristics perform exceptionally well.

Severity of illness methods have successfully adjusted mortality rates and lengths of PICU stay for the case mix differences of different PICU populations.

Severity of Illness

Severity of illness assessment has been crucial for a wide range of pediatric, neonatal, and adult ICU uses, including quality assessments, clinical studies (i.e. to control for severity of illness), and studies of ICU resource utilization and management. Although severity of illness is a familiar medical concept, it is sometimes difficult to define. In the context of intensive care, a rational and objective way to define and quantify severity of illness is through the development of probabilistic models predicting mortality risk. Such predictive models have been developed for all age groups.

In the 1970s, only indirect assessments of severity of illness were used. Some were qualitative (e.g. the Clinical Classification System) and others were objective but indirect (e.g. the Therapeutic Intervention Scoring System [TISS]). In the 1980s, physiologic status was used as a direct reflection of mortality risk. Physiology-based predictors such as those developed by Knaus et al. (i.e. the Acute Physiology and Chronic Health Evaluation [APACHE]), Lemeshow, Teres, et al. (i.e. the Mortality Prediction Model [MPM]), and Pollack et al. (i.e. the Physiologic Stability Index [PSI] and the Pediatric Risk of Mortality [PRISM]) demonstrated excellent performance in predicting two outcome states (i.e. life and death). The multi-centered trials of PSI, PRISM, APACHE, and MPM clearly indicated that there is a consistent relationship between physiologic status in patients of all ages and mortality risk.

Early studies demonstrated the need to directly assess severity of pediatric illness. In our first national study, the hypothesis that mortality rate differences among PICUs could be explained by differences in the distributions of severity of illness was accepted even though there was a 6-fold PICU mortality rate difference among the participating ICUs. The study was acknowledged in a New England Journal of Medicine editorial.

Over time, new ICU therapies develop, new patient groups evolve, and there are general advances in medicine. These developments necessitate a periodic revision of all severity of illness scores that relate physiologic status to mortality risk. Therefore, we re-evaluated all physiologic variables, variable ranges, and other risk factors using a contemporary sample of over 11,000 PICU patients. The result, PRISM III, is a third generation severity of illness score for children.

Of special importance to pediatric studies, unmeasured variables are assumed to be normal when calculating the PRISM III score; therefore, extra tests are not required. In critically ill children, all tests that physicians deem necessary are performed; the benefit of the information sampled by the PRISM variables is clearly more important than patient comfort. This was insured at the initiation of score development when clinicians chose the variables and variable ranges based on clinical importance. PRISM III variables are either routinely recorded at the

bedside (e.g. vital signs), are a routine part of intensive care laboratory monitoring, or have clear indications. Recently, we studied whether or not this assumption had the potential to bias institutional results. Only 6% of all explained variability could be attributed to individual PICUs, while other factors such as diagnosis, length of stay, and severity of illness accounted for the vast majority of the variability. Therefore, it is very unlikely that this issue will bias individual PICU evaluations.

The major success of ICU severity of illness methodologies pertinent to this project is their use for benchmarking and quantitative quality assessment. The constancy of the relationship between physiologic status and outcome is the backbone for this application. If the observed number and distribution of outcomes are similar to those predicted, then the performance of an institution is equivalent to those institutions that contributed to the development and validation of the predictor in the multi-centered trial. PRISM III has been developed from a sample of 32 PICUs (about 10% of PICUs in the United States) that represent a wide diversity of patient populations and structural and organizational characteristics.

If the performance of a particular ICU, or set of ICUs, is different from expected, an explanation must be sought. While some reasons for better or worse performance may be organizational or structural, most are local. This project is an effort to bring this service to PICUs in a manner that will identify potential problems as well as excellence. However, the final conclusion rests with the ICU staff.

Cost and cost containment issues are also pertinent to *PICUEs*. Investigations of cost and cost containment require objective risk estimates as well as tracking of therapies. Therefore, we developed a method of adjusting length of stay expectations for severity of illness as well as updated methods to quantify efficiency of intensive care. This enabled a comparative assessment of PICUs on these parameters.

Chapter 4

PRISM III

The relationship between physiologic status and mortality risk may change as new treatment protocols, therapeutic interventions and monitoring strategies are introduced. Patient populations may also change as new protocols ameliorate the requirement for ICU care, or entirely new patient groups may emerge as a result of other medical advances. Predictive models may also evolve as databases become larger and additional patient characteristics can be integrated into the predictive algorithms.

The Pediatric Risk of Mortality (PRISM) is a second-generation physiology-based predictor of survival or death for PICU patients. PRISM was initially derived from the Physiologic Stability Index (PSI). The goal of the PRISM III study was the development and validation of a third generation score, based on a sample of 11,165 consecutive admissions to 32 PICUs representing a wide diversity of organizational and structural characteristics. Specifically, the physiologic variables and their ranges, as well as diagnostic and other risk variables reflective of mortality risk, were re-evaluated to update and improve the performance of the score. In addition, since minimizing the time period for assessing mortality risk is advantageous for evaluating ICU quality (because there is less effect from monitoring and therapeutic interventions), we developed a 12-hour prediction model as well as a 24-hour one. Concepts that guided this effort included maximizing the predictive performance while keeping the number of variables and their ranges to a minimum, using variables that are readily available and clearly definable while maintaining the assumptions inherent in the PSI and PRISM that unmeasured variables are assumed to be normal, and avoiding the use of therapeutic variables that may be unduly influenced by practice patterns.

Prior to the study, specific inclusion and exclusion criteria were developed, and other data issues were carefully considered. Initially we considered 34 physiologic variables. We used statistical methods to objectively assign ranges and evaluate the contribution of each variable and its ranges to mortality prediction. We evaluated both the highs and the lows of variables, when relevant. Age dependent variables were stratified into the following age groups: neonates (<1 month), infants (1 to 12 months), children (12 to 144 months), and adolescents (>144 months). When relevant, we attempted to combine age groups into a composite variable. After development of the physiologic portion

of the PRISM score, diagnostic and other risk intervals were considered for inclusion.

