Notable COVID-19 vaccine studies in KSA

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Technical Consultation Meeting for the EM Regional COVID-19 Vaccine Effectiveness Studies
12–13 November 2023 | Cairo, Egypt

COVID-19 Research

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Disclaimer:

- This presentation is not an official representation of the Health Authority in KSA nor the Gulf CDC. It is an expert participation and reflection on some studies on COVID-19 vaccines.

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COVID-19 Vaccine Studies in KSA

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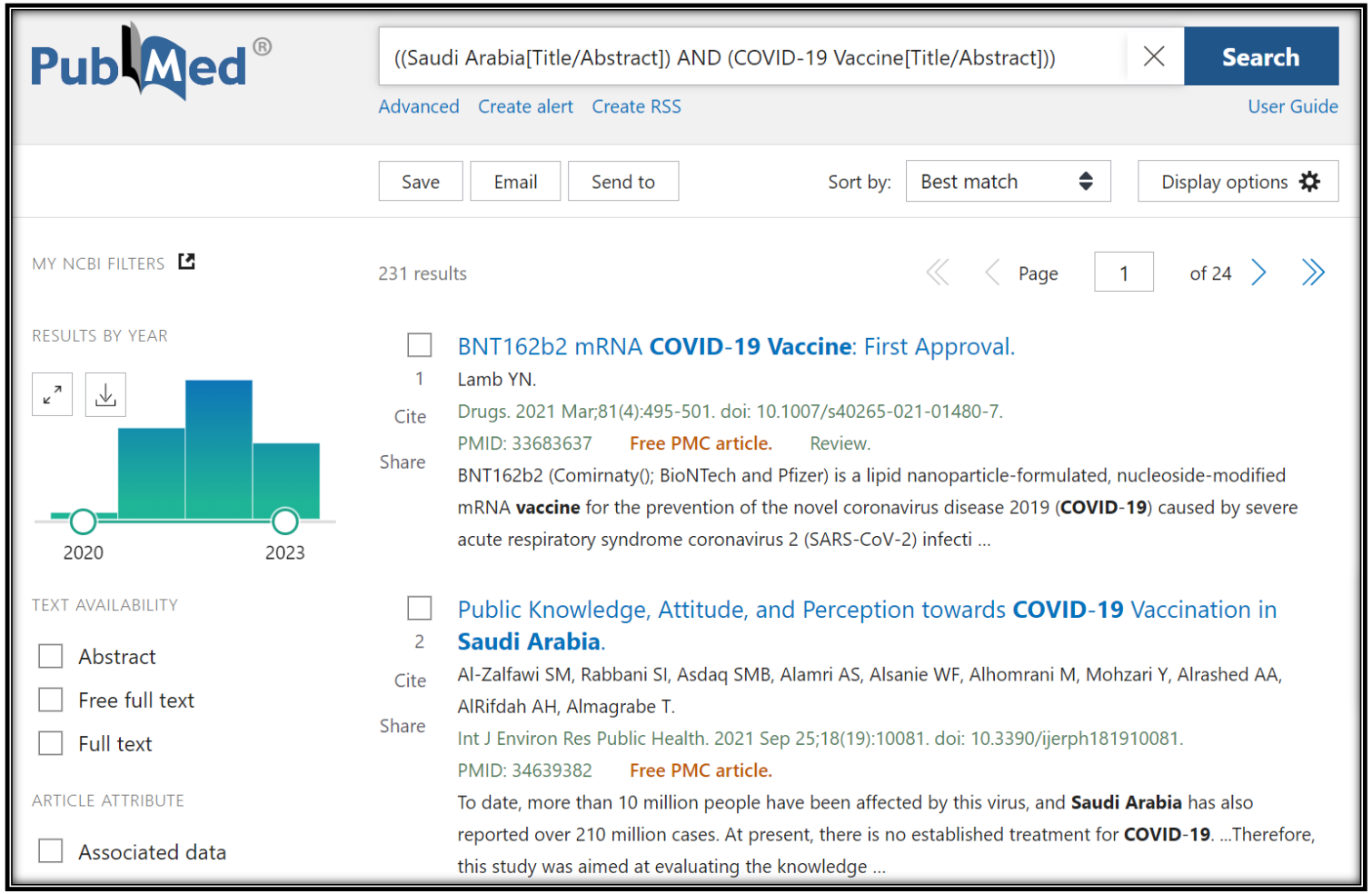

