**Validation of ICD-9-CM/ICD-10-CM Codes for**

**Automated Electronic Scoring of APACHE II, APACHE III, and SAPS II**

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**Funding:**

This study will not be funded, it will be performed entirely by the investigators and utilize only those resources available at the location.

**Study location:**

Memorial Hermann- Texas Medical Center

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**Objective:**

To evaluate the validity of ICD-9-CM and ICD-10-CM coding algorithms in the scoring of APACHE II, APACHE III, and SAPS II in patients admitted to an intensive care unit (ICU).

**Specific Aims:**

1. To evaluate the accuracy of automated electronic APACHE II, APACHE III, and SAPS II scoring derived from variations of ICD-9-CM and ICD-10-CM code sets against chart reviews in ICU patients.
2. To assess which ICD-9-CM and ICD-10-CM code set for APACHE II, APACHE III, and SAPS II scoring would be most reliable and practical for use in retrospective cohort studies.

**Introduction/Background:**

In 1893, a health classification system now known as *The International Statistical Classification of Diseases and Related Health Problems* (ICD) was introduced. The World Health Organization (WHO) was entrusted with this universal tool for monitoring health trends and statistics as well as reporting diagnoses and health conditions in 1948.1 *The* *International Classification of Diseases, Clinical Modification* (ICD-9-CM) is an adaptation of this tool and is managed by the U.S. National Center for Health Statistics (NCHS) as well as the Centers for Medicare and Medicaid Services to assign diagnostic and procedure codes in medical billing.2 Periodically, ICD is revised to reflect current medical practice.1 For example, ICD-10-CM replaced ICD-9-CM in October 1, 2015 to provide additional codes.3 These codes provide great insight on health information and are useful in conducting large-scale health care research. Data extraction permits analysis of quantitative health information for research, but analysis of qualitative information such as diagnosis and pertinent patient history can be challenging. Using ICD-9-CM and ICD-10-CM coding as a surrogate for qualitative patient factors may overcome this barrier. Charlson and Elixhauser comorbidities are validated algorithms that use ICD codes to measure burden of disease and are models for utilization of administrative data in clinical outcomes research.4,5

Certain scoring tools for use in guiding patient treatment or describing prognosis may be automated through manipulation of administrative data. For example, Navar-Boggan et al developed an automated electronic algorithm for CHADS2 and CHA2DS2-Vasc scoring to identify patients with atrial fibrillation at risk for stroke.6 Other scoring tools that could be automated include APACHE II, APACHE III, and SAPS II. The Acute Physiology and Chronic Health Evaluation (APACHE) II classification system uses a 0 to 71 points scale based on 12 routine physiologic measurements, age, and comorbid conditions to provide ICU mortality prediction.7 The APACHE III prognostic system, quantified on a score of 0 to 299 by medical/surgical disease categories, acute physiologic abnormalities, age, preexisting functional limitations, and major comorbidities, was created to more accurately predict ICU hospital mortality risk.8 Lastly, the Simplified Acute Physiology Score (SAPS) II uses 12 physiological variables, age, type of admission, and 3 comorbid conditions to estimate ICU risk of death with a score of 0 to 163.9

APACHE II, APACHE III, and SAPS II may be used to stratify risk, determine prognosis, or reflect baseline patient demographics in research. Retrospective cohort studies evaluating ICU patients apply ICU scoring tools such as those listed above to describe acuity of illness in their patient population. Although the scoring tools are designed for use within the first 24 hours of ICU admission, time constraints limit feasibility and use in real world application. Researchers desiring the score for their studies must manually calculate the score for each patient if not listed in the electronic medical record. An automated electronic coding algorithm for ICU scoring tools will enable large-scale research and decrease time spent on work-intensive manual calculation. This study aims to validate the use of ICD-9-CM/ICD-10-CM codes for automated electronic scoring of APACHE II, APACHE III, and SAPS II in patients admitted to the ICU.

**Methods:**

*Design:*

This is a single center, retrospective cohort study.

*Population:*

Anticipated sample size:

Approximately 200 patients. All patients who were admitted to an intensive care unit between 07/01/14 and 06/30/16 will be considered for inclusion.

Inclusion criteria:

* Patients 18 years or older
* Patients admitted to an ICU

Exclusion criteria:

* Patients with incomplete data
* Pregnant patients
* Prisoners

*Study Design:*

This will be a retrospective observational study. No interventions will be used and patients will not be prospectively assigned to groups. We will simply observe the care that patients have already received and analyze the data we collect based on past admissions.

*Data Retrieval:*

Data Source: Data will be collected through review of electronic medical records. Patients will be identified by randomly selecting from stratified groups to ensure an equal number of patients with ICD-9-CM and ICD-10-CM codes for a total of 200 patients admitted to the ICU between 07/01/14 and 06/30/16.