Our approach to PRISM III development assumed that deviations of physiologic variables from the mid-range (i.e. the 40th to 60th percentiles) of survivors positively contributed to mortality risk, with larger deviations reflecting higher mortality risks. Appropriate variable ranges that significantly contributed to mortality prediction were investigated initially using univariate logistic regression analysis.

Multivariate logistic regression followed the univariate methods and resulted in the PRISM III score consisting of 17 physiologic variables subdivided into 27 ranges. The PRISM III score obtained from the first 12 hours is denoted as PRISM III-12 and the score obtained from the first 24 hours is denoted as PRISM III-24. If both high and low ranges are included for a physiologic variable, PRISM points may be assigned for both the high and the low range if abnormalities occur in both ranges. The variables most predictive of mortality, as indicated by the highest PRISM III scores, were minimum systolic blood pressure, abnormal pupillary reflexes, and stupor/coma.

After selection of the PRISM III physiologic variables and their ranges, additional predictive terms were tested for significant contribution to mortality prediction by building logistic regression models with either PRISM III-12 or PRISM III-24 as a covariate. This resulted in the inclusion of a $(\text{PRISM III})^2$ term, two acute diagnoses (diabetes and non-operative cardiovascular disease), two diagnoses reflecting acute and chronic health status (chromosomal anomalies and oncologic disease), and four additional risk variables reflecting pre-ICU risk factors (operative status, pre-ICU care area, pre-ICU cardiac massage, and previous ICU admissions). In particular, the additional risk variables contribute 5% to the variance explained by the models while PRISM III contributes 95%.

Overall, the development of PRISM III resulted in several improvements over the original PRISM. First, the physiologic variables and their ranges were re-evaluated. The variables and the ranges in PRISM originally had been selected by the subjective opinions of physicians who helped develop the PSI. When the PRISM score was developed from these variables, objectivity was added, but a re-evaluation of the original ranges was not undertaken. We objectively re-assessed the physiologic variables and their ranges, eliminating some ranges that did not contribute significantly to mortality risk, and revising the ranges of the retained physiologic variables. Some physiologic variables have been eliminated and others, including temperature, pH, PaO_2, creatinine, blood urea nitrogen, white blood cell count, and platelet count have been added. Although these are important changes, the variables with the greatest importance in outcome prediction are the same in both scores (i.e. low systolic blood pressure, altered mental status, and abnormal pupillary reflexes).

Second, age issues, clear data collection instructions, precise variable definitions, and strict rules for patient inclusion and exclusion were addressed at the outset of this study. While age was included as an explicit variable in the original PRISM score, it is included in the PRISM III score in a logically and clinically more convincing form by using appropriate age-adjusted physiologic variable ranges. Subsequent model fit evaluations demonstrated the success of these adjustments. A formal, operational method for assessing mental status also was established to account for the frequent use of sedation and paralysis. Variables included in the prediction model are better defined, making the score less vulnerable to "gaming." Two diagnostic entities, chromosomal abnormalities and oncologic disease, reflect underlying health status as well as acute disease status. Two acute diagnoses include non-operative cardiovascular disease and acute diabetes (primarily diabetic ketoacidosis). Other risk factors include operative status, pre-ICU care area, pre-ICU cardiac massage, and previous ICU admission.

Third, the relationship between physiologic status measured by PRISM III and outcomes has been calibrated to a large, contemporary, well-defined reference sample. The set of 32 PICUs represents about 10% of all PICUs in the United States. These units encompass a wide diversity of organizational structures and patient mixes. This diversity makes the sample sufficiently representative, enabling PRISM III to be used in the comparative assessment of ICU outcomes in essentially all PICUs.

As our database grew with *PICUEs Software Versions 1 and 2*, so did our research data sets. In 1999, we recalibrated our PRISM III algorithms using a database of almost 20,000 patients. As the *PICUEs* program becomes more widely used, our database will grow larger, our recalibrations will be based on larger numbers of patients, and our comparative samples will also grow.

Variables in addition to the physiologic components of PRISM III include: (PRISM III-12)[2], admission for treatment of acute complications of diabetes, non-operative cardiovascular conditions (e.g. congenital heart disease, cardiomyopathies, myocarditis, heart failure, dysrythmias, cardiac complications of drugs, cardiogenic shock from any etiology, systemic hypertension, pulmonary hypertension, vasculitis), chromosomal anomalies, oncologic diseases (acute or chronic), admission from an inpatient care area (excluding operating room or recovery room), post-operative status, previous PICU admission, and pre-ICU cardiac massage. Newer versions also contain head trauma and age.

The performance of our most recent products can be found on our web site (www.PICUEs.org). Performance measures include overall performance (i.e. standardized mortality rate [i.e. the ratio of observed to expected mortality]), the goodness-of-fit test (calibration), and the area under the receiver operating characteristic (ROC) curve (discrimination).

Chapter 5

Data Analysis and Reports

Reliability

Data analysis, especially quantitative quality assurance, will not be reliable unless the data is collected accurately. In the previous studies and software versions, we tested the accuracy of the data collection process by randomly selecting 25-30 patients from the datasets that have been submitted by the participating institution and then asking that the institution re-abstract or re-collect data (via medical record review) for these patients. This effort concentrates on the data that is used for mortality risk calculation. Intra-class correlation is performed on the original and re-abstracted samples, and institutions with intra-class correlations less than 0.70 are asked to review their data collection methods. Data reliability is suspect if the intra-class correlation is less than 0.70.

For institutions using *PICUEs Software Version 3*, we will perform a similar validation at the initiation of the data collection effort, provided the institution agrees to submit data. In addition, every several years, we will offer to provide the institution with updated algorithms and comparative reference sets in exchange for the institution's data. Of course, a re-validation can be done at any time, provided the institution agrees to submit data.

Data Analysis

In *PICUEs Software Version 3*, all reports that were previously generated at the *PICUEs* Data Center are contained in the software and can be generated by the software user.

Descriptive data will be tabulated for each institution. These will include an analysis of numbers of patients, age of patients, days of care, etc., cross-tabulated for characteristics such as clinical service, admission source, etc.

