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**EFFECT OF COVID-19 VACCINATION STATUS ON ADVERSE EVENTS AND OUTCOMES IN ADVANCED NON-SMALL CELL LUNG CANCER (ANSCLC) PATIENTS TREATED WITH IMMUNOTHERAPIES**

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**Background** Immunotherapy is one of the most prominent therapies for NSCLC patients. While there is a lot of promise, adverse events (AEs) due to immunotherapies are a concern. Entering the era of COVID-19, the interaction of COVID-19 vaccination status with immunotherapy is not fully understood.<sup>1-2</sup> As most newly diagnosed NSCLC patients will be vaccinated, understanding this interaction is important for managing their treatment. This study aims at determining whether COVID-19 vaccination status has any significant effect on AEs and outcomes of aNSCLC patients treated with immunotherapies in 1st line.

**Methods** This retrospective study leverages ConcertAI's NSCLC Patient360™ dataset, a deeply curated real-world oncology dataset with patients from across the United States. aNSCLC patients who started 1st line treatment containing an immunotherapy at least 30 days after their last COVID-19 vaccine were included in the vaccine-primed cohort (N=138). 1st line treatment in these patients started between January 2021 – April 2022. Similarly, a cohort of vaccine-naïve patients was created by including all patients in the dataset who received their 1st line immunotherapy treatment between January 2019 – April 2020 (N=1537) to ensure none of them received COVID-19 vaccine prior to immunotherapy treatment. Descriptive analysis on these cohorts showed no significant differences in terms of age, race, gender and treatment patterns. AEs for each patient during the course of 1st line immunotherapy treatment were identified. These AEs were categorised into 5 levels (table 1). To normalise the effect of length of treatment, AE/time on immunotherapy was calculated. Progression-Free Survival (PFS) and Overall Survival (OS) from start of L1 was also compared between the two cohorts.

**Results** 56% vaccine-naïve and 54% vaccine-primed patients had an AE while on immunotherapy. The distribution of severity of AEs between the two cohorts was also quite similar (table 2). Although the AE/time was higher in the vaccine-naïve cohort (p-value=0.03) (figure 1), this effect was mostly driven by 41 (2.6%) outlier patients who had many AEs in a very short span of time after starting immunotherapy. We believe such outliers were not seen in the vaccine-primed cohort primarily due to its smaller sample size. OS and PFS were similar between the two cohorts (figures 2 and 3).

**Conclusions** COVID-19 vaccination status does not affect frequency or severity of immunotherapy related AEs or have a significant impact on patients' outcomes. As more data becomes available on the vaccine-primed cohort the impact on rarer patient sub-populations can be evaluated

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**REFERENCES**

1. Mei Q, Hu G, Yang Y, *et al* Impact of COVID-19 vaccination on the use of PD-1 inhibitor in treating patients with cancer: a real-world study. *Journal for Immunotherapy of Cancer* 2022;**10**:e004157. doi: 10.1136/jitc-2021-004157.

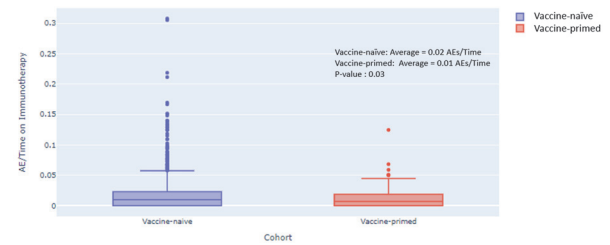
2. Brest P, Mograbi B, Hofman P, *et al*. COVID-19 vaccination and cancer immunotherapy: should they stick together?. *Br J Cancer* 2022;**126**, 1–3. <https://doi.org/10.1038/s41416-021-01618-0>

Level	Name	Examples
1	Minor medical intervention	Vitamin A deficiency, Hypocalcemia
2	Major medical intervention	Anemia, Neutropenia, Polyneuropathy
3	Hospital admission or similar	Renal failure, Dyspnea, Pulmonary embolism
4	Life threatening events	Leading to emergency room visit
5	Death	Death

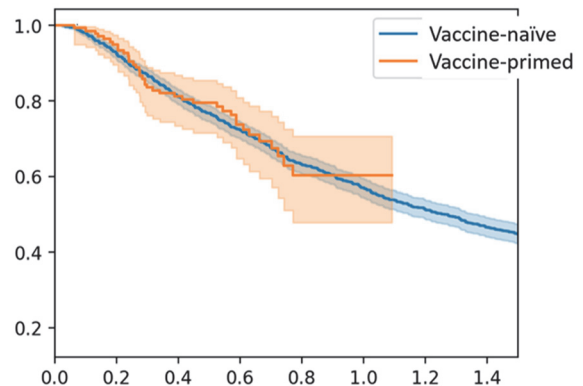
**Abstract 922 Table 1** Categorization of level of AEs based on the level of medical intervention required

Level	Vaccine-naïve	Vaccine-primed
# of patients with adverse events within Line 1	865 (56%)	75 (54%)
# of adverse events	2332	166
1 Minor medical intervention	398 (17%)	38 (22%)
2 Major medical intervention	920 (39%)	70 (42%)
3 Hospital admission or similar	770 (33%)	49 (30%)
4 Life threatening events	241 (10%)	11 (7%)
5 Death	3 (0%)	

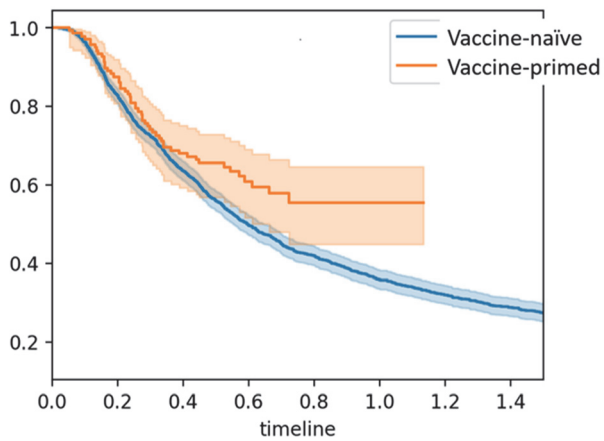
**Abstract 922 Table 2** The distribution of frequency and severity of AEs between the vaccine-naïve and vaccine-primed cohorts



**Abstract 922 Figure 1** Distribution of AEs/Time for the vaccine-naïve vs vaccine-primed cohorts



**Abstract 922 Figure 2** Overall survival of vaccine naïve vs vaccine primed patients from start of first line of therapy. Median survival for Vaccine-naïve = 1.27 year and was not reached for the vaccine-primed cohort. P-value = 0.84



**Abstract 922 Figure 3** Progression free survival of vaccine naïve vs vaccine primed patients. Median PFS for Vaccine-naïve = 0.6 year and was not reached for the vaccine-primed cohort. P-value = 0.02

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