Conclusions. IS, CKD, DM, SCD, ND, and obesity were associated with increased odds of hospitalization in adolescents presenting with mild to moderate COVID-19. Adolescents with these comorbidities should be prioritized for consideration of treatment with monoclonal antibodies.

Disclosures. Gabriella S. Lamb, MD, MPH. Nothing to disclose.

583. SARS-CoV-2 Spike Protein S1/S2 Antibodies after Vaccination with Sinopharm in Peruvian Physicians

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Session: P-25. COVID-19 Vaccines

Background. Peru started its national vaccination campaign in February 2021 using Sinopharm vaccine, targeting healthcare personnel on its initial phase. Although the immunogenicity of this vaccine was tested in clinical trials, there are no studies that evaluate the humoral response post vaccination in Peru.

Methods. We conducted a cross sectional study, which objective was to evaluate the humoral immunogenicity triggered by the Sinopharm vaccine in Peruvian physicians. We collected demographic and epidemiologic data via an electronic. The SARS-CoV-2 spike protein S1/S2 antibodies were measured by chemiluminescence (Liaison1). A positive test was defined as >15 U/ml, which has correlation of 95% with neutralizing antibodies measured by plaque reduction neutralizing test.

Results. 92 participants were enrolled in the study. The epidemiologic characteristics are described in Table 1. The mean level of antibodies measured at least 2 weeks from the second vaccine dose was 67.5 ± 70.5 U/ml of 85.7% of the study cohort had positive S1/S2 antibodies. In the univariate analysis, an imperfect negative correlation was found between the level of antibodies and participants age (r = −0.24; regression F test 5.25; p = 0.0282). A weak negative correlation was observed between the antibody titer and the time elapsed from the second vaccine dose and the day of antibody measurement (r = −0.17). A higher antibody level post vaccine was found in individuals who worked in COVID units (105.5 U/ml vs 85.2 U/ml; p = 0.0125), and in participants with history of COVID (216.5 U/ml vs 81.2 U/ml; p = 0.0000). Hypertension was associated with lower antibody titers (36.9 U/ml vs. 74.6 U/ml; p = 0.0464). In the multivariate analysis, working in COVID units, having previous COVID infection and shorter time from second vaccine dose and day of antibody measurement were associated with higher antibody levels post vaccine (table 2).

Table 1. Epidemiological Characteristics

| Factor                     | Mean ± SD   |
|----------------------------|-------------|
| Age (yr; mean ± SD)        | 31.95 ± 14.35 |
| Male gender [n %]          | 45 (50.9%)  |
| No comorbidity [n %]       | 47 (51.9%)  |
| With comorbidity [n %]     | 44 (89.1%)  |
| One comorbidity [n %]      | 36 (79.1%)  |
| Two comorbidities [n %]    | 7 (17.6%)   |
| Three comorbidities [n %]  | 2 (2.7%)    |
| Diabetes [n %]             | 9 (9.8%)    |
| Hypertension [n %]         | 17 (18.48%) |
| Autoimmune disease without immunosuppression [n %] | 2 (2.7%) |
| Body Mass Index (kg/m2)    | 26.28 ± 3.56 |
| Work with COVID-19 [n %]   | 20 (22.2%)  |
| Previous COVID-19 [n %]    | 5 (4.3%)    |

585. Safety of Pfizer-BioNTech COVID-19 Vaccine in Healthcare Workers, Singapore

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Session: P-25. COVID-19 Vaccines

Background. On 14 December 2020, the Pfizer-BioNTech coronavirus disease 2019 (COVID-19) vaccine was granted emergency use authorization in Singapore. Healthcare workers (HCW) were prioritized to receive the vaccine. We aim to investigate the side effects and risk factors for allergic reactions in our institution.

Methods. All HCW’ vaccinations were recorded in an electronic centralized database. All reactions occurring within a 30 minute observation period post vaccination were recorded. Staff were required to report any vaccine-related medical consult including hospitalization occurring within 14 days after vaccination. Moderate/severe reactions were assessed by a medical team and determined if the reactions were probable allergic reactions with consultation with an Allergist. We extracted data from 8 Jan 2021 to 30 April 2021.