Data Collection: *Data collection sheet and supplementary material listing codes attached.*

Data to be collected includes:

1. Patient Demographics
   1. Age
   2. Gender
   3. Weight
   4. Race
      1. African American
      2. Asian
      3. Hawaiian/Pacific Islander
      4. Native American
      5. Other
      6. Unknown
      7. White/Caucasian
   5. Type of admission
      1. Scheduled surgical
      2. Medical
      3. Unscheduled surgical
   6. ICU length of stay
   7. Discharge disposition
2. Laboratory (minimum and maximum value during the first 24 hours of the first CU admission)
   1. Basic metabolic panel
      1. Sodium
      2. Potassium
      3. Bicarbonate
      4. Creatinine
      5. BUN
      6. Glucose
   2. Comprehensive metabolic panel
      1. Albumin
      2. Bilirubin
   3. Arterial Blood Gas
      1. Arterial pH
      2. PaCO2
      3. PaO2
   4. Venous Blood Gas
      1. VO2 Saturation
      2. VpO2
      3. VpCO2
      4. Venous pH
      5. Bicarbonate
   5. CBC
      1. WBC
      2. Hematocrit
   6. Urine output (total recorded value for in the first 24 hours of ICU admission)
3. Vital signs (minimum and maximum value during the first 24 hours of ICU admission)
   1. Temperature
   2. Heart rate
   3. Systolic blood pressure
   4. Diastolic blood pressure
4. Oxygenation (minimum and maximum value during the first 24 hours of ICU admission)
   1. Respiratory rate
   2. Mechanical ventilation or CPAP
   3. FiO2
   4. PaO2
   5. PaCO2
5. Cardiac arrest (within 24 hours prior to ICU admission)
   1. Yes
   2. No
6. Glasgow coma score (minimum during the first 24 hours of ICU admission)
   1. Glasgow coma score eye
   2. Glasgow coma score verbal
   3. Glasgow coma score motor
7. Diagnosis and procedural coding (all diagnosis and procedural codes for the encounter)
   1. ICD-9-CM or ICD-10-CM codes
   2. DRG code
8. Comorbidities (identifiable in the H&P or first ICU progress note; the corresponding ICD-9-CM and ICD-10-CM code assignments for each comorbidity are listed in the protocol Supplementary Material)
   1. Liver
      1. Cirrhosis
      2. Upper GI bleeding
      3. Hepatic Failure
      4. Encephalopathy
      5. Coma
   2. Cardiovascular
      1. Heart failure
   3. Respiratory
      1. Chronic restrictive, obstructive, or vascular disease
      2. Chronic hypoxia
      3. Hypercapnia
      4. Secondary polycythemia
      5. Pulmonary hypertension
      6. Respiratory dependency
   4. Renal
      1. Acute renal failure
      2. Receiving chronic dialysis
   5. Immunocompromised
      1. Metastatic cancer
      2. Immunosuppression
      3. Chemotherapy
      4. Radiation
      5. Long-term or high-dose steroids
      6. Leukemia
      7. Multiple myeloma
      8. Lymphoma
      9. AIDS

*Definitions:*

Scheduled surgical: at least 24 hours in advance

Medical: without surgical procedures within 7 days of ICU admission

Unscheduled surgical: added to OR schedule within 24 hours of the operation

*Data storage*:All data will be stored on an encrypted computer only accessible to the investigators. Data will be de-identified upon being entered into the database.

**Outcomes:**

*Primary endpoint:*

1. The difference in score between electronic and manual scoring for each of APACHE II, APACHE III, and SAPS II.

*Secondary endpoints:*

1. The difference in predicted mortality between electronic and manual scoring for each risk score.
2. The difference in number of comorbidities identified by electronic and manual scoring for each risk score.
3. The number of comorbidities identified by electronic or by manual scoring but not by both.

*Statistical analyses:*

All analyses will be considered significant with p<0.05. Calculations assume α<0.05, 80% power.

Statistical tests:

The student’s t-test will be used for continuous data following a normal distribution, Wilcoxon’s rank sum will be used for continuous data following a non-normal distribution, and chi-squared test or fisher’s exact test will be used for categorical data for the groups being compared.

**Risks and Benefits:**

*Potential Risks:*

The only potential risk for subjects is loss of confidentiality; however, this risk will be minimized by de-identifying data and storing it on an encrypted computer.

*Management of PHI:*

Any protected health information (PHI) identifiers, medical record number, abstracted or obtained from medical chart records or received from medical providers will be kept strictly confidential and will not be shared with anyone not directly associated with the study. Any data collected in log format will be kept under lock and key, and access will only be permitted by the primary investigators and the research staff. Data transferred to an electronic database will be maintained on a computer that is encrypted with access only by the research staff.

Records will be kept until the end of the study and then any PHI that has not been de-identified will be destroyed. Any codes or links relating back to individually identifiable PHI will also be destroyed. Electronic records will be deleted and paper records or logs will be shredded.

*Potential Benefits:*

The primary benefit of this study will be to validate an automated electronic APACHE-II, APACHE-III, and SAPS II scoring tool for use in retrospective cohort studies.

**Informed consent:**

As this is a retrospective study using medical records from Memorial Hermann-Texas Medical Center and patient information will be de-identified a waiver of informed consent will be filed with this application.

**Recruitment and Advertising/ Compensation/Specimens and Cell Lines:**

Patients will not be recruited and there will be no advertising for this study. Therefore, there will also be no compensation and as this is a retrospective, observational study there will be no specimens or samples involved.

**Expedited Review:**

This study is being submitted for expedited review since it is retrospective and observational in its design.

**References:**

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