Individual institutional quantitative quality assurance analysis will utilize comparisons of overall mortality rates with the expected mortality rates. For institutions with deviations from the expected at a significance level of less than

0.20, we will compute observed and expected mortality risk in at least 3 mortality risk intervals (i.e. 0 to 5%, 5% to 30%, and greater than 30%. The goodness-of-fit test will be used to assess both the number and the distribution of outcomes. If the data still indicates a potential excess of deaths, the deaths in the mortality risk interval most different from expected will be identified and recommended for focused reviews.

Comparative institutional assessments will be provided by comparing the standardized mortality rate of the participating institution to the rates of institutions that comprise the reference sample used in constructing the PRISM III score combined with sites that have been submitting data to our *PICUEs* database. As more sites are added, relevant groupings of sites may also be reported (e.g. American sites, European sites, etc.).

Confidentiality

The data center will not divulge any institution or patient-level identification information without the permission of the participating institution.

Data from this project may be publishable. When appropriate, participating sites will be identified in these publications, but only after they have given permission to do so.

Chapter 6

Patient Inclusion and Sample Size

All PICU admissions are included except those listed below. Each admission to the PICU (for a particular patient, during a particular hospital stay) is counted separately. Since PRISM is calibrated to PICU patients, only PICU patients should be included. If the ICU is used as a post-operative recovery room, post-procedure recovery room, or for dialysis, these patients should not be included.

In some PICUs, the ICU is used as a step-down, or intermediate care, unit as well as an ICU. Step-down patients should not be included until they are admitted to the ICU. ICU patients changed to intermediate or step-down status are considered discharged from the ICU.

Exclusions:

- Non-ICU patients admitted to the ICU.
- Patients who are pre-terminal on admission to the ICU (see below).
- Patients staying in the ICU for less than 2 hours (see below).

The power of the institutional quality assessment using a standardized mortality ratio is dependent on the number of deaths (i.e. for standardized mortality computations at least 15 consecutive deaths are recommended, and 20 deaths are preferred). In the *PICUEs* project, the patient sample is defined by a specified start and stop date (e.g. PICU admission date greater than or equal to July 1st and less than or equal to September 30th [for a 3rd quarter report). Greater than 99% of all patients admitted to the PICU during this time period and 100% of all deaths that occurred during this time period should be entered in the database.

Patients presenting to the PICU in cardiac arrest or in such extremis that vital signs consistent with life are never achieved are not included. For those patients who achieve vital signs consistent with survival, but become unsalvageable during the data collection period, physiologic data during the pre-terminal period is not used. This is explained in more detail in the following section.

Chapter 7

Time Periods for Collection of Physiologic Data

The most abnormal physiologic data is collected for the first 12 hours (*PICUEs Software Version 3* only uses the first 12 hours of care for physiologic data). The minimum time period for data collection is two hours. If survivors stay less than two hours, do not include them. If non-survivors stay less than two hours prior to death, do not include them either. ***NON-SURVIVORS REQUIRE AT LEAST TWO CARDIOPULMONARY VITAL SIGNS, COMPATIBLE WITH SURVIVAL AND COLLECTED DURING CONSECUTIVE HOURS IN ORDER TO BE INCLUDED***. For example, a patient who receives cardiopulmonary resuscitation (CPR) for most of the three hours of his/her ICU stay would not be included. However, a patient with vital signs compatible with eventual survival (even if they are abnormal) for the first two hours of stay in the ICU is included, even if the patient dies at hour three.

The pre-terminal period is *not* included in the data collection period. Determining the pre-terminal period is only important if the patient dies during the first 24 hours of ICU stay. If it is difficult to determine when the pre-terminal period begins, delete the last two to four hours of data. If insufficient data remains after deleting the last two hours (e.g. there are less than two hours of data remaining), assess the information available if the first two hours of care are included. If this includes an obvious pre-terminal period, do not include the patient. If it does not include an obvious pre-terminal period, use the first two hours of data for data collection (e.g. delete less than the last two hours of data) and include the patient.

Example 1. Often, a cardiac arrest will initiate the pre-terminal period; do not include the cardiac arrest unless the patient is successfully resuscitated and lives for greater than or equal to two hours with vital signs consistent with eventual recovery after the resuscitation.

Example 2. Thirty minutes after admission, a patient suffers a severe hypotensive episode. Although the patient lives for another four hours, the blood pressure is consistently less than 40, and active therapy is stopped. Do not

include this patient because he/she did not have vital signs consistent with survival for at least two hours.

Example 3. A patient is stable but suddenly suffers a cardiac arrest and dies. Prior to the cardiac arrest, the patient had vital signs consistent with survival. The pre-terminal period began with the cardiac arrest. Include all data prior to the cardiac arrest, but do not include data from the cardiac arrest.

Example 4. The patient in Example 3 is resuscitated and lives for another six hours (with vital signs consistent with survival) before suddenly arresting again and dying. Include the first cardiac arrest data since the pre-terminal period begins with the second arrest.

Chapter 8

Crediting Outcome

In most situations, the ICU outcome is clear, but there are some infrequent situations that need clarification.

For example, if an ICU patient goes to the operating room and dies, the death is included as an ICU death if the operative procedure was part of the therapy for an ICU illness. If the operative procedure was for a different illness, do not include the patient as an ICU death. For example, a patient is admitted to the ICU with congestive heart failure and congenital heart disease, cannot be managed medically, goes to the operating room for a surgical procedure, and dies. This patient should be included as an ICU death (but physiologic data from the operating room should not be included).

A patient is admitted to the ICU with respiratory synsycial virus (RSV) and congenital heart disease, recovers from the RSV but stays in the ICU (e.g. because the nursing staff knows him), and then goes to the operating room for repair of the heart defect. If this patient dies in the operating room he should be considered an ICU survivor (but hospital death) because his ICU illness was treated successfully and he could (should) have been discharged from the ICU.

If a terminally ill patient is transferred from the ICU for "comfort care" after technologic support (e.g. mechanical ventilation) has been discontinued, and lives less than 24 hours after discharge from the ICU, he/she should be considered an ICU death. However, if a terminally ill patient is transferred from the ICU for "comfort care" and technologic support is not discontinued, assume the ICU care continues until 24 hours after the technologic support has been stopped. If the patient dies while he/she is receiving technologic support in the hospital, he/she should be considered an ICU death.

