Table 1 BRIVAC checklist: items to be included when reporting quantitative benefit–risk models applied to vaccines

From: Benefit-Risk Assessment of Vaccines. Part II: Proposal Towards Consolidated Standards of Reporting Quantitative Benefit-Risk Models Applied to Vaccines (BRIVAC)

Section/item	Item no.	Recommendation	Item has been reported
Title and abstract			
Title	1	Identify the work as a 'quantitative benefit–risk model', identify the vaccines of interest and, if applicable, the targeted geographical areas	☒ p1
Abstract	2	Provide a structured summary of the background and objectives, methods (including the targeted population(s), geographical location and time frame of the qBRm, perspectives, alternatives, choice of benefit and risk outcomes, time horizon and choice of model), key results and conclusions (interpretation and generalisability)	☒ p1
Introduction			
Background	3	Provide an explicit statement of the relevant literature stressing the magnitude of the infectious disease burden and the benefit and risk outcomes of all health interventions available, the rationale for conducting the analyses and the relevance of the study question. If the study was performed at the request of a specific stakeholder, this should be clearly stated	☒ p2
Objectives	4	Detail the specific study objectives in conjunction with items 5–9 and 11	☒ p2-3
Methods			
Targeted populations	5	Define the targeted populations by describing their characteristics and the rationale for selection. If several populations or sub-populations are targeted in the qBRm study, all of them should be reported	☒ table 1
Geographical location and time frame of the qBRm	6	Describe the geographical areas and the study period	☒ p3

Section/item	Item no.	Recommendation	Item has been reported
Perspectives	7	Describe the perspectives involved in the analyses (analysis performed at individual or population level, or both)	☒ p3
Alternatives	8	Identify the alternatives compared with the vaccines of interest in the analyses and describe their relevance	☒ p2,9-10
Choice of benefit and risk outcomes	9	Describe what outcomes were considered to define the benefits and risks of the vaccines of interest and the reasons to select these criteria. Specify measures (or unit) chosen to express benefit and risk outcomes. Providing a visual representation that displays the benefit and risk outcomes is strongly recommended	☒ p3-5
Measurement and valuation of preference	10	If applicable, describe the preference-elicitation techniques used to weight benefit and risk outcomes as well as the size and characteristics of the population from which the preference values were obtained	□
Time horizons	11	Describe the relevant time horizons for the benefit and risk outcomes evaluated and state why they are appropriate	☒ p3
Discount rates	12	If applicable, report the use of discount rates for benefit and risk outcomes and mention why they are relevant	□
Choice of model	13a	Model type: Describe the type of model used (simulation or non-simulation) and provide the rationale for its structure	☒ p3
	13b	Modelling attributes: Identify the key characteristics of the selected model, such as: Dynamic vs. static model Open vs. closed model Probabilistic vs. deterministic model Model integrating aggregated vs. individual-based data Waning effect vs. no waning effect Herd immunity vs. no herd immunity	☒ p3
Analytical methods	14	Describe all analytical methods employed in the analyses, any data transformation conducted prior to the analyses and the analytical software used	☒ p3-5
Model input parameters	15	List all model input parameters feeding the model and provide their values, ranges, sources and criteria for selection. When probabilistic simulation models are used (see items 13a and 13b), the probability	☒ Table 1

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		distribution used for each input parameter should also be described. Providing a tabular representation summarising this information is strongly recommended	
Results			
Benefit and risk outcomes	16	Report measures, values and ranges resulting from the analyses to quantify the benefits and risks. Providing a visual representation summarising this information is strongly recommended	☒ p5-8
Sensitivity/scenario analyses	17	If applicable, describe sensitivity and/or scenario analyses performed to characterise uncertainty	☒ appendix
Discussion			
Key results	18	Describe the key results in light of the study objectives	☒ p11
Limitations	19	Identify all the possible and relevant limitations of the model. Discuss the impact of these limitations on the findings	☒ p10-11
Interpretation and generalisability	20	Provide an overall interpretation of the results considering similar analyses and other relevant evidence. Discuss the generalisability of the results and potentially suggest recommendations regarding the use of the vaccines assessed	☒ p8-10
Other			
Source of funding	21	Describe any sources of funding and the role of any funders in the study	☒
Conflicts of interest	22	Describe all relevant financial and non-financial relationships and activities and conflicts of interest that could be perceived as potentially influencing the submitted work	☒

1. *BRIVAC* the consolidated criteria for reporting quantitative Benefit-RIsk models applied to VACcines, *qBRm* quantitative benefit-risk models