The VAccine cLinical study reporting gUidEline: the VALUE checklist with explanation and elaboration

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Summary

Background The number of clinical vaccine studies published each year is large and increasing as vaccinology and biotechnology advance. CONSORT and STROBE provide reporting guidelines for randomised clinical trials and observational studies, but neither addresses vaccine-specific items that should be included in vaccine study reports. Thus, there is a need to develop a guideline for reporting studies of a vaccine's characteristics such as immunogenicity, efficacy, effectiveness, reactogenicity, and safety.

Methods Using the EQUATOR Network's "Guidance for Developers of Health Research Reporting Guidelines," we established a core working group to conduct a systematic literature review and develop an initial list of reporting elements for vaccine studies based on CONSORT and STROBE. A 42-member Delphi expert group, composed of clinical vaccine researchers, methodologists, medical journal editors, and other experts, provided comments and suggestions on the initial checklist through two rounds of Delphi surveys. Working group members refined and finalised the checklist after each round, with the approval of advisory group members.

Findings Two rounds of Delphi surveys with 42 multidisciplinary global experts generated 87 qualitative comments, producing a final 22-item checklist across 15 domains, including 9 dedicated vaccine-specific reporting items. All items were refined with detailed explanations and representative clinical study examples.

Interpretation VAccine cLinical trial reporting gUidEline (VALUE) aims to provide a minimum set of vaccine-specific reporting items for experimental and observational clinical studies that evaluate characteristics of vaccines. Developed with methods recommended by the EQUATOR collaborative network, VALUE complements CONSORT and STROBE statements by addressing vaccine-specific needs, aiming to serve as a valuable resource for vaccine researchers and improve reporting of clinical vaccine studies.

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Keywords: Vaccine clinical study; Report guideline; VALUE; EQUATOR; Delphi method

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Research in context

Evidence before this study

We searched PubMed, Web of Science, and the EQUATOR Network database from Jan 1, 2000, to Jul 1, 2026, without language restrictions, using terms including "vaccine clinical research reporting guideline", "CONSORT vaccine extension", and "vaccine study reporting standards". Studies were included if they addressed vaccine clinical research reporting guidelines or core reporting characteristics. Most evidence stemmed from descriptive analyses or single-centre observational studies, focussing on gaps in general clinical research guidelines (e.g., CONSORT, STROBE) rather than vaccine-specific needs. This gap hinders consistent reporting of a vaccine's critical elements such as immunogenicity, efficacy, effectiveness, reactogenicity, and safety in the vaccine clinical studies. To address this, we developed the VAccine cLinical trial reporting gUidEline (VALUE), which is an evidence-based, consensus-driven checklist tailored for vaccine clinical studies.

Added value of this study

Our study combined a systematic literature review (2018–2026), two rounds of international Delphi consensus (42 multi-disciplinary global experts), and stakeholder consultation to develop the VALUE (VAccine cLinical trial reporting gUidEline) checklist. VALUE delivers a minimum set of reporting items tailored to vaccines, catering to the unique reporting requirements of both experimental and observational vaccine clinical studies. Specifically, targeted reporting of vaccine-specific features (e.g., platform/adjuvant, immunogenicity/safety outcome grading, efficacy calculation formulae, adverse event classification) emerges as the more fitting framework for transparent, reproducible vaccine research. Our goal is to develop a clinical reporting guideline specifically tailored for vaccine clinical studies. We hope it can serve as a valuable resource for vaccine researchers and improve reporting of clinical vaccine studies.

Implications of all the available evidence

Together with existing literature, our findings suggest that standardised, vaccine-specific reporting is a reproducible cornerstone of high-quality vaccine clinical research, with the VALUE guideline helping address gaps in reporting practices. These results refine the global clinical research reporting guideline system, highlighting critical reporting elements that directly impact the reliability of vaccine efficacy, safety, and immunogenicity assessments—findings highly relevant to human health and public health decision-making for both basic and clinical vaccine research.