Results. 5030 and 159 HCW completed 2 doses and 1 dose of the vaccine respectively. There were 1056 HCW’s (20.3%) with self-reported pre-existing allergy. There were 14 (1.1%) reactions occurring without consultation post vaccine, and 64 (5.61%) were related to first dose of vaccine. The most common side effect experienced was aches or pain on any part of the body (n=46, 40.4%) followed by fatigue and/or giddiness (n=45, 39.5%), palpitations and/or shortness of breath (n=22, 19.3%), systemic rash and/or angioedema (n=12, 10.5%) and nausea and/or vomiting (n=12, 10.5%).

Table 2. Multivariable linear analysis of antibody titers

| Independent variables | Coefficient (95% CI) | SE | t | p |
|-----------------------|----------------------|----|---|---|
| Age                   | -0.3 (-1.3, 0.72)    | 0.52 | 2.1 | 0.12 |
| Diabetes              | -1.65                 | 0.07 | 2.1 | 0.06 |
| Hypertension          | -19.0 (53.4, 15.13)  | 17.1 | 1.1 | 0.27 |
| Time from 2nd dose to Ab test | -1.2 (-3.3, 0.10) | 0.55 | 1.2 | 0.28 |
| Working in COVID-19 units | -18.7 (7.6, 66.1)  | 16.3 | 2.7 | 0.008 |
| Prevalent COVID-19 infection | 10.5 (6.3, 15.6)  | 12.3 | 2.1 | 0.043 |

Conclusion. Our study showed that the time elapsed from the second vaccine dose and the day of antibody measurement, having previous COVID-19 infection and working in COVID-19 units may help to predict higher antibody titers post vaccine. Larger studies to evaluate the humoral response post Sinopharm vaccine and its clinical implications are still needed in Peru.

Disclosures. All Authors: No reported disclosures.

584. Phase 1 Placebo-Controlled Trial of COVI-VAC™, an Intranasal, Live Attenuated COVID-19 Vaccine

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Session: P-25. COVID-19 Vaccines

Background. COVI-VAC™ is an intra-nasal live-attenuated SARS-COV-2 synthetic viral vaccine being developed for the prevention of COVID-19. COVI-VAC is attenuated through deletion of the furin cleavage site and introduction of 283 silent deoptimizing mutations that maintain viral amino acid sequence but result in significant changes in the translation in the human host cell. Notably, COVI-VAC includes all viral antigens and is not limited to spike. COVI-VAC has demonstrated attenuation, immunogenicity and single dose protection in both Syrian golden hamster and non-human primate models.

Methods. 48 healthy young adults were enrolled in an inpatient quarantine setting to one of three dose escalating cohorts and randomized to COVI-VAC or saline placebo given as nose drops, as a single 0.5ml dose or 2 doses 28 days apart. Endpoints included solicited and unsolicited adverse events, serum cytokines, viral shedding and sequence stability, mucosal and serum antibody responses and IFN ELISpot. Subjects will be followed for 1 year for late safety events and durability of immune response.

Results. Dosing is complete. There has been no trend in solicited reactogenicity events, and all unsolicited adverse events reported to date have been mild. There have been no SAEs or Grade 3 or 4 events. Vaccine virus from anonymized subjects was shed at levels lower than that likely to result in onward transmission, and the deoptimized sequence of the shed virus remained unchanged compared to the original vaccine sequence. Unblinded data including immunogenicity will be available prior to the IDWeek meeting.

Conclusion. COVI-VAC appears safe and well tolerated in healthy young adults. Vaccination resulted in minimal viral shedding without sequence instability. Safety and shedding data supports continued development in a wider Phase 2/3 population.

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585. OFID 2021:8 (Suppl 1) • Abstracts

S394
A total of 23 HCWs complained of systemic rash and/or angioedema that occurred anytime post vaccination. Fifteen HCWs (0.29% of the cohort) were considered to have probable allergic reaction to the vaccine. None of the reactions were classified as anaphylaxis or severe reactions, but 4 HCWs required short hospitalization stay for observation. HCWs with pre-existing allergy had 2.6 times the risk of having probable vaccine-related allergic reaction than HCWs without pre-existing allergy (RR 2.6, 95% CI 0.9 to 7.3, p=0.068) but this was not statistically significant.

**Conclusion.** No anaphylaxis or severe reactions were observed in our institution. Acute side effects in our cohort were in line with published trial reports. We noted a raised relative risk of 2.6 of pre-existing allergy with probable vaccine-related allergic reaction but this was not statistically significant.

**Disclosures.** All Authors: No reported disclosures

### 586. Immunogenicity of COVID-19 mRNA Vaccines in Patients with Lymphoid Malignancies

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**Session:** P-25. COVID-19 Vaccines

**Background.** Patients with lymphoid malignancies are at high risk of severe COVID-19 disease and were not included in the phase 3 mRNA vaccine trials. Many patients with lymphoid malignancies receive immunosuppressive therapies, including B-cell depleting agents, that may negatively impact humoral response to vaccination.

**Methods.** We recruited patients with lymphoid malignancies and healthy participants who planned to receive two doses of SARS-CoV-2 mRNA vaccine (BNT162b2 or mRNA-1273). Blood was drawn at baseline, prior to second dose of vaccine, and 28 days after last vaccination. Disease characteristics and therapies were extracted from patients’ electronic medical record. An ultrasensitive, single molecule array (Simoa) assay detected anti-Spike (S), anti-S1, anti-receptor binding domain (RBD), and anti-Nucleocapsid (N) IgG from plasma at each timepoint.

**Results.** 23 healthy participants and 37 patients with lymphoid malignancies were enrolled (Table 1). Low titers of anti-N (Fig 1A) demonstrate no prior exposure or acquisition of COVID-19 before vaccination or during the study. 37.8% of the lymphoid malignancy cohort responded to the vaccine, using an internally validated AEB cutoff of 1.07. A significantly higher magnitude of anti-S (p<0.0001), anti-S1 (p<0.0001) and anti-RBD (p<0.0001) are present in the healthy as compared to lymphoid malignancy cohort. Responders within 12 months from the vaccine had no response (Figure 3).

**Conclusion.** The vaccine-induced immune response was poor among treatment-experienced patients with lymphoid malignancies, especially among those who received CD20 therapies within 12 months.

### Table 1. Demographics

|                              | Healthy Cohort (n=23) | Lymphoid Malignancy (n=37) |
|------------------------------|-----------------------|---------------------------|
| **Median Age (Range)**       | 24 (22-56)            | 68 (30-82)                |
| **Female Sex, %**            | 13 (56.5)             | 23 (56.8)                 |
| **Vaccine Type, %**          |                       |                           |
| mRNA-1273                    | 14 (60.0)             | 12 (32.4)                 |
| BNT162b2                     | 9 (39.3)              | 25 (67.6)                 |
| **Disease Type, %**          |                       |                           |
| CLL                          | NA                    | 21 (56.8)                 |
| DLBCL                        | NA                    | 2 (5.4)                   |
| MCL                          | NA                    | 4 (10.8)                  |
| FL                           | NA                    | 3 (8.1)                   |
| MZL                          | NA                    | 2 (5.6)                   |
| HI                           | NA                    | 4 (10.8)                  |
| T-cell lymphoma              | NA                    | 1 (2.7)                   |
| **Treatment Status, %**      |                       |                           |
| Treatment Received           | 8 (34.8)              | 29 (78.4)                 |
| Treatment Exceeded           | NA                    | 20 (54.1)                 |
| Prior CD20 Ab Therapy, %     | Yes                   | 17 (45.9)                 |
| No                           |                       |                           |

**Disclosures.** No reported disclosures

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**Abstracts • OFID 2021:8 (Suppl 1) • S395**