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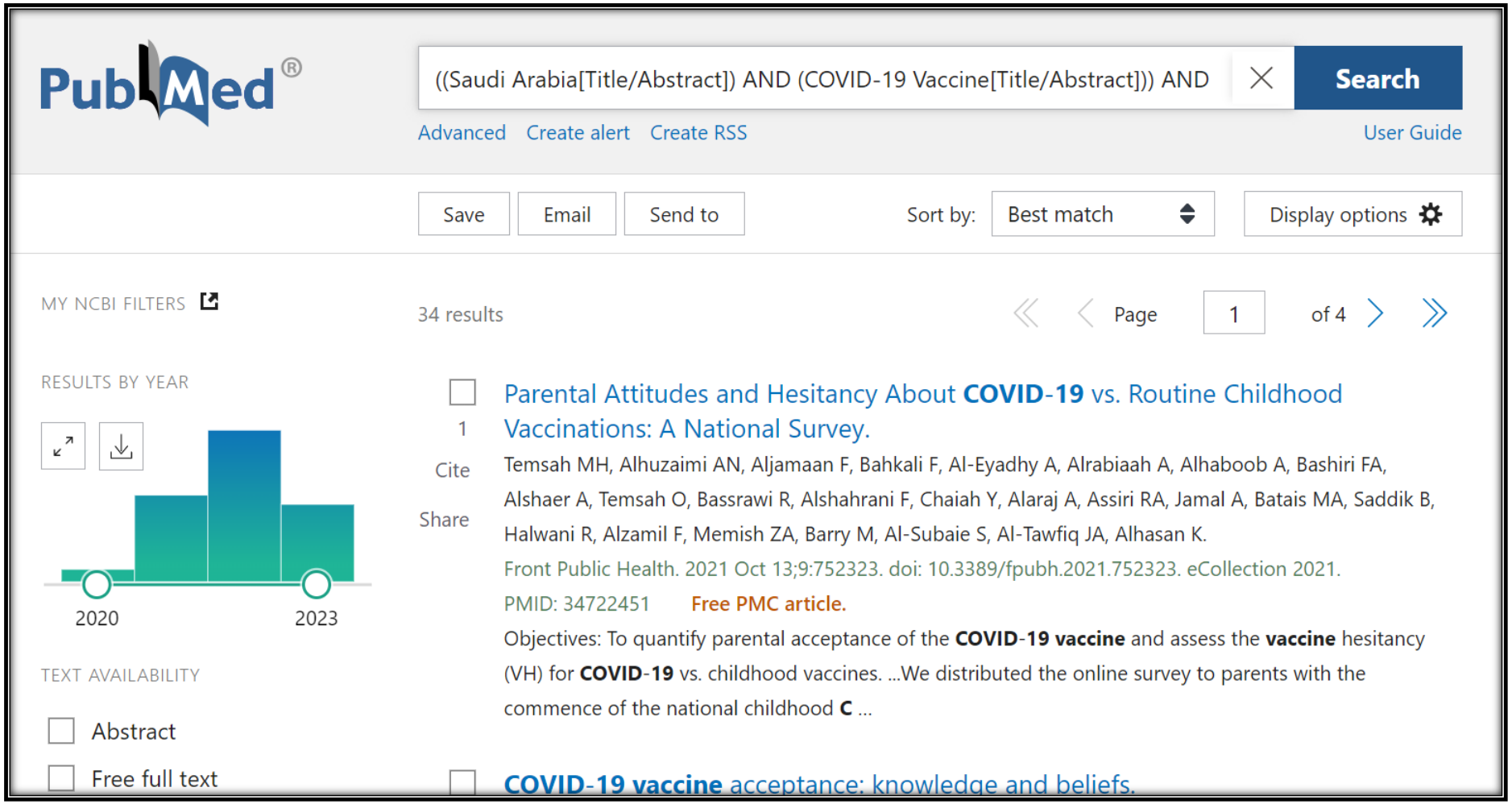

Outcomes of single dose COVID-19 vaccines: Eight-month follow-up of a large cohort in Saudi Arabia

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Original Article

Outcomes of single dose COVID-19 vaccines: Eight month follow-up of a large cohort in Saudi Arabia

