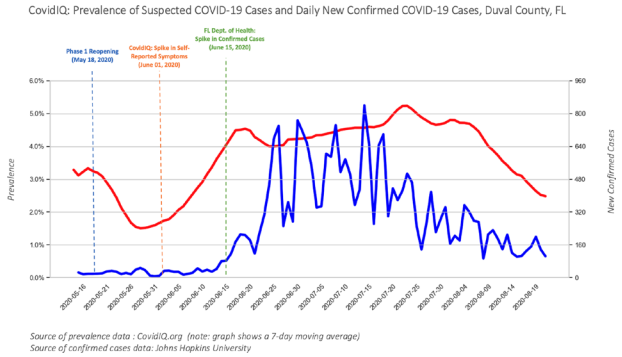

Conclusion. CovidIQ is a novel tool developed to augment the public health response to this ongoing crisis by informing the public sector of potential new hot spots before areas experience a surge as compared to the current reporting structure.

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
Saturday, October 24, 2020: 2:15 PM

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-FNLCR) 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-FNLCR for presence/absence of SARS-CoV-2 IgM and IgG antibodies using a SARS-CoV-2 spike enzyme linked immunosorbent assay (ELISA). NCI-FNLCR 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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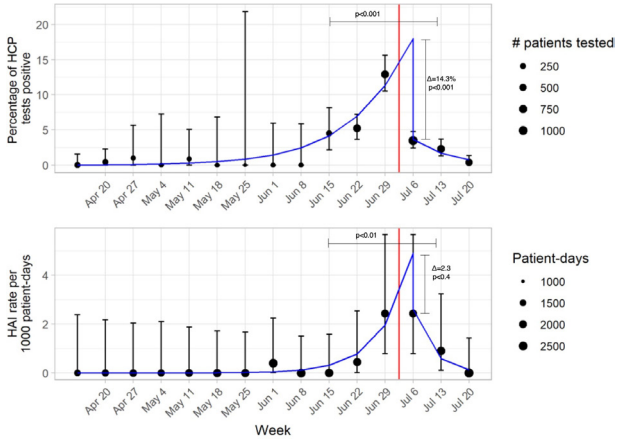
Session: LB2. Late Breaking COVID-19 Abstracts
Saturday, October 24, 2020: 2:25 PM

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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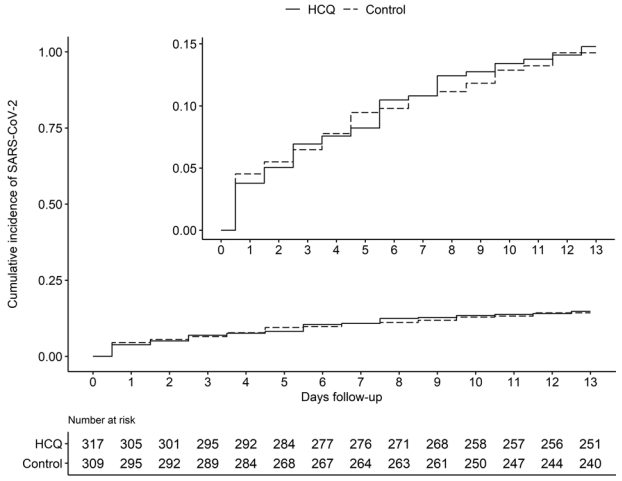
Session: LB2. Late Breaking COVID-19 Abstracts
Saturday, October 24, 2020: 2:35 PM

Background. Prevention interventions for coronavirus disease (COVID-19), caused by Severe Acute Respiratory Syndrome Coronavirus 2 (SARS-CoV-2), are currently limited to non-pharmaceutical strategies. Observational and laboratory data suggested that hydroxychloroquine (HCQ) had biologic activity against SARS-CoV-2. A blinded trial of HCQ in persons with confirmed exposure and virologic and clinical endpoints is needed.

Methods. We conducted a national, householdrandomized, double-blind, controlled trial of HCQ post-exposure prophylaxis, with entirely remote study procedures. We enrolled close contacts exposed to persons with SARS-CoV-2 infection in the past 96 hours. Participants were randomized to either HCQ (400 mg daily for three days followed by 200 mg daily for eleven days) or ascorbic acid (500 mg followed by 250 mg daily), as a placebo-equivalent control. Participants self-collected mid-turbinate swabs daily (days 1–14) for SARS-CoV-2 PCR testing. The primary outcome was PCR-confirmed, incident SARS-CoV-2 infection among persons SARS-CoV-2 negative at enrollment. Symptoms were assessed using criteria from the US CDC.

Results. From March-August 2020, 623 households were randomized; 311 households (381 participants) to the HCQ group and 312 households (400 participants) to the control group. Ninety- one percent of participants were retained up to day 14 and 9,595 of 10,588 (91%) of swabs were tested. Among participants who were SARS-CoV-2 negative at baseline (n=626/781, 80%), the cumulative incidence of SARS-CoV-2 was 14.5% (95% CI: 11.6–17.4) and the cumulative incidence of COVID-19 symptoms was 11.6% (95% CI: 8.9–14.2) at day 14. By day 14, there was no difference between the HCQ group and control group in SARS-CoV-2 acquisition (46 vs. 43 events, aHR= 0.99, 95% CI 0.64–1.52, p=0.95) or symptomatic disease (40 vs. 32 events, aHR= 1.23, 95% CI: 0.76–1.99, p=0.40). The adverse event frequency was similar between groups (59 [15.5%] participants in the HCQ and 45 [11.3%] in the control group, p=0.092).

Cumulative incidence of RT-PCR-confirmed SARS-CoV-2 infection among close contacts of diagnosed cases, by study group



Conclusion. This randomized, double-blind, controlled trial among persons with recent exposure and high incidence of SAR-CoV2 provides strong evidence that HCQ post-exposure prophylaxis did not prevent SARS-CoV-2 infection or modify clinical disease.

Disclosures. **Anna Bershteyn, PhD**, **Bill and Melinda Gates Foundation** (Grant/Research Support)**Gates Ventures** (Consultant)**National Institutes of Health** (Grant/Research Support) **Kristopher M. Paolino, MD, MTM&H**, Nothing to disclose **Raphael J. Landovitz, MD, MSc**, **Gilead** (Advisor or Review Panel member)**Merck** (Advisor or Review Panel member)**Roche** (Other Financial or Material Support, Speaker Honoraria) **Anna Wald, MD, MPH**, Aicuris (Individual(s) Involved: Self): Consultant; Gilead (Individual(s) Involved: Self): Consultant; GlaxoSmithKline (Individual(s) Involved: Self): Scientific Research Study Investigator; Merck (Individual(s) Involved: Self): DSMB participation; provision of vaccine for a study, Other Financial or Material Support; Sanofi (Individual(s) Involved: Self): Scientific Research Study Investigator; X-Vax (Individual(s) Involved: Self): Consultant **Helen Y. Chu, MD MPH**, **Cepheid** (Grant/Research Support)**Ellume** (Grant/Research Support)**Glaxo Smith Kline** (Consultant)**Merck** (Consultant)**Sanofi-Pasteur** (Grant/Research Support)

LB-18. Broad and Prevalent SARS-CoV-2 CD8+ T Cell Response in Recovered COVID-19 Individuals Demonstrates Kinetics of Early Differentiation

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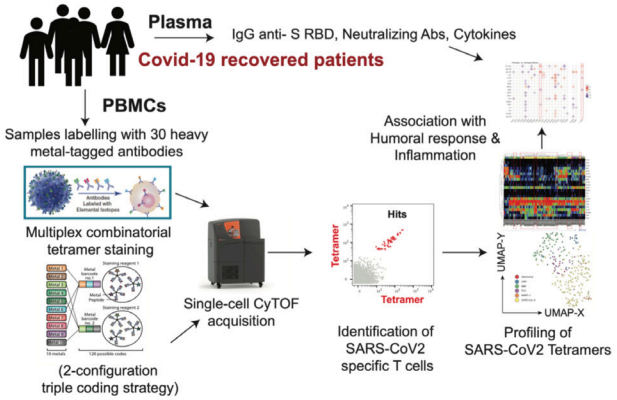
Session: LB2. Late Breaking COVID-19 Abstracts
Saturday, October 24, 2020: 2:45 PM

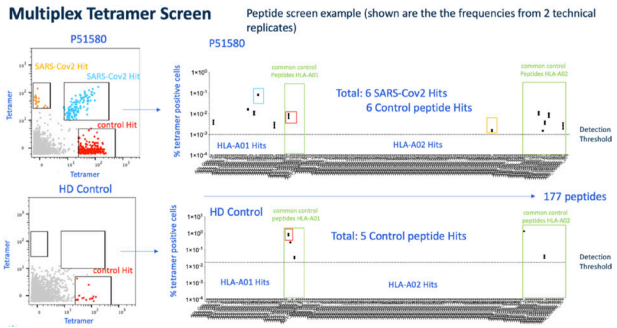
Background. Understanding the diversity, breadth, magnitude, and functional profile of the T cell response against SARS-CoV-2 in recovered COVID-19 individuals is critical to evaluate the contribution of T cells to produce a potentially protective immune response.

Methods. We used a multiplexed peptide-MHC tetramer approach to screen a total of 408 SARS-CoV-2 candidate peptide epitopes for CD8+ T cell recognition in a cohort of 30 individuals recovered from COVID-19. The peptides spanned the whole viral genome and were restricted to six prevalent HLA alleles; T cells were simultaneously characterized by a 28-marker phenotypic panel. The evolution of the SARS-CoV-2 T cell responses was then statistically modeled against time from diagnosis, and in relation to humoral and inflammatory response.

Workflow for Study. A multiplexed peptide-MHC tetramer approach was used to screen SARS-CoV-2 candidate peptide epitopes in a cohort of 30 COVID-19 recovered patients across 6 prevalent HLA alleles, and T cells profiled with a 28-marker phenotypic panel.



Multiplex tetramer screen. One representative COVID-19 recovered patient and one healthy donor were screened for HLA- relevant SARS-CoV-2 epitopes, as well as epitopes for CMV, EBV, Influenza, Adenovirus and MART-1. Shown are the frequencies of tetramer-positive CD8 T cells from 2 technical replicates per subject.



Results. Almost all individuals screened showed a T cell response against SARS-CoV-2 (29/30): 132 SARS-CoV-2-specific CD8+ T cells hits were detected, corresponding to 52 unique reactive epitopes. Twelve of the 52 unique SARS-CoV-2-specific epitopes were recognized by more than 40% of the individuals screened, indicating high prevalence in the subjects. Importantly, these CD8+ T cell responses were directed against both structural and non-structural viral proteins, with the highest magnitude against nucleocapsid derived peptides, but without any antigen-driven bias in the phenotype of specific T cells. Overall, SARS-CoV-2 T cells showed specific states of differentiation (stem-cell memory and transitional memory), which differed from those of MART-1, influenza, CMV and EBV-specific T cells.