Patients transferred out of the ICU with technologic support who are not considered terminal (e.g. chronic mechanical ventilation) are ICU survivors when they leave the ICU.

Readmissions to the ICU are counted as a separate patient.

Chapter 9

The PICUEs Data Collection Form

This chapter provides definitions for data fields, and describes guidelines, requirements, and other instructions for completing the paper PICUEs Data Collection Form. Two different electronic (i.e. rich text format) versions of the PICUEs Data Collection Form are located on the software CD in the Additional Materials folder. The user should use the following definitions, guidelines, requirements, and other instructions when completing the form.

Section 1. Patient Background Data

A. Data Collector Initials.

Record the data collector's initials. This will allow the user to review the work of individual data collectors.

B. Medical Record Number.

Record the patient's medical record number. This will enable the user to view and distinguish records in the system as well as identify patients deemed appropriate for review. Patient confidentiality is maintained because the participating institution is in control of the patient identification information and this data need not be sent if the user ever chooses to transfer data to the PICUEs Data Center (i.e. see the notes regarding the batching process in the *PICUEs Software Version 3 Software Manual*). If the medical record number must be replaced with another code, the code should be linked to the medical record number and kept at the participating site.

Note: In the database, the medical record number field is defined as alphanumeric text, so the user should use a consistent format for data entry (e.g. leading zeros, hyphens, dashes, etc., should be retained because (as an alphanumeric text field) the system will recognize "0999" as different from "999", and will sort "100" before "90").

C. Last Name.
Record the patient's last name. This will enable the user to view and distinguish records in the system according to patient name in addition to patient medical record number.

D. First Name.
Record the patient's first name. This will enable the user to view and distinguish records in the system according to patient name in addition to patient medical record number.

E. Method of Payment.
Record the method of payment. In the PICUEs system, this field is an expandable drop-down list that presents a list of all previous entries made in this field. This allows the user the flexibility of either entering payer names verbatim or else creating customized payer categories (e.g. Managed-Care, Non-Managed Care, Medicaid, Self-Pay, HMO, etc.). The user should document his/her institution's classification/categorization scheme.

F. Local Identification Number.
Record the local identification number. This field should only be used if the institution is tracking certain patients for particular reasons. For example, if the institution is enrolling patients in some kind of intervention study the user might use this field to record which intervention group a particular patient was assigned to or which identification number a particular patient was assigned in a randomized clinical trial.

G. Date of Birth.
Record the patient's date of birth. This is required for age and PRISM III calculations.

H. Gender.
Record the patient's gender.

I. Weight and Units.
Record the patient's PICU admission day weight and specify the units (kilograms or pounds).

J. Race.
Record the patient's race. In the *PICUEs* system, this field is an expandable drop-down list that presents a list of all previous entries made in this field. This allows the user the flexibility of either entering races verbatim or else creating customized race categories. The user should document his/her institution's classification/categorization scheme.

K. Account Number.
Record the patient's account number. This field may be useful for establishing links to financial information in other databases.

L. Referring Hospital.
Record the referring hospital. In the PICUEs system, this field is an expandable drop-down list that presents a list of all previous entries made in this field. This allows the user the flexibility of either entering referring hospital names verbatim or else creating customized referring hospital categories. The user should document his/her institution's classification/categorization scheme.

M. Referring Physician.
Record the referring physician's name. In the PICUEs system, this field is an expandable drop-down list that presents a list of all previous entries made in this field. This allows the user the flexibility of either entering referring physician names verbatim or else creating customized referring physician categories. The user should document his/her institution's classification/categorization scheme and be consistent (i.e. always enter the physician's last name, followed by a comma, followed by the physician's first name, or some format like this).

N. Primary Physician.
Record the primary physician's name. In the PICUEs system, this field is an expandable drop-down list that presents a list of all previous entries made in this field. This allows the user the flexibility of either entering primary physician names verbatim or else creating customized primary physician categories. The user should document his/her institution's classification/categorization scheme and be consistent (i.e. always enter the physician's last name, followed by a comma, followed by the physician's first name, or some format like this).

O. Hospital Admission.
Record the date and time of admission to the hospital (for time use a 24-hour clock). Admission is defined as the time of the first vital sign to an inpatient unit, not the time of admission to the intake area or emergency department, and not the time recorded by the admission's office

P. PICU Admission.
Record the date and time of admission to the PICU (for time use a 24-hour clock). This is required for age, PRISM III, efficiency, and observed and severity-adjusted length of stay calculations. Admission is defined as the time of the first vital sign in the ICU.

Section 2. PICU Admission Data

A. Admission Status (i.e. Elective/Emergency).

Record the PICU admission status. Elective admissions are defined as admissions that are scheduled and could be postponed if sufficient advanced notice was available. Examples of elective ICU admissions include: elective surgery requiring post-operative ICU care and scheduled medical procedures such as semi-elective exchange transfusions in a sickle cell patient. In addition, if admission status is emergent, record the method of transport to the hospital. If more than one method was used, indicate the most sophisticated method (i.e. fixed wing aircraft is the most sophisticated, followed by helicopter, ambulance/rescue squad, and private vehicle).

B. Post-Operative Care.

Record whether or not the patient was admitted to the ICU for post-operative care. Admission for post-operative care refers to PICU admission immediately following surgery or PICU admission in which the patient receives surgery during the first 24-hours of ICU care. If the patient is coming from surgery, the patient is either admitted directly from the surgical suite or recovery room. Admissions following catheterization procedures are not considered post-operative. In addition, record the operation that was performed (only a general description is needed [e.g. central shunt, appendectomy, etc.]) and indicate whether the operation was corrective, palliative, or unknown (to the best of your ability).

C. PICU Admission Source (i.e. Patient Was Admitted From...).

Record where the patient was admitted to the PICU from (i.e. your hospital, another hospital, a clinic/MD's office, or home). If the patient was transported from another inpatient unit, and stopped in your emergency department, consider the patient an admission from another hospital. If the patient was transferred from another emergency department to yours, consider the patient an admission from your hospital. Occasionally, patients are admitted directly from a clinic or physician's office, or even from home. In addition, if the patient was admitted from your or another hospital, specify the last nursing area that delivered medical care prior to PICU admission (i.e. the Emergency Department, Operating/Recovery Room, Catheterization Laboratory, Other Inpatient Care Area, or Other Area). For example, if the patient moves from the emergency department to the CAT scan area and then to the ICU, the admission would be from the emergency department, not the CAT scan area, because the CAT scan area is not a hospital area delivering routine nursing care while the emergency department is. Post-operative patients will either come from the recovery room or the operating room (unless they received their operation in the first 24-hours of ICU stay). Also, if the patient came from the emergency department, record the amount of time (in minutes) that the patient remained in the emergency department.

D. Any Previous PICU Admissions During this Hospitalization?

Record whether or not the patient had any previous PICU admissions during this hospitalization. If the patient did have previous PICU admissions during this hospitalization then record all previous PICU admission dates.

Section 3. Diagnostic Data

A. Acute Diagnosis (Primary [A] and Secondary [B]).

Record a single primary diagnosis and all pertinent secondary diagnoses. If there is a question of what the primary diagnosis is, make your best assessment. This assessment is made from information known during the first 24-hours of ICU stay. Only those diagnoses with a known or a suspected contribution to outcome are listed. Please record those diagnoses that are not listed, but that you feel are important, as "other". Inexperienced data collectors will often use the symptoms as a diagnosis (e.g. respiratory distress). It is best to use diagnoses that represent the best effort at the end of the first 24-hours of care.

Depending on the diagnostic selection, more data may be required (see the "Do" column). For example, if cancer is noted, the user should record whether or not the cancer is in remission, whether or not chemotherapy was received in the last month, and what is the primary system or region of the cancer.

Refer to the following notes for specific acute diagnoses:

- Cancer (Oncologic Disease): Refers to malignant disease.
- Cardiac Arrest Within 24-Hours of PICU Admission: Requires cardiac massage.
- Chromosomal Abnormalities: Refers to gross anomalies, not hereditary conditions.
- Cardiovascular Disease - Acquired: Refers to conditions noted in diagnosis-related data section 3F, such as vasculitis, cardiogenic shock, etc.
- Cardiovascular Disease - Congenital: Generally refers to congenital heart disease. This selection includes patients admitted following repair of congenital defects.
- Hypoxic-Ischemic Encephalopathy: Refers to acute central nervous system dysfunction following hypoxia and/or ischemia.
- Medical Device Malfunction: Refers to malfunction of a medical device such as a ventriculo-peritoneal shunt.
- Seizures: Includes complications of seizure therapy such as apnea after therapy.

- Suicide Attempt: Includes suicide attempt and intentional drug overdose.

C. Chronic Diagnoses.

Record all pertinent chronic diagnoses. Refer to the following notes for specific chronic diagnoses:

- Bronchopulmonary Dysplasia: Refers to chronic lung disease following a neonatal insult.
- Cerebral Palsy: Refers to a central nervous system dysfunction following a neonatal insult. If there is central nervous system dysfunction following a non-neonatal insult, check static encephalopathy.
- Intraventricular Hemorrhage: Refers to an event from the perinatal period.
- Static Encephalopathy: Refers to mental retardation, etc., following a non-neonatal insult (see cerebral palsy).

D-Q. Diagnosis-Related Data.

These sections contain conditionally required, follow-up data (i.e. data that is dependent on entries made in previous diagnostic sections). Most sections are self-explanatory. In section G (Congenital Heart Disease) record the diagnosis closest to the major defect. Not all defects are included.

Section 4. Chronic Care Devices Data

Record whether or not the patient uses chronic care devices or services. If the patient uses chronic care devices or services, specify which ones (i.e. Chronic Care Hospitalization, Feeding Tubes, Home IV Access, Home Parenteral Nutrition, Home Mechanical Ventilation, Home Oxygen, or Tracheostomy).

Section 5. Clinical Services Data

The clinical services are classified into primary (5A), co-managing (5B), and consulting (5C) services.

A. Primary Clinical Service.

The clinical service of primary responsibility refers to the service with primary responsibility for patient management. Institutions with co-physician management usually specify a single service as the primary clinical service. This information can be obtained, depending on the institution, from the patient stamp/nameplate, service writing the ICU admission orders, or the service writing the ICU admission history and physical. In many institutions, there is an accepted routine that the data collectors may use. If there is shared responsibility between more than one service and a primary service

cannot be identified, list the "best" primary service. The other primary services should be considered co-managing services.

B. Co-Managing Clinical Services

Record the physician services that provided co-managing services while the patient was cared for in the ICU. Co-management may be indicated in different ways in different institutions. For example, the patient stamp/nameplate may list multiple physicians, the ICU may have policies that "automatically" determine co-management, etc.

C. Consulting Clinical Services

Record the physician services that provided consulting services while the patient was cared for in the ICU. Consultative services are determined by consult sheets, order writing, and notes. Please only indicate physician consultative services, not non-physician consultative services such as dietary. Data on consultative services may be difficult to obtain without extensive effort. This data is not required.

D. Admitting Physicians

Record the names of all admitting physicians. In the PICUEs system, this field is an expandable drop-down list that presents a list of all previous entries made in this field. This allows the user the flexibility of either entering admitting physician names verbatim or else creating customized admitting physician categories. The user should document his/her institution's classification/categorization scheme and be consistent (i.e. always enter the physician's last name, followed by a comma, followed by the physician's first name, or some format like this).

E. Consulting Physicians

Record the names of all consulting physicians. In the PICUEs system, this field is an expandable drop-down list that presents a list of all previous entries made in this field. This allows the user the flexibility of either entering consulting physician names verbatim or else creating customized consulting physician categories. The user should document his/her institution's classification/categorization scheme and be consistent (i.e. always enter the physician's last name, followed by a comma, followed by the physician's first name, or some format like this).

F. Critical Care Physicians

Record the names of all critical care physicians. In the PICUEs system, this field is an expandable drop-down list that presents a list of all previous entries made in this field. This allows the user the flexibility of either entering critical care physician names verbatim or else creating customized critical care physician categories. The user should document his/her institution's classification/ categorization scheme and be consistent (i.e.

always enter the physician's last name, followed by a comma, followed by the physician's first name, or some format like this).