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- Observational prospective cohort study on 20k vaccinated individuals
- The study was conducted during the pandemic restrictions on travel, mobility, and social interactions (Dec-2020 to Apr 2021)
- All received single dose and were followed up for 3-8 months
  (Last vaccination: 14th April 2021 and last follow-up: 10th August 2021)
- 18.5k subjects met the study criteria
  (incl. no documented COVID-19 pre-vaccination or within 2 weeks post-vaccination, lack of PCR confirmation)
- Data collection:
  - Clinical data from medical records,
  - adverse events (AEs) from a self-reporting system, and
  - COVID-19 infection data from the MoH national databases

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Outcomes of single dose COVID-19 vaccines: Eight-month follow-up of a large cohort in Saudi Arabia

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- Prospective cohort study on 20k vaccinated individuals.
- Of the 18,543 vaccinees,
  - 410 (2.3%) received BNT162b2 and 18,133 (97.8%) received AZD1222.
  - 11,145 (60.1%) were males and 7398 (39.1%) were females.
  - The participants were relatively young with a median age of 33 years (IQR: 26–42).
  - The median body mass index (BMI) was 27.3 (IQR: 23.8–31.4).

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	No infection post-vaccination (n=17091)	Infection post-vaccination (n=1452)	P value
Male	10188 (59.62%)	957 (65.91%)	<0.0001
Female	6903 (40.38%)	495 (34.09%)	
Nationality	Saudi= 12026 (70.36%)	Saudi= 1189 (81.89%)	<0.0001
	Non-Saudi= 5065 (29.64%)	Non-Saudi= 263 (18.11%)	
Diabetes mellitus	1602 (9.37%)	161 (11.09%)	0.0325
Hypertension	1916 (11.21%)	62 (11.16%)	0.9505
Hyperlipidemia	1009 (5.90%)	77 (5.30%)	0.3494
Chronic kidney disease	213 (1.25%)	18 (1.24%)	0.9826
Chronic lung disease	604 (3.53%)	61 (4.20%)	0.1894
Asthma	578 (3.38%)	58 (3.99%)	0.2182
Malignancy	183 (1.07%)	16 (1.10%)	0.9118
Morbid obesity	603 (3.53%)	75 (5.17%)	0.0014
Haemodialysis	93 (0.54%)	8 (0.55%)	0.973
Organ Transplant	11 (0.06%)	4 (0.28%)	0.0254

Table 1: Co-morbidities and other characteristics of subjects vaccinated with either BNT162b2 or AZD1222 COVID-19 vaccines.

This dataset was analysed according to vaccine type; statistical significance of the same 5 factors was associated with infection post-vaccination regardless of vaccine type.

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Table 2: Odd ratios from a multivariate logistic regression analysis modelling the probability of COVID-19 infection post-vaccination.
modeling

Variable	Odds Ratio	CI	P Value
Gender: Male	1.167	1.039-1.311	0.0091
Nationality: Saudi	1.805	1.567-2.079	<0.0001
Obese	1.327	1.033-1.705	0.0271

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Table 3: Reported adverse events post COVID-19 vaccination.

- **> 1.1k (5.8%) reported AE**
- **Lack of report does not mean lack of AEs**

AE	# of cases	AE	# of cases
Injection site pain	800	**Cardiac (Chest pain, palpitation, dyspnea)**	12
Injection site swelling (and redness)	216	**Dizziness**	11
Fatigue	732	**Gastrointestinal (Abdominal pain, vomiting, diarrhea)**	8
Fever	714	**Lymphadenopathy**	7
Myalgia	678	**Skin rash**	4
Headache	657	**CNS (Syncope, numbness)**	3
Joint pain	399	**Blurred Vision**	2
Malaise	399	**Cough**	1
Chills	312	**Profuse sweat**	1
Nausea	164		

