An explanation about how the risk for PTLD is calculated for the SOT recipients; in this example the risk of developing PTLD is calculated in the next 180 days

### Calculation of an Individual’s PTLD Risk-Score

A patient with the prediction for PTLD below, would have a score of 79 points, placing them in the high risk of developing PTLD category (risky for PTLD). If the patient has a score above 177 points, the patient would have a score of 79 points, placing them in the low risk of developing PTLD category (not risky for PTLD). If the patient has a score between 177 and 224, the patient would have a score of 177 points, placing them in the moderate risk of developing PTLD category (moderately risky for PTLD).

Performance of the PTLD score in the derivation and validation cohorts (low-risk group: score≤17 points; high-risk group: score>17 points)

**Conclusion.** The risk score had a good discriminatory ability in both cohorts and helped to identify patients with higher risk of developing PTLD, so they can be monitored more often. This is the first risk-score developed and externally validated to predict risk of PTLD among SOT recipients.

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

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**24. Longitudinal Assessment of Immune Responses to COVID-19 Vaccines in Solid Organ Transplant Recipients**

Megan Powell, BA; Amy C. Sherman, MD; Julia Klopfer, na; Michael Desjardins, MD; Chi-An Cheng, PhD; Yasmeen Senussi, MBBS; Sae Ratnaparkhi, MPH; Xiomi Mitre, BA; Monica Feeley, BA; Andres A. Avila Paz, BA; Andy J. Kim, BS; Henry Rutherford, BA; Jessica Cauley, B.A.; Austin Kim, B.S.; Jun Bai Park Chang, Bachelor of Arts; Alexis Liakos, PA-C; Ann E. Woolley, MD, MPH; David Walt, PhD; Lindsey R. Baden, MD; BWH Division of Infectious Diseases, Boston, Massachusetts; 2Harvard Medical School/Brigham and Women’s Hospital, Boston, Massachusetts; 3Brigham and Women’s Hospital, Boston, Massachusetts; 4Brigham and Women’s Hospital/Dana-Farber Cancer Institute, Boston, Massachusetts; 5Harvard Medical School/Brigham and Women’s Hospital/Wyss Institute, Boston, Massachusetts

**Session:** O-05. Clinical Quandaries in Viral Infections in ICH

**Background.** mRNA vaccines for coronavirus disease 2019 (COVID-19) illicit strong humoral and cellular responses and have high efficacy for preventing and reducing the risk of severe illness from COVID-19. Since solid organ transplant (SOT) recipients were excluded from the phase 3 trials, the efficacy of the COVID-19 vaccine remains unknown. Understanding the serological responses to COVID vaccines among SOT recipients is essential to better understand vaccine protection for this vulnerable population.

**Methods.** In this prospective cohort study, a subset of SOT recipients who were part of our center’s larger antibody study were enrolled prior to receipt of two doses of the BNT162b2 (Pfizer, Inc) vaccine for high resolution immunophenotyping. To date, plasma has been collected for 10 participants on the day of their first dose (baseline), day of their second dose, and 28 days post second dose. 23 healthy participants planning to receive either BNT162b2 or mRNA-1273 (ModernaTX, Inc) were also enrolled, providing plasma at the same timepoints. Ultrasensitive single-molecule array (Simoa) assays were used to detect SARS-CoV-2 Spike (S), S1, receptor-binding domain (RBD) and Nucleocapsid (N) IgG antibodies.

**Results.** Participant demographics and SOT recipient characteristics are summarized in Table 1. Low titers of anti-N IgG at all timepoints indicate no natural infection with COVID-19 during the study (Fig 1A). There were significantly lower magnitudes for anti-S (p< 0.0001), anti-S1 (p< 0.0001), and anti-RBD (p< 0.0001) IgG titers on the day of dose 2 and 28 post second dose for SOT recipients compared to healthy controls (Fig 1B,C,D). Using the internally validated threshold of anti-S IgG >1.07 based on pre-pandemic controls, only 50% of the SOT sub-cohort responded to vaccine after series completion (Fig 2). There was a positive trend between months from transplant and anti-S IgG titer (Fig 3).

