

Conclusion. CovidIQ is a novel tool developed to augment the public health response to this ongoing crisis by informing the public sector of potential new hot spots before areas experience a surge as compared to the current reporting structure.

Disclosures. All Authors: No reported disclosures

LB-15. A Trans-Governmental Collaborative Effort to Independently Evaluate SARS-CoV-2 Serology Assays Using Well-Characterized Sample Panels

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Session: LB2. Late Breaking COVID-19 Abstracts
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Background. The emergence of the novel coronavirus, SARS-CoV-2, created a crucial need for accurate tests for diagnosis, assessment of prior infection, and understanding its natural history. Serology assays play an important role in the assessment of anti-viral immune responses and previous infections. Evaluation of serology assays with well-characterized serum and/or plasma samples is critical to determine assay performance. CDC, FDA and NCI’s Frederick National Laboratory for Cancer Research (NCI-FNLRCR) have established a collaborative network to independently evaluate commercial antibody tests prior to their authorization.

Methods. Positive (n=30) serum samples with a range of anti-SARS-CoV-2 antibody titers (Table) and negative (n=80) serum and/or plasma samples were selected to establish performance evaluation panels (PEVs). Three PEVs with similar overall antibody titer distribution have been created. Negative samples were collected prior to 2020, before the SARS-CoV-2 pandemic. Positive samples were from patients previously confirmed to have SARS-CoV-2 using a nucleic acid amplification test. Each sample was characterized at CDC and NCI-FNLRCR for presence/absence of SARS-CoV-2 IgM and IgG antibodies using a SARS-CoV-2 spike enzyme linked immunosorbent assay (ELISA). NCI-FNLRCR also performed a SARS-CoV-2 spike Receptor Binding Domain (RBD) IgG ELISA. Positive samples were assessed at multiple dilutions. Manufacturers submitted their serology assays for evaluation by this program. The sensitivity of each test was assessed for each antibody class (IgG and IgM) and in a combined manner, where a positive result for either antibody was considered as a positive result. For combined specificity, a negative result meant a sample was negative for both antibodies (IgG and IgM).

Number of positive samples with anti-SARS-CoV-2 spike antibodies for each panel (n=30)

Titer	IgG			IgM		
	Panel 1	Panel 2	Panel 3	Panel 1	Panel 2	Panel 3
1:100	1	0	0	13	12	11
1:400	7	6	7	11	11	12
1:1600	12	12	11	6	6	6
1:6400	10	12	12	0	1	1

Results. To date, 53 serology assays have been evaluated. Sensitivity ranged from 30.0% to 100% for IgG, from 10.0% to 100% for IgM, and the combined specificity ranged from 57.5% to 100%. For 2 assays that measure total Ig, sensitivity was 96.7% and 100%.

Conclusion. This program completed over 50 performance evaluations with well-characterized PEVs. Results have been used to inform FDA regulatory decisions and are publicly available on FDA’s website.

Disclosures. Cristina Cassetti, PhD, Nothing to disclose

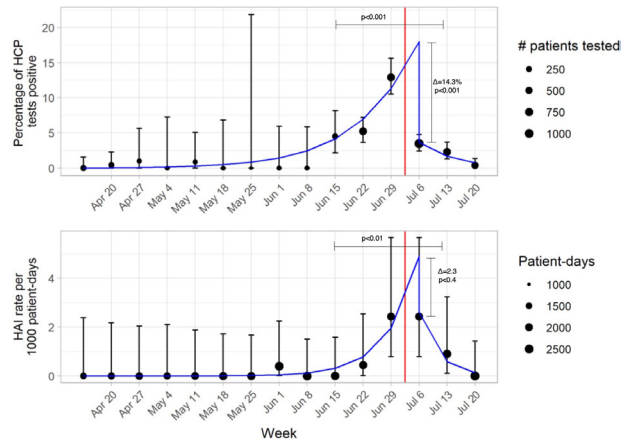
LB-16. Association Between Universal Face Shield in a Quaternary Care Center and Reduction of SARS-COV2 Infections Among Healthcare Personnel and Hospitalized Patients

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Background. SARS-COV2 transmission to healthcare personnel (HCP) and hospitalized patients is a significant challenge. Our hospital is a quaternary healthcare system with more than 500 beds and 8,000 HCP. Between April 1 and April 17, 2020, we instituted several infection prevention strategies to limit transmission of SARS-COV2 including universal masking of HCP and patients, surveillance testing every two weeks for high-risk HCP and every week for cluster units, and surveillance testing for all patients on admission and prior to invasive procedures. On July 6, 2020, we implemented universal face shield for all healthcare personnel upon entry to facility. The aim of this study is to assess the impact of face shield policy on SARS-COV2 infection among HCP and hospitalized patients.

Figure 1 - Interrupted time series



Methods. The preintervention period (April 17, 2020-July 5, 2020) included implementation of universal face masks and surveillance testing of HCP and patients. The intervention period (July 6, 2020-July 26, 2020) included the addition of face shield to all HCP (for patient encounters and staff-to-staff encounters). We used interrupted time series analysis with segmented regression to examine the effect of our intervention on the difference in proportion of HCP positive for SARS-COV2 (using logistic regression) and HAI (using Poisson regression). We defined significance as p values < 0.05.

Results. Of 4731 HCP tested, 192 tested positive for SARS-COV2 (4.1%). In the preintervention period, the weekly positivity rate among HCP increased from 0% to 12.9%. During the intervention period, the weekly positivity rate among HCP decreased to 2.3%, with segmented regression showing a change in predicted proportion positive in week 13 (18.0% to 3.7%, p< 0.001) and change in the post-intervention slope on the log odds scale (p< 0.001). A total of 14 HAI cases were identified. In the preintervention period, HAI cases increased from 0 to 5. During the intervention period, HAI cases decreased to 0. There was a change between pre-intervention and post-intervention slope on the log scale was significant (p< 0.01).

Conclusion. Our study showed that the universal use of face shield was associated with significant reduction in SARS-COV2 infection among HCP and hospitalized patients.

Disclosures. All Authors: No reported disclosures

LB-17. Efficacy of Hydroxychloroquine (HCQ) for Post-exposure Prophylaxis to Prevent Severe Acute Respiratory Syndrome Coronavirus 2 (SARS-CoV-2) Infection: A Blinded, Randomized, Controlled Trial

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