G. Co-Managing Physicians

Record the names of all co-managing physicians. In the PICUEs system, this field is an expandable drop-down list that presents a list of all previous entries made in this field. This allows the user the flexibility of either entering co-managing physician names verbatim or else creating customized co-managing physician categories. The user should document his/her institution's classification/ categorization scheme and be consistent (i.e. always enter the physician's last name, followed by a comma, followed by the physician's first name, or some format like this).

Section 6. Physiologic Data

Physiologic data is collected for the PRISM III score. Since the PRISM III score is under constant revision and reassessment, the user is also asked to collect physiologic variables that are under consideration for inclusion in future versions. Mortality risks will be calculated using the most updated PRISM III score.

Only data obtained in the ICU is admissible. Data from the pre-ICU care time is not admissible with the exception of neurologic status if the patient was sedated or paralyzed during the ICU time period (see below).

The most abnormal *recorded* data in the first 12-hours of care in the ICU should be included. Sources include the bedside records, nurse's notes, laboratory reports, etc.

Please carefully review the following notes for completing the physiologic data. They include answers to the most commonly asked questions as well as indications of the most commonly made mistakes.

A. Cardiovascular Data (Systolic Blood Pressure, Diastolic Blood Pressure, Heart Rate, Respiratory Rate, and Temperature).

Cardiovascular PRISM components are straightforward. Data are collected from the cardio-respiratory vital sign sheet and should reflect the patient's medical state, not agitation, crying, etc. *Therefore, do not use data that are collected when crying or other basal-state-altering activities are noted.*

For systolic blood pressure, if both arterial and cuff blood pressures are available, use the arterial catheter data (if the catheter is functional).

If the patient undergoes cardiac massage or cardiac arrest, record the most abnormal measured values for blood pressure and heart rate. Remember, most cardiac arrests in the ICU occur after mechanical ventilation is

instituted. Under these circumstances, the respiratory rate is that of the ventilator. (For example, a patient who arrests on a mechanical ventilator will not get respiratory points because the respirator has been supplying ventilation). In general, a "real" cardiac arrest requires more than 30 seconds of cardiac massage. For resuscitation with chest compressions and absent blood pressure, record the systolic blood pressure value as 0; if asystole, record the heart rate as 0. If apnea lasts longer than 20 seconds, record the respiratory rate as 0.

Respiratory rates should include the total respiratory rate of the ventilator plus the patient. However, "unique" or "institutional" respiratory care protocols may include "high frequency" (jet, oscillator) ventilation. When high respiratory rates result from jet or oscillatory ventilation, do not include them. Instead, record the respiratory rate as 99. In general, only exceptionally ill patients should have high respiratory rates from the mechanical ventilator.

For temperature use rectal, oral, blood, ear, or other sites known to be close to the core temperature. Do not use skin temperature.

B. Acid-Base/Blood Gases Data (pH, PaO_2, and PCO_2).

Blood gas PRISM components are designed to detect acute respiratory disease and acid base status. They are assessed from the respiratory flow sheets or directly from the laboratory data sheets. Data should be used only when it is reliably obtained. Therefore, only arterial blood gases are included for PaO_2 determinations. Transcutaneous PO_2, capillary PO_2, transcutaneous oxygen saturations, etc. are not included.

PCO_2 may be estimated from arterial, venous, or capillary blood gases because these methods are reasonably accurate in determining broad ranges of abnormalities. $PaCO_2$ during brain death apnea testing should not be included.

pH should be used from arterial, capillary, or venous sites.

C. Chemistry Tests Data (Sodium, Potassium, Bicarbonate [Total CO_2], Blood Urea Nitrogen [BUN], Creatinine, Glucose, Total Calcium, Ionized Calcium, Total Bilirubin, and Albumin).

Laboratory PRISM components are assessed from the laboratory flow sheets or the laboratory records. Accuracy should always be assessed. For example, specimens noted as hemolyzed will not provide accurate potassium determinations and should not be used.

More and more ICUs are using whole blood determinations for tests that previously used serum or plasma. If whole blood is used for sodium determinations, increase the value by 3 mmol/l. If whole blood is used for

potassium, increase the value by 0.4 mmol/l. If whole blood is used for glucose, increase the value by 10%.

Units of measurement are gradually changing. For those with potential to change in the near future, we have required that you stipulate the unit of measurement.

Bicarbonate is determined from the measured specimen (done with the Na and K and Cl determinations), not from the blood gases. If your laboratory primarily used calculated bicarbonate values instead of measured total CO_2 values, use the calculated bicarbonate values.

Record the bilirubin for all ages.

Only data from the ICU time period is admissible.

D. Hematology Tests Data (Hemoglobin, WBC Count, % Segmented Forms, Platelet Count, PT, and PTT).

These are generally self-explanatory. Percent segmented forms is considered the sum of segmented, banded, and more immature forms, if present. Only data from the ICU time period is admissible.

E. Neurologic Vital Signs Data (Pupillary Reflexes, Coma Status, Glasgow Coma Scale).

Neurologic vital signs are the most problematic of the PRISM III variables, but also the most important to obtain. The neurologic PRISM components are designed to detect prognostic data for patients with *known or suspected acute neurologic disease (in particular, patients with cardiac arrest, diabetes, drug overdose, hypoxic-ischemic encephalopathy, meningitis, seizures, shock, and/or trauma).* They are assessed from the neurologic vital sign sheets, relevant sections of the cardio-respiratory vital sign sheets, and/or the nurse's notes. There must be access to the medication record to determine whether or not the patient is paralyzed and/or sedated. Institutions not assessing mental status in terms of the Glasgow Coma Scale (GCS) score can use the coma status field.

Coma status is included only if the patient has *known or suspected acute neurologic disease* (e.g. head trauma) or if there is a *reasonable possibility that acute neurologic disease is present* (e.g. s/p severe shock). There must be a reasonable medical condition accounting for the neurologic dysfunction. Chronic "coma" or chronically altered mental status is not included. Patients are only scored if the coma occurs in the ICU and if it is *not caused by drugs.*

Since iatrogenic "coma" is not evidence of disease severity, do not include scores for at least the first two hours following anesthesia, sedation, or paralysis. Some institutions use the neurologic vital sign notations to track patient activity. Therefore, sleeping may be noted as unconsciousness, etc.