Introduction

Clinical studies, when properly designed, conducted, analysed, and reported, serve as a crucial reference for evaluating clinical interventions.[1,2] Well-conducted clinical studies not only assist clinicians in making accurate diagnoses and improving patient outcomes, but also promote the dissemination and sharing of knowledge within the medical community.[3] However, without a rigorous design and standardised reporting, achieving the desired outcomes becomes challenging.

Research interest in vaccines has increased, accelerated by the COVID-19 pandemic, with an increasing number of scholars focussing on vaccine-related studies.[4,5] A search for "vaccine clinical study" on the Cochrane library yielded over one hundred Cochrane reviews. Additionally, the World Health Organisation (WHO) has launched a dedicated section on COVID-19 vaccines, emphasising that clinical studies are essential to demonstrate their safety and efficacy.[6] The heightened attention to vaccine clinical studies implies greater need for standardised reporting.

High-quality clinical studies on vaccines are essential for advancing medicine,[7] however, no specific reporting guidelines for vaccine clinical studies currently exist. Vaccine-related studies often adhere to CONSORT[8,9] and STROBE[10] statements,[11] which provide general guidance for randomised trials and three types of observational studies, respectively, but neither addresses important vaccine-specific attributes such as the type of vaccine, the mode of vaccination, and potential adverse safety events.[12] Vaccine clinical research has methodological and reporting requirements that differentiate it from conventional pharmaceutical clinical trials, creating reporting gaps unaddressed by CONSORT[8,9] and STROBE.[10] Vaccine trials require standardised disclosure of unique product attributes including vaccine technical platform, adjuvant composition, vaccination schedule, and administration routes, which are irrelevant to oral/injectable small-molecule drugs. Many vaccine trials rely on immunogenicity endpoints (seroconversion, geometric mean antibody titres, cellular T-cell responses) with standardised measurement definitions that have no equivalent in most non-vaccine clinical research. Vaccine research requires standardised adverse event reporting by vaccination dose, time window, and solicited/unsolicited event classification. These specific methodological and reporting requirements distinguish vaccine trials from conventional pharmaceutical clinical trials and create persistent reporting gaps unaddressed by CONSORT[8,9] and STROBE,[10] thus justifying the development of the VALUE guideline tailored exclusively for vaccine clinical studies.

Our study aims to develop a reporting guideline specifically for vaccine clinical research, based on the CONSORT[8,9] and STROBE[10] statements. The proposed guideline is designed to assist vaccine researchers, journal editors, and healthcare professionals enhance the quality of vaccine study reporting.

Methods

Research design

We registered the VALUE guideline project on the Enhancing the QUAlity and Transparency Of health Research (EQUATOR) network on January 25, 2022, following recommended procedures.[13] This study strictly followed all pre-defined procedures outlined in the registered protocol without post-hoc modifications to consensus rules or literature scope.

This study followed the EQUATOR Network's 'Guidance for Developers of Health Research Reporting Guidelines' and implemented a three-phase process (Details can be found in Fig. 1.): (i) establishing a core working group, a Delphi consensus group, and an advisory group, (ii) conducting a systematic literature review to develop an initial guideline checklist, (iii) refining the checklist through a Delphi consensus process to finalise the guideline.

Establishing the core working group, Delphi consensus group, and advisory group

The core working group was established with Professor Bian Zhaoxiang, Director of the Chinese EQUATOR Centre, Professor Yu Li from the Chinese Academy of Medical Sciences and Peking Union Medical College, Professor Lin Yu in the Guangzhou Medical University, and their colleagues. The group addressed methodological issues related to the development of reporting guidelines and participated in the development of the initial checklist. The selection of Delphi consensus group follows three approaches: i) clinical researchers and journal editors in the field of vaccines identified through the VALUE baseline survey; ii) vaccine policy makers from the CDC, the European Union, and government agencies; and iii) experts affiliated with the EQUATOR Network. The process involved a snowball sampling method, where initial experts recommend additional specialists in the field, culminating in the formation of the Delphi consensus group through invitations sent via email to those who consented. Consensus group members had to have an MD and/or PhD degrees and expertise in vaccine research or related fields. The Delphi consensus group ultimