Assay development improvements at the South Carolina Public Health Laboratory

CSTE Stories FROM THE Field

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CATEGORY: **Epidemiology & Laboratory Capacity (ELC)**

CATEGORY: **Laboratory Data Exchange**

The South Carolina Public Health Laboratory established an Assay Development team to support a new test implementation process to improve scientific rigor, cross-division communication, and overall efficiency.

The "What"

The South Carolina Public Health Laboratory (SCPHL) is legally obligated to evaluate the performance of every new test. Historically, this responsibility fell to overburdened supervisors who were forced to balance evaluations with daily laboratory operations. As a result, new test implementation was slow across the laboratory. In addition, studies were underpowered and lacked rigorous scientific standards. This approach undermined the laboratory's ability to quickly adapt to accommodate testing for emerging threats.

Epidemiology and Laboratory Capacity for the Prevention and Control of Emerging Infectious Diseases (ELC) funding helped SCPHL establish an Assay Development team. The team has restructured the new test implementation process at SCPHL to improve scientific rigor, cross-division communication, and overall efficiency. The team established laboratory-wide standards and tailored, section-specific approaches to avoid unnecessary delays in test adoption.

The "So What"

In just 17 months, the Assay Development team has validated 23 new assays with an average completion time of 81 days. Increased efficiency has been accompanied by concurrent enhancements in study design, data analysis, and documentation. Studies exceed regulatory standards with rigorous statistical analysis performed whenever necessary. Real-world impact was exemplified when a life-threatening case of spinal muscular atrophy was identified through newborn screening just weeks after the test was adopted in the laboratory. Any delays in test implementation would have resulted in the case being missed.

The "Now What"

The Assay Development team is at the core of the restructured new test implementation process at SCPHL. The team is responsible for validating an average of 2 new tests per month. Without the team all the current and future gains in efficiency and scientific rigor would not be possible. In addition, the Assay Development team will begin long-term monitoring to ensure current tests are performing as expected. Early returns on this project include the detection of demographic influences in the lab's current Krabbe screen and the identification of an extremely rare genetic disease from specimens used in test validation.

Key contributors to this project include Nicolas Epie, PhD; Ona Adair, PhD; Cory Weaver, PhD; Katie Waites, all with the South Carolina Department of Health & Environmental Control Public Health Laboratory

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