Coma indicates a condition characterized by lack of meaningful responsiveness to painful stimulus and does not include sleeping children.

If the patient has been iatrogenically sedated or paralyzed during the entire ICU observation period, use the most recent, accurate mental status assessment prior to the ICU admission (e.g. the coma status in the emergency department).

Pupils must be greater than 3 millimeters to qualify as fixed and dilated. Pin-point pupils are too small to observe reactivity reliably. Unequal pupils must be a minimum of 1 millimeter in difference. Small, "fixed" pupils do not receive points. Chronically altered pupils from previous disease are not scored. Drugs can affect pupils, but rarely. In general, only atropine interferes with this assessment. If the pupillary findings are iatrogenic, they should not be scored.

GLASGOW COMA	**Activity**	**Score**
Eye Opening	Spontaneous	4
	To Speech	3
	To Pain	2
	None	1
Verbal Response	Oriented	5
	Confused/Appropriate Crying	4
	Best Verbal Response for Infants	4
	Inappropriate	3
	Incomprehensible	2
	None	1
Motor Response	Obeys Commands	6
	Localizes Pain	5
	Best for Infants	5
	Withdraws to Pain	4
	Decorticate - Abnormal Flexion	3
	Decerebrate - Abnormal Extension	2
	None	1
COMA STATUS	**Activity**	**Score**
Normal	Awake/Normal	4
Lethargy	Arousable with Stimulation to a State Capable of Communication	3
Stupor	Arousable with Vigorous and Repeated Stimulation to Withdrawal and/or Moaning	2
Coma	Nonpurposeful or No Response to Vigorous Stimulation	1

Section 7. PICU Outcome Data

A. PICU Discharge/Death Date and Time.
Record the date and time of PICU discharge or death.

B. PICU Outcome.
Record the PICU outcome.

If the PICU outcome was survival, record where the patient was discharged to (i.e. Your Hospital, Another Hospital, Chronic Care Facility, Home, or Other). If the patient was discharged to your or another acute care hospital, record where in the hospital the patient was discharged to (i.e. Routine Care Area, Step-Down Unit, Another PICU, Neonatal ICU, or Adult ICU). In addition, if the patient survived, record whether or not the patient was terminally ill and discharged for comfort care. If the patient was terminally ill and discharged for comfort care, indicate whether or not the patient was receiving technologic support when discharged and how soon after discharge the patient died (i.e. Within 24-Hours of Discharge or Discontinuation of Technologic Support, After 24-Hours of Discharge or Discontinuation of Technologic Support, or Did Not Die).

If the PICU outcome was death, indicate the circumstances under which the patient died (i.e. Failed Resuscitation with Cardiac Massage, Failed Resuscitation without Cardiac Massage, Do Not Resuscitate Order, Associated with Withdrawal or Limitation of Care, Brain Death), whether or not an autopsy was performed, and whether or not the patient served as an organ donor.

Notes on Terminally Ill Patients and Those Discharged for "Comfort Care".
Some patients are discharged with measures that are provided for comfort only while not receiving full or perhaps even partial ICU-level support. Technologic support includes mechanical ventilation, continuous positive airway pressure (CPAP), and vasoactive agent infusions (i.e. those technology-intensive therapies associated with the ICU). Comfort may refer to both the patient and the family.

Notes on Circumstances Surrounding PICU Death.
More than one of these responses may apply. Failed resuscitation indicates that active efforts were made to keep the patient alive, with or without cardiac massage. A Do Not Resuscitate (DNR) order refers to a *written* order to limit resuscitation. Withdrawals or limitations of care include DNR orders. However, for this question, it is meant to assess limitation or withdrawals *in excess of* the DNR order. For example, limitations might include no increase in the vasoactive agent infusion or in ventilatory support. Withdrawals are actions of taking away. For example, extubation or stopping

vasoactive agent infusions. Similarly, Brain Death is the *formal* determination of brain death. Patients who have clinical finding consistent with brain death, but whose care is discontinued PRIOR to making the declaration of brain death formal (e.g. correct number of exams, apnea tests, etc.) are not brain dead, but have had withdrawal of care.

Section 8. Hospital Outcome Data

A. Hospital Outcome.
Record the hospital outcome.

B. Hospital Discharge/Death Date and Time.
Record the date and time of hospital discharge or death.

C. When Did the Patient Die?
If the patient survived the PICU stay, but died prior to hospital discharge, indicate when the patient died (i.e. Died in the PICU After Subsequent PICU Admission, Died in the Operating Room, Died in Another PICU, NICU, or adult ICU, or Died within 24-Hours of PICU Discharge).

Section 9. Functional Status Data

The Pediatric Cerebral Performance Category (PCPC) and the Pediatric Overall Performance Category (POPC) are included for those units wishing to collect this data. Methods for categorizing young children who are naturally dependent have not been published. Therefore, the opportunity to collect this data is presented for those units finding value in it. The reliability and reproducibility are not sanctioned by *PICUEs*.

Section 10. Ethics Data

Record whether or not orders were given for limitation or withdrawal of care. In addition, record the best rationale for these orders (including imminent death, no relational potential based on chronic disease status, no relational potential based on acute disease status, burdens outweigh benefits based on chronic disease status, and burdens outweigh benefits based on acute disease status). See the following notes regarding rationales and specific orders.

Notes on Rationales:

- Imminent Death: Refers to hopeless prognosis for current survival (imminent death, no medical therapy will successfully result in continued existence).
- No Relational Potential: Refers to coma, vegetative states, very severe mental retardation preventing meaningful interactions with the environment,

or extended survival with other neurologic deficits and no potential for recovery or relationships. This may be based on chronic (i.e. greater than 30 days) or acute (i.e. this ICU admission) conditions.

- Burdens Outweigh Benefits: Refers to extended survival with unacceptable burden (the burden/benefit ratio is such that prolonged survival would inflict more suffering than is worth living for). This may be based on chronic (i.e. greater than 30 days) or acute (i.e. this ICU admission) conditions.

Notes on Do Not Resuscitate (DNR) Orders. The *do not resuscitate* (DNR) order indicates that no resuscitation attempts will be made. It may be limited (e.g. no intubation), part of a no escalation of care effort, or part of a withdrawal of care effort.

A minority of patients, but many of the deaths, will have decisions that involve withdrawals and limitations of care. Please record the indicated information. The data collector may find it useful to ask for the assistance of the involved personnel (i.e. physicians, nurses, social workers, etc.). Since this section involves only a few patients it is worth the effort to track down this information. Definitions in this section are very important.

Notes on Limitation of Care Orders. A limitation of care is considered a decision *not to institute care or not to escalate care*. Sometimes the circumstances are specified, and sometimes they are not. The most well known example of a limitation of care is the "Do Not Resuscitate (DNR)" order. This is also called a "no code" order, "no code blue" order, "no code red" order, etc. Circumstances may include "no intubation if respiratory arrest, but full cardiac support excluding cardiac massage" or "bag but do not intubate." There are other limitations of care that may be harder to identify but are just as important. These include decisions not to perform therapies such as dialysis, mechanical ventilation, or surgery.

Notes on Withdrawal of Care Orders. A withdrawal of care is an *active* response that *takes away a therapy that is already being used* when it is still perceived to be beneficial for maintaining *physiologic survival*. Examples of withdrawals of care include discontinuing the ventilator and discontinuing vasoactive drugs. Sometimes it is difficult to distinguish between a withdrawal and a limitation of care. For example, a drug may be "weaned off" and orders may be written to not reinstitute or not increase the drug. Use your best interpretation.

Limitations and withdrawals of care *after* brain death has been documented are *not* included. The patient is considered dead when death is *formally* declared (i.e. when brain death is determined).

Section 11. Care Items Data

This section contains information for a wide variety of therapeutic interventions and monitoring modalities. These data are included to compute standardized length of stay ratios (which requires monitoring of admission day mechanical ventilation) and efficiency rates (which requires daily monitoring of mechanical ventilation and vasoactive infusion use), as well as follow other potential outcome variables (i.e. unplanned extubations and risk-adjusted nosocomial infection rates).

Except for admission day mechanical ventilation, this section is not required. It will increase the effort that institutions must put into the project because it requires rather intense daily data collection. However, institutions can gage the amount of effort they expend so that they can maximize the amount of information they wish in return. For example, standardized length of stay calculations requires only admission day monitoring of mechanical ventilation, while efficiency studies require only daily monitoring of mechanical ventilation and vasoactive agent infusion use. Risk adjusted nosocomial infections require all data be collected. Specific data such as unplanned extubations can be collected, but this information will not be useful unless the user also collects daily mechanical ventilation use to control for the number of mechanical ventilation days.

Each column on the data collection form and data entry screen refers to a specific 24-hour period, defined by the original PICU admission and discharge dates and times. Within each column (i.e. for each specific 24-hour period that the patient resides on the unit), the user should record therapies and monitoring modalities that were used (by placing a check mark in the box). Use of the intervention or modality for any amount of time during the 24-hour period is sufficient to count as use for that period. For example, if mechanical ventilation was used for only 30 minutes, it is sufficient to indicate mechanical ventilation use for the entire day. See the following notes of explanation for specific therapeutic interventions and monitoring modalities.

A. Therapeutic Interventions:

- Mechanical ventilation: self-explanatory.
- Unplanned extubations: record the number of unplanned extubations that occur during a particular 24-hour period.
- Vasoactive infusions: vasoactive agent continuous infusions include “drips” of the following agents: dopamine, dobutamine, epinephrine, norepinephrine, amrinone, nitroprusside, nitroglycerin, phentolamine, phenylephrine, etc.
- Antimicrobials: includes any and all antibiotics, antiviral agents, and antifungal agents that the institution chooses to monitor.

- Steroids: includes any and all parenteral or oral steroids that the institution chooses to monitor.
- H-2 blockers: includes any and all parenteral or oral histamine-2 receptor blockers that the institution chooses to monitor.
- Cardiac compressions: includes closed or open chest cardiac massage during a cardiac arrest or episode of severe hypotension.
- ECMO: self-explanatory.
- Parenteral Nutrition: includes *central or peripheral* intravenous protein and glucose, with or without fat emulsion.
- Hemofiltration: includes continuous veno-venous hemofiltrations (CVVH) or continuous arterial-venous hemofiltration (CAVH).
- Hemodialysis: self-explanatory
- Peritoneal dialysis: self-explanatory

B. Monitoring Modalities:

- Arterial pressure monitor: indicates an *intra*-arterial catheter.
- Central venous catheter: indicates a catheter used for central venous *pressure* measurements or other central venous catheters. Central venous catheters used for parenteral nutrition are included as well.
- Intracranial pressure monitoring: indicates the use of any intracranial device with concomitant recording of pressure. A cerebral-spinal fluid drain is not included if it is not used to measure pressure.
- Urinary catheter: self-explanatory.

Section 12. Nosocomial Infections Data

Nosocomial (i.e. hospital-acquired) infections are adverse PICU outcomes that are important quality of care indicators. In brief, PICU nosocomial infections are defined as localized or systemic conditions resulting from an adverse reaction to the presence of an infectious agent or its toxins in absence of evidence that the condition was present or incubating at the time of admission to the PICU.

The definitions for nosocomial infections at specific body sites are very precise, so the following reference should be used if the user wants this data to be consistent with Centers for Disease Control (CDC) definitions:

- Emori TG, Culver DH, Horan TC, et al: National nosocomial infections surveillance system (NNIS): Description of surveillance methods. *Am J Inf Cont* 1991; 19:19-35).

In addition, the user may choose to consult with members of his institution's epidemiology staff to determine which PICU patients developed nosocomial infections that are attributable to his/her stay in the PICU. The epidemiology staff may routinely collect this information and may be able to provide the user

with a list of onset dates, primary infection sites, and organisms implicated in PICU nosocomial infections.

A. 24--Hour Period (i.e. Onset Date).
Record the period of infection onset.

B. Primary Infection Site.
Record the primary infection site(s).

C. Organism.
Record the name of the organism(s) that are implicated at the infection site(s). In the software there is a drop-down list with over 1000 specific organisms.

Note: Be sure to use multiple rows per onset date if there were multiple infection sites and/or multiple organisms during that date.