

FDA breathes life into Etiometry's algorithm for neonatal hypercapnia risk

By Meg Bryant, Staff Writer

Premature babies face challenges in the neonatal intensive care unit (NICU) as their heart, lungs and neurological system continue to develop outside the womb. Roughly half of neonates born at 26 weeks to 28 weeks gestation experience respiratory distress. These infants often need extra oxygen and help breathing, as well as constant monitoring to ensure oxygen is absorbed and carbon dioxide (CO₂) is dispelled. To that end, Etiometry Inc. received FDA clearance for its IVCO₂ Index, a software tool for use in monitoring risk of hypercapnia in NICU patients weighing less than 2 kg.

Many NICU patients need constant monitoring for hypercapnia, or high levels of CO₂ in the blood, to ensure healthy neurological development and prevent complications. Conventional monitoring, such as transcutaneous monitoring, is challenging in infants because of accuracy and hardware limitations.

The IVCO₂ (inadequate ventilation of carbon dioxide) Index, which requires no hardware, takes in data from devices and health records to flag a patient's risk for hypercapnia and alert NICU staff. Vital signs monitored by the algorithm-driven software include heart rate, oxygen saturation, respiratory rate, minute ventilation, fraction of inspired oxygen, partial pressure of CO₂ in arterial and venous blood, end tidal CO₂ and mean airway pressure.

"The Etiometry platform takes all the data from patients, including lab results, vital signs, fluids, medications and monitoring solutions, and applies dynamic models of human physiology to provide an individualized risk estimation of the fundamental pathways patients deteriorate in critical care," Dimitar Baronov, Etiometry's co-founder and chief technology officer, told *BioWorld*. The IVCO₂ Index for neonates was built using more than 150 million hours of data acquired through the company's Quality Improvement app.

"The IVCO₂ Index is a first-of-its-kind algorithm that increases the ability to detect hypercapnia risk without reading additional hardware attached to these fragile patients," Baronov said. "It allows clinicians to prioritize care for patients who need it most."



Etiometry's IVCO₂ Index alerts risk of hypercapnia in critical care patients. It recently received U.S. FDA clearance for use on neonates. Credit: Business Wire

The index is already cleared for use in pediatric cardiac ICUs and pediatric ICUs. Boston-based Etiometry plans to offer it to existing NICU customers who are already using other capabilities of its platform this fall, as well as to any new customers.

On a streak

The FDA nod for use of the IVCO₂ Index in NICU patients is Etiometry's ninth 510(k) clearance and its second this year. In January, the Boston-based company got the green light for its IDO₂ Index for use in alerting adult critical care teams when patients are experiencing insufficient oxygen supply. The IDO₂ (inadequate delivery of oxygen) algorithm marked Etiometry's first FDA clearance for adults in the U.S. and followed CE mark and Health Canada approvals for children and adults last year.

First introduced for pediatric use in 2016, Etiometry's platform offers risk analytics for critical care settings. The platform's capabilities include risk indices, data aggregation and

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visualization, automated clinical pathways and the Quality Improvement App. It currently boasts four algorithms – the ACD Index for acidosis and HLA Index for hyperlactatemia, in addition to the IVCO₂ and IDO₂ indices.

“The challenges clinicians experience with patient monitoring technologies in these high-acuity environments center around the ability to understand when to escalate and when it’s safe to de-escalate care, as well as achieve the elusive balance between individualized and standardized care across a unit,” Baronov said. “This is due to the data overload from numerous patient monitoring devices, difficulties in achieving a unified view of the patient condition among the team and the cognitive burden it places on care team members to interpret the data vs. being more immediately actionable.”

The clinical pathway feature allows hospitals to embed

Etiometry’s indices in hospital-specific workflows to drive care efficiencies, standardization and quality improvements, he said.

Etiometry’s aim is to make all its algorithms available in the U.S., Canada and the EU for all patient populations. Next on deck is gaining FDA clearance for the IVCO₂ Index for adults, as well as the ACD and HLA indices, Baronov said. The company is also looking into incorporating Etiometry’s algorithms into new clinical pathways that could improve quality and outcomes. Baronov noted, for example, that some customers are using the IVCO₂ Index to determine if it is safe to extubate a patient and the IDO₂ Index to determine if a patient can be weaned from vasoactive medications.

“Our next step is incorporating algorithms into more clinical workflows to have an even bigger impact on outcomes in critical care,” he said.