Checklist for improved quality of studies assessing SARS-CoV-2 vaccine-induced neutralizing antibody responses

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PREPARED BY:

Maeva Katzmarzyk (*Department of Viral Immunology, Helmholtz Centre for Infection Research*) and

Robert Naughton (*Independent Consultant*) and

Ioannis Sitaras, PhD, MRes (*Department of Molecular Microbiology and Immunology, Johns Hopkins Bloomberg School of Public Health*) and

Henning Jacobsen, PhD (*Department of Viral Immunology, Helmholtz Centre for Infection Research*).

And by:

Melissa Higdon and Maria Deloria Knoll at the *International Vaccine Access Center, Johns Hopkins Bloomberg School of Public Health*.

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For comments or questions, please contact: Maeva Katzmarzyk at maeva.katzmarzyk@helmholtz-hzi.de.

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Background:

During the COVID-19 pandemic, SARS-CoV-2 vaccine-induced neutralizing antibody studies have been a highly valuable source of data for informing vaccine policy. However, reported neutralizing antibody titers show high heterogeneity across a large number of publications, complicating interpretation. We established a Quality Assessment Tool (QAT) to evaluate neutralization study quality with a focus on data reliability and reporting quality. Based on this tool, we established the below checklist to aid researchers in systematic and standardized reporting. This checklist aims to improve comparability, consistency and reliability across studies thereby increasing utility for vaccine decision-making and optimizing response to the ongoing COVID-19 pandemic and potential future pandemics.

Checklist for consistent conduct and reporting of SARS-CoV-2 neutralizing antibody studies based on the QAT

Categories		Parameters	
1	Sample size	1.1	How many samples were included?
2	SARS-CoV-2 infection	2.1	Was any SARS-CoV-2 infection prior to completion of the primary vaccine regimen considered?
		2.2	Was presence or absence of pre-vaccination infection confirmed?
		2.3	Were breakthrough infections considered in the study cohort?
		2.4	Were breakthrough infections confirmed?
		2.5	Were infection-naïve/previously infected/ breakthrough infected samples stratified in the analyses?
3	Vaccination regimen	3.1	Do the authors report booster dosing interval?
		3.2	Are the booster dosing intervals comparable?
		3.3	Do the authors stratify for partial and complete primary regimen?
4	Sample collection period	4.1	Were all samples taken at least seven days post last immunogenic event?
		4.2	Are the results stratified OR are all samples taken ≥ two weeks and ≤ 4 months post last immunogenic event?
5	Demographic characterization	5.1	Is the age distribution of all subjects reported?
		5.2	Are results stratified by age group?
		5.3	Is the sex distribution of all participants reported?
		5.4	If only a subgroup of the initial study cohort was analyzed, did the cohort selection happen unbiased?
		5.5	Was the infecting variant/ or variant prevalence reported?
		5.6	Was the study period and geographic location reported?
		5.7	If (multiple) breakthrough infections occurred, were the results stratified for the infecting variant(s)?
6	Clinical characterization	6.1	Is any relevant clinical characterization reported?
		6.2	Are the results stratified for immunocompromised?
7	Protocol	7.1	Is the precise assay type and endpoint reported?
		7.2	Do the authors provide a precise protocol for the neutralization assay within the manuscript?
8	Live virus	8.1	Is the virus lineage reported?
		8.2	Has the sequence been confirmed by sequencing?
9	Pseudo virus	9.1	Are the construct details reported?
		9.2	Are all variant-associated spike mutations included to the pseudo virus?
		9.3	Has the sequence been confirmed by sequencing?
10	Assay standardization	10.1	Is the amount of infectious virus input (virus titer) used for neutralization assays reported and if so, are they consistent and with small input variance?
		10.2	Was the intended virus titer used for neutralization assays confirmed by back-titration or virus controls?
		10.3	Are precise details on cell culture reported?
11	Data reporting	11.1	Is the raw data for neutralization titers reported?
		11.2	Is the reference virus used for calculating variant-specific fold-changes reasonable?
		11.3	Are appropriate statistics provided?