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**CRC Protocol Description**

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#### **A. Study Purpose and Rationale**

Over the last few decades, an undetermined number of pediatric hospitals have opened intermediate care units (IMCU), which generally provide a level of care between that required in a pediatric intensive care unit (PICU) and a general inpatient pediatric unit<sup>1</sup>. IMCUs have been shown to allow hospitals to better stratify patients by level of illness, so that scarce resources, such as nursing staff and continuous monitoring equipment, can remain available to the patients who need it most<sup>2</sup>. This allows hospitals to more accurately titrate level of care based upon patient acuity, affecting both cost and quality of care<sup>2,3</sup>.

Very little is known specifically about pediatric IMCUs at this time. Initiation of an IMCU at one institution decreased acuity on the general ward floors<sup>4</sup>. Mortality has been shown to be unaffected by the initiation of an IMCU at another institution, while nursing hours (a major driver of cost) were decreased<sup>2</sup>. Adult data has suggested an increase in readmission rates when PICU patients are discharged to an IMCU compared to a general unit<sup>5</sup>. To our knowledge, the effects of an IMCU on length-of-stay in PICUs are not known, nor are the characteristics of patients transferred between IMCUs and PICUs or vice versa. To address these gaps in knowledge, we propose a retrospective study of PICU admissions that originated from or were discharged to IMCUs, and of the impact of having an IMCU on PICU length of stay. Such a study would further illuminate the type of PICU patients utilizing these “step-down” units, and how and how frequently these units are being utilized by PICUs.

#### **B. Study Design and Statistical Analysis**

We intend to conduct a multi-institutional retrospective cohort study using the Virtual Pediatric Intensive Care Unit Performance Systems (VPS) database. The study period will be July 1, 2009 to March 31, 2011. All patients admitted to North American VPS PICUs during the study period will be included. The dataset already exists, and includes greater than 86,000 patients during this study period.

Summary statistics and bivariate analyses will be used to characterize institutions with and without IMCUs, and to characterize and compare admissions stratified by 1) whether they were admitted from an IMCU and 2) whether they were discharged to an IMCU. The most common acute and chronic diagnoses of IMCU patients will be described. Using multilevel mixed-effects linear regression, we will estimate the impact of having an IMCU on PICU medical and physical length of stay. Given the size of the dataset and the number of encounters in the two groups (64814 without an IMCU, 42231 with an IMCU), the minimum effect size that should be visible is 0.22 days using alpha of 0.05 and a power of 0.80.

#### **C. Study Procedure**

No further data need be collected for this study. Regarding the VPS database itself: VPS is a collaboration between the Children’s Hospital and Health System in Wisconsin, and Children’s Hospital Los Angeles. Encounter-level information on all admissions is entered by trained clinicians at participating sites. Data are collected from pediatric medical, surgical, and cardiac ICUs. Data are not collected from neonatal, intermediate or special care units, or general wards. Some data were required of all sites (such as gender, length-of-stay, patient origin, primary diagnosis). Other data were voluntarily submitted by individual sites (such as race, illness and functionality scores, and secondary diagnoses). Names, medical record numbers and dates of birth were encrypted at the central VPS database and de-identified by assigning unique ID numbers both at the individual and encounter level. No identifying information is

available within the database to be analyzed in the proposed study, and the study investigators do not and will not ever have access to any such information.

All of the decision-making regarding medical management and procedures was at the discretion at the individual physicians working in the VPS PICU sites. No particular areas of study or questions were indicated, and there should have been no effect on clinical care.

**D-F. Study Drugs, Medical Devices, and Questionnaires:** not applicable to this study

#### **G. Study Subjects**

All patients admitted to participating US PICU sites in 2008 and 2009 will be included in this study's data analysis. All diagnoses will be included. This study is attempting to identify characteristics of pediatric ICUs with and without intermediate units, and so it is important to include all pediatric patients admitted to ICUs in the data analysis.

#### **H. Recruitment of Subjects**

Subjects were not recruited for this study. All patients admitted to participating PICUs were submitted to the database after being approved and exempted by the individual site IRBs.

#### **J. Conflict of Interests**

The study investigators have no conflicts of interests to declare.

#### **K. Location of the Study**

The data was recorded at multiple pediatric ICU sites in the US as noted in the sections above. CPMC/CHONY participated in VPS data submission during the study period. Patients admitted to the pediatric ICU located in 9 Tower, 9 Central, and 9 North are included in the study data, but no study activities outside of routine clinical management occurred on site.

**L, M, N, O, & P. Potential Risks, Potential Benefits, Alternative Therapies, Compensation to Subjects, and Costs to Subjects:** Not applicable to this study.

#### **Q. Participation of Minors**

No participation is required; data were passively recorded from routine PICU management across multiple sites.

#### **R. Radiation or Radioactive Substances**

Not applicable to this study.

#### *References*

1. Jaimovich, David. Admission and discharge guidelines for the pediatric patient requiring intermediate level care. *Pediatrics* 113.5 (2004): 1430-1433.
2. Joseph, Christa. "Effects of a monitored care unit on research utilization in a pediatric ICU." *American Journal of Critical Care* 6.4 (1997): 296-301.
3. Porath et al. "The intermediate care unit as a cost-effective method for the treatment of medical patients in critical condition." *Israel Journal of Medical Sciences* 31.11 (1995): 674-80.

4. Hillier et al. "The pediatric intermediate care unit: one institution's experience." Poster presented at: Critical Care, *Pediatric Academic Societies*, 2013 May 5; Washington, DC.
5. Kramer et al. "Intensive care unit readmissions in U.S. hospitals: Patient characteristics, risk factors, and outcomes." *Critical Care Medicine* 40.1 (2012): 3-10.