**Table 1: Demographics**

| Variable | Healthy Cohort (n=23) | Solid Organ Transplant Recipients (n=50) |
|----------|-----------------------|----------------------------------------|
| Age (Range) | 24 (23-26) | 56 (27-72) |
| Female no. (%) | 13 (56.5) | 4 (0.0) |
| Race - no. (%) | | |
| White | 11 (47.8) | 8 (0.0) |
| Black | 4 (17.4) | 11 (0.0) |
| Asian | 3 (13.0) | 11 (0.0) |
| Native American/Alaskan Native | 1 (4.3) | 0 |
| Ethnicity - no. (%) | | |
| Hispanic/Latina | 8 (32.1) | 0 |
| Vaccine type - no. (%) | | |
| Moderna | 14 (60.0) | 0 |
| Pfizer | 9 (36.1) | 10 (40.0) |
| Median Time from Transplant Months (Range) | N/A | 8-12 (8-28.2) |
| Organ Transplant Type - no. (%) | | |
| Kidney | N/A | 5 (0.0) |
| Lung | N/A | 4 (0.0) |
| Heart | N/A | 1 (0.0) |
| Median Recent Lymphocyte Count (Range) | N/A | 1.96 (0.81-5.04) |
| Diagnosis for Transplant - no. (%) | | |
| Cystic Fibrosis (lung) | N/A | 2 (0.0) |
| Short bowel syndrome (lung) | N/A | 3 (0.0) |
| COPD (lung) | N/A | 1 (0.0) |
| IgA Nephropathy (kidney) | N/A | 2 (0.0) |
| FSGS minimal change disease (kidney) | N/A | 1 (0.0) |
| Glomerulonephritis (kidney) | N/A | 1 (0.0) |
| Unknown (kidney) | N/A | 1 (0.0) |
| Non-ischmic cardiomyopathy (heart) | N/A | 1 (0.0) |
| Current Immunosuppressive regimen - no. (%) | | |
| Tacrolimus | N/A | 8 (0.0) |
| Prednisone | N/A | 7 (0.0) |
| Mycophenolate mofetil | N/A | 5 (0.0) |
| Azathioprine | N/A | 4 (0.0) |
| Cyclosporine | N/A | 2 (0.0) |
| (IV) in last 3 months - no. (%) | N&A | 1 (0.0) |

**Figure 1:** Anti-N, Anti-S, Anti-S1, Anti-RBD and Anti-N Ig G for healthy v. SOT cohort

**Figure 2:** Anti-S IgG titer comparison between healthy controls and SOT recipients

Black error bars denote median and 95% CI. The dotted line on panel B denotes an internally validated cutoff of 1.07, anti-S IgG titer greater than 1.07 denote a positive response.
SOT recipients further out from transplant tend to have a higher anti-S IgG response. The dotted line denotes an internally validated cutoff, with anti-S IgG titers greater than 1.07 indicating a positive response.

**Conclusion.** SOT recipients had a significantly decreased humoral response to mRNA COVID-19 vaccines compared to the healthy cohort, with those further out from transplant more likely to respond. Further research is needed to evaluate T-cell responses and clinical efficacy to maximize the SARS-CoV-2 vaccine response among SOT recipients.

**Disclosures.** Ann E. Woolley, MD, MPH, COVAX (Consultant) David Walt, PhD, Quanterix Corporation (Board Member, Shareholder)

25. Immunogenicity and Reactogenicity of COVID-19 mRNA Vaccines in Allogeneic Stem Cell Transplant Recipients

Bruce P. Bausk, BS1; Amy C. Sherman, MD2; Michael Desjardins, MD3; Natalie E. Izaguirre, MSc4; Chi-An Cheng, PhD5; Megan Powell, BA6; Yasmeen Senussi, MBBS7; Tal Gilboa, PhD8; Jonathan H. Krauss, n/a9; Bonnie Dirz, NP10; Elyssa Power, NP11; Lisa Stewart, NP12; Omolola Ometoruwa, Bachelors13; Lewis A. Novack, MS14; Bethany Evans, B.S.15; Tenazuzu Woods, M.S.16; Alexandra Tong, B.S.17; David Walt, PhD18; Robert Seifker, MD19; Vincent T. Ho, MD20; Nicolas C. Issa, MD21; Lindsey R. Baden, MD22; Bonnie Dirz, NP23; Tenaizus Woods, M.S.24; Alex Tong, B.S.25; David Walt, PhD26; Robert Seifker, MD27; Vincent T. Ho, MD28; Nicolas C. Issa, MD29; Lindsey R. Baden, MD30; Tenaizus Woods, M.S.31; Alex Tong, B.S.32; David Walt, PhD33; Robert Seifker, MD34; Vincent T. Ho, MD35; Nicolas C. Issa, MD36; Lindsey R. Baden, MD37.