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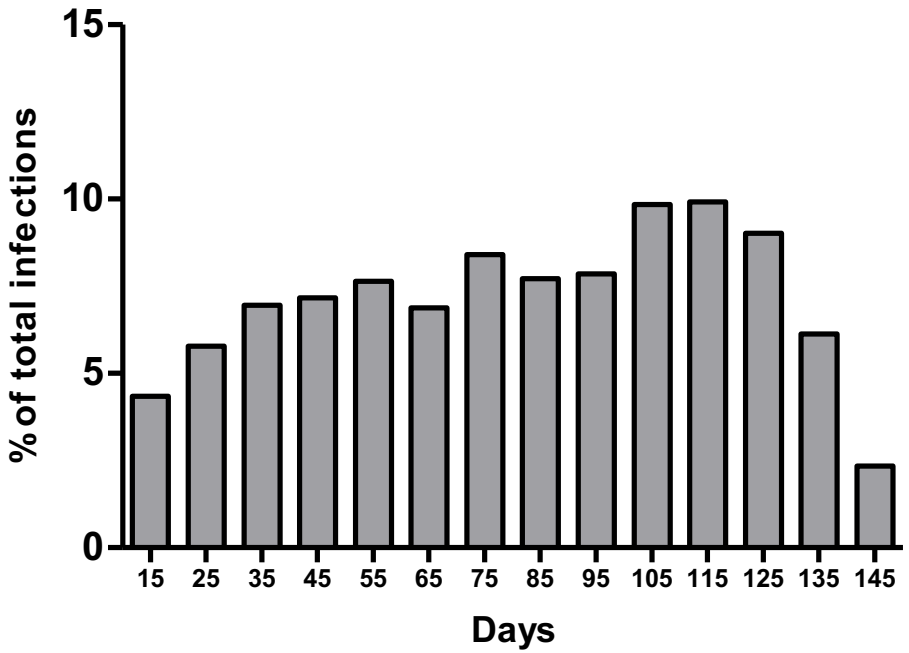
The data showed that the time between vaccination and infection was between 15 and 146 days (median = 82 days)



		Median (IQR)		Median (IQR)	P Value
Gender	Female	76 (47-112)	Male	86 (54-112)	0.0607
Nationality	Saudi	81 (50-111)	Non-Saudi	93 (51-115)	0.0624
Diabetes	No	83 (51-112)	Yes	75.5 (50-110)	0.2679
Hypertension	No	83 (50-113)	Yes	76 (54-107)	0.2129
Hyperlipidemia	No	83 (51-112)	Yes	80 (46-105)	0.4144
Renal diseases	No	82 (51-112)	Yes	88 (54-113)	0.662
Lung diseases	No	83 (51-112)	Yes	70 (37-104)	0.0376
Asthma	No	83 (51-112)	Yes	68.5 (37-105)	0.0425
Cancer	No	82 (51-112)	Yes	82 (51.5-108)	0.7421
Morbid obesity	No	83 (51.5-112)	Yes	66 (44-100)	0.0276
Haemodialysis	No	82 (51-112)	Yes	88 (54-89)	0.9363

Conclusion

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1. Single-dose of BNT162b2 and AZD1222 COVID-19 vaccines showed a **protection rate of 92.17%** (in 18,543 subjects) in three to **eight months** follow-up.
   - In clinical trials, the efficacy rates, in preventing symptomatic SARS-CoV-2 infections, were 52% (95% CI: 30–86%) after one dose and 95% (95% CI: 90–98%) after two doses of BNT162b2; and 70% (95% CI: 55–81%) after two doses of the AZD1222 vaccine.
   - Furthermore, real-world data showed that two doses of BNT162b2 vaccine reduced the risk of SARS-CoV-2 infection by 90% between Dec. 2020 and Mar. 2021 in the USA
2. Diabetes mellitus, organ transplantation, and obesity were found to be associated with the risk of infection post-vaccination.
3. **Saudi, male, and obese** subjects were more likely to get post-vaccine infection than other infected groups.
4. The vaccine type did not impact on the number of days between vaccination and post-vaccine infection.
5. Lung diseases, asthma, or cancer, for which treatment by chemotherapy predisposes patients to microbial infection due to leukocytopenia, did not affect the likelihood of infection among vaccinated subjects.

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Persistence of Anti-SARS-CoV-2 Spike IgG Antibodies Following COVID-19 Vaccines

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Infection and Drug Resistance

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ORIGINAL RESEARCH

Persistence of Anti-SARS-CoV-2 Spike IgG Antibodies Following COVID-19 Vaccines

Naif Khalaf Alharbi[1,2], Jaffar A Al-Tawfiq[3–5], Amal Alwehaibe[1], Mohamed W Alenazi[1], Abdulrahman Almasoud[1], Abdullah Algaisi[6], Fahad A Alhumaydhi[7], Anwar M Hashem[8,9], Mohammed Bosaeed[1,2,10], Suliman A Alsagaby[11]

