The VALUE checklist

Domain	Item no.	Item	Completion Notes (e.g. section, page number)
Title	1.1	"Vaccine" needs to be included in the title.	
	1.2	The study design needs to be stated in the title, for example, case-control, cohort, cross-sectional, randomised controlled trial, pragmatic randomised trial.	
	1.3	For clinical trials, the phase(s) should be specified in the title when appropriate, e.g., Phase 1, Phase 2, Phase 3, Phase 1/2, or Phase 2/3.	
Keywords	2	The terms "vaccine" need to be included in the keywords.	
Background and Rationale	3	Explain the need for or the purpose of the vaccine(s) in the background and rationale section.	
Objectives	4	Clearly state all pre-specified objectives and hypotheses within the objectives section of the manuscript.	
Eligibility Criteria for Participants	5	State the inclusion and exclusion criteria for participants.	
Settings and Locations	6	Describe the settings and locations where data will be collected.	
Vaccine description	7	Describe relevant vaccine-related characteristics, and if applicable, the comparator should be described.	
Outcomes	8.1	Describe prespecified primary and secondary outcomes.	
	8.2	For studies aiming to evaluate the safety of vaccines, defined and grade the vaccine safety and reactogenicity outcomes, and describe how they were identified and reported.	
	8.3	Define the immunogenicity outcomes, humoral and/or cell-mediated.	

	8.4	For the efficacy/effectiveness outcomes, provide the formula used to calculate vaccine efficacy/effectiveness.	
Sample Size	9	Specify the basis and results of the target sample size calculation.	
Safety Results	10	For studies aiming to evaluate the safety of vaccines, report the results along with specific time points and dose number. Listing and describing the solicited and unsolicited adverse events, adverse drug reactions, and serious adverse events.	
Summary and Prospect	11.1	Interpret the main strengths and limitations of the vaccine based on study results, if possible.	
	11.2	Describe the clinical and societal impact of the vaccine as appropriate.	
	11.3	Consider the predominant costs and their potential impact on vaccine implementation and adoption within a contextual framework, if applicable.	
Generalisability	12	Outline the specific scenarios under which the vaccine may be used and promoted (use cases), as appropriate.	
Registration and Protocol	13	Provide information regarding accessibility to clinical research registration and protocols.	
Data Availability	14	Provide the availability of data and analytical code.	
Declaration of Interests	15	Provide the declaration of potential conflicts of interest.	

Note: our VALUE checklist is designed as a complementary list to CONSORT and STROBE, providing references for reporting clinical studies on intrinsic characteristics of vaccines, including RCTs of vaccines for immunogenicity, efficacy and safety.