**Delivery Science Grants Program**

*Successful Validation and Implementation of a 0/2-hour High-Sensitivity Troponin Algorithm for Emergency Department Patients with Possible Acute Coronary Syndromes*

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| Challenge | **In advance of KPNC’s adoption of a high-sensitivity troponin assay (Access hsTnI, Beckman-Coulter), we designed a hybrid algorithm for the assessment of possible non-ST elevation acute coronary syndrome (KPNC NSTE-ACS algorithm). The KPNC algorithm was informed by two of the most well-validated hsTnI-based accelerated diagnostic pathways (0/2- hour European Society of Cardiology and HIGH-STEACS) with the goal of maintaining or improving upon historic practice efficiencies within KPNC. Though designed using external evidence, the KPNC NSTE-ACS algorithm requires internal validation to assure safety and efficacy, as well as an assessment of utilization impact. In addition, few of the external refences studies were conducted using the Access hsTnI assay, and assay-specific validation and calibration is recommended for all hsTn-based algorithms.**  |
| Existing Evidence | The HIGH-STEACS pathway, which informed the “rule-out” portion of the KPNC NSTE-ACS algorithm, has been validated outside the US with a negative predictive value for 30-day type 1 myocardial infarction or cardiac death of 99.7%. However, these studies were conducted using the Architect hsTnI assay, which is not fully interchangeable with the Access hsTnI assay. Likewise, while cutpoints for the Access hsTnI assay have been published for use within the 0/2-hour European Society of Cardiology protocol, these values were derived in retrospect from frozen plasma samples taken from non-US populations and have not been validated in practice. In both cases, US population-specific validation is lacking.  |
| Target Population | Adult emergency department patients presenting with a complaint of chest pain or discomfort who subsequently underwent hsTn testing.  |
| Intervention or Exposure | Implementation of the Access hsTnI assay (Beckman-Coulter) and KPNC NSTE-ACS algorithm |
| **Outcomes/Key Findings** | **Overall, the KPNC NSTE-ACS algorithm was both safe and efficacious, identifying 70% of encounters as ruled-out (very low or low risk) with a combined negative predictive value of 99.7% for 30-day myocardial infarction or death (LR- of 0.06) while flagging 7% of encounters as high-risk with a positive predictive value of 60% (LR+ of 24.3).** While the negative predictive value of a rule-out designation was suboptimal among patients with ischemic coronary artery disease or advanced chronic kidney disease in particular, “real-world” performance of the algorithm in these clinical subgroups remained acceptable when accounting for realized emergency department discharge dispositions. **Compared to the pre-implementation period, utilization in the post-implementation period improved, with a 4% absolute adjusted increase in emergency department discharges (75% to 79%) a 12% adjusted decrease in 30-day cardiac testing (36% to 24%), with no increase in downstream risks of 30-day myocardial infarction or death (6.2% vs 5.6%).** Though average emergency department length of stay increased from 4.5 hours to 5.3 hours (0.8 hour absolute/18% relative), this was a lower than the increase observed for all other emergency department patients during the same time periods (3.3 hours to 4.6 hours, 1.3 hour absolute/39% relative). Thus the observed increases in length of stay were likely driven by external factors (annual ED volume, hospital inpatient capacity) rather than factors intrinsic to the KPNC NSTE-ACS algorithm itself, considering that implementation of similar accelerated evaluation protocols typically results in decreased evaluation times and lower lengths of stay. |
| **Resulting Action/Change** | **Reassurance of key stakeholders regarding the overall safety, efficacy and positive utilization impacts of the KPNC NSTE-ACS algorithm, with emphasis on the added value of clinical judgement, particularly in subgroups with established coronary artery disease or chronic kidney disease.**  |
| Additional Recommendations | Consider adding language to the algorithm concerning “at risk” clinical subgroups, particularly in the low risk strata. |
| Implementation Tools  | Published KPNC NSTE-ACS algorithm |
| Implementation Measurement | Dissemination of the algorithm |
| Reference | Summary validation results of the KPNC NSTE-ACS algorithm |