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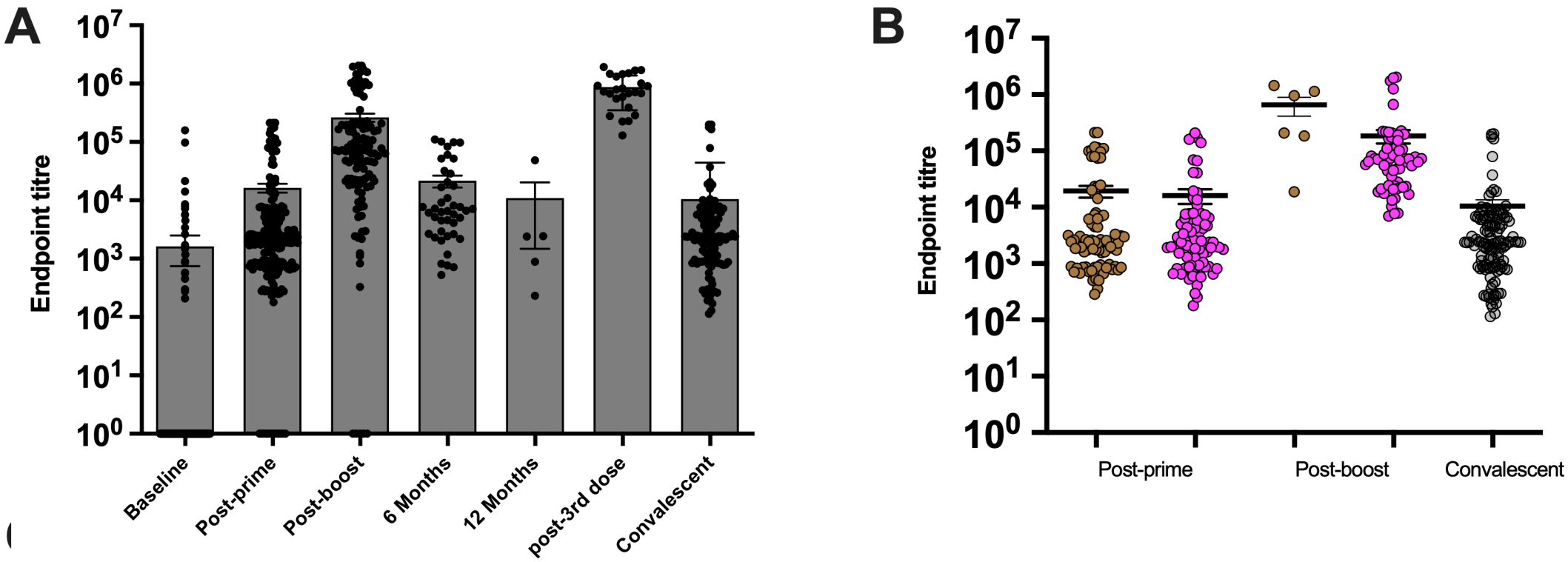

(A) IgG induced by COVID-19 vaccination was evaluated in serum samples of non-infected people at six time points: pre-vaccine (baseline), post-prime, post-boost, 6 months, 1 year, and 3 weeks post-third dose. (B) Antibody responses are shown as per type of vaccine: AZ1222: brown symbols and, BNT162b2: pink symbols. Data in A and B are shown in comparison to non-vaccinated COVID-19 convalescent cases (grayed circles).

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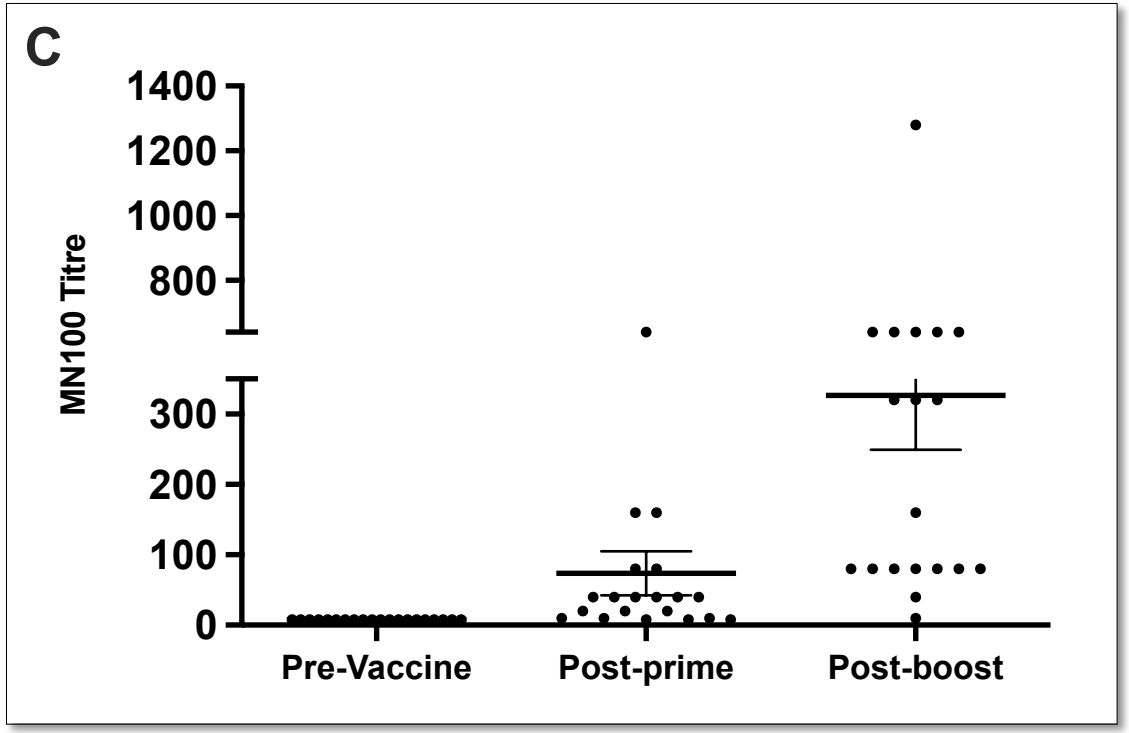

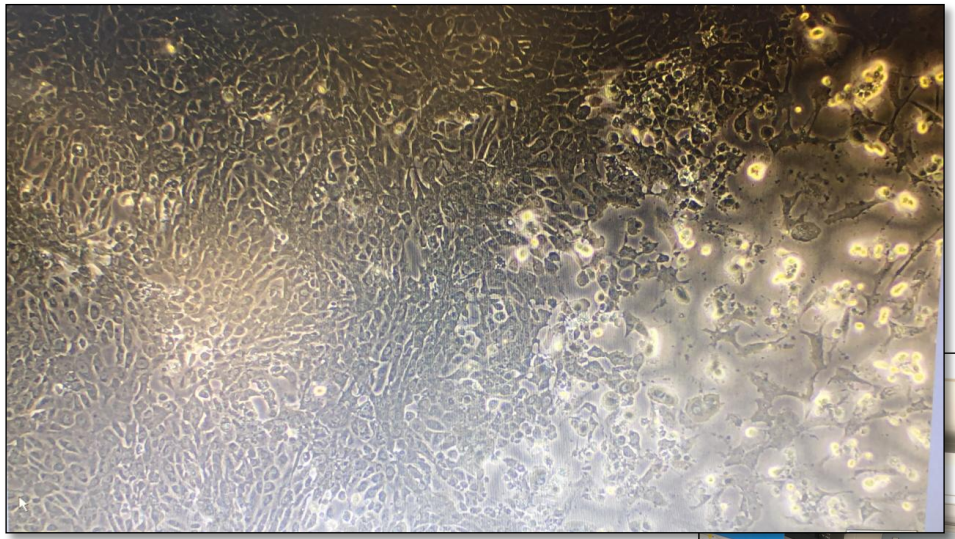

Neutralizing activity of COVID-19 vaccine-induced antibodies were determined. Horizontal lines represent means with SEM

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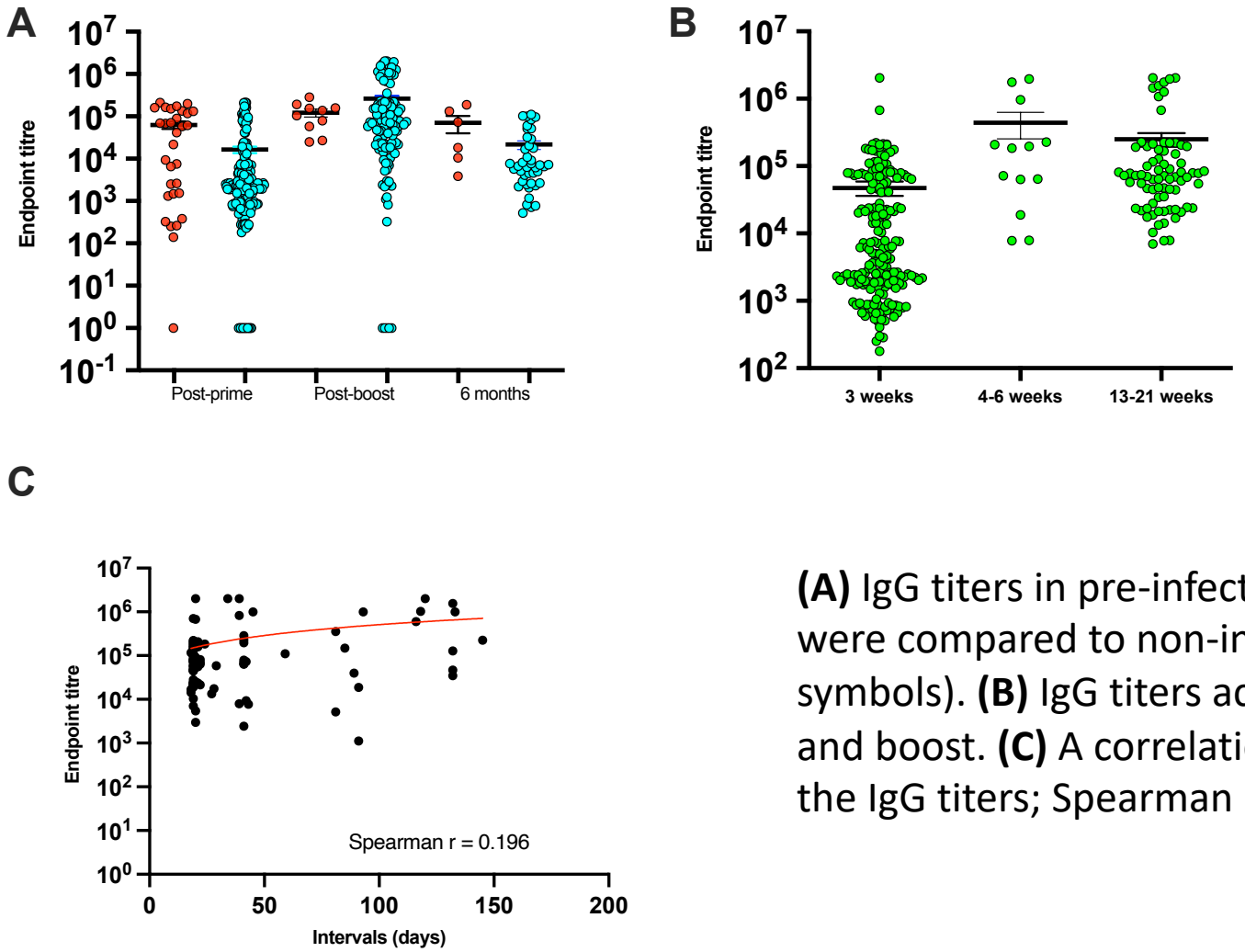

(A) IgG titers in pre-infected vaccinated individuals (shown as open symbols) were compared to non-infected vaccinated individuals (shown as blue symbols). **(B)** IgG titers according to the duration of interval between prime and boost. **(C)** A correlation between the number of days in the interval and the IgG titers; Spearman r=0.3. Horizontal lines represents mean with SEM.

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Challenges and lessons learned

- Data is electronically available but requires the right channels of approvals and communications; requires a dedicated team for data cleaning and analysis.
- Comparator group
- Vaccine type couldn’t be selected, it depends on what was available.
- Safety and AE relies heavily on self-reporting
- Lab testing requires huge logistical support.

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Safety and Efficacy of the COVID-19 Vaccine in Kidney Transplant Recipients

Abdulrahman Altheaby [1], Duha Alloqmani [2], Rawaby AlShammari [2], Albatoul Alsuhaibani [2], Anadel Hakeem [2], Syed Alam [1], Shroug Alharbi [1], Mohammed Al Zunitan [2], Mohammad Bosaeed [3], Naif K. Alharbi [4]

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vaccines

MDPI

Article

Salivary Antibody Responses to Two COVID-19 Vaccines following Different Vaccination Regimens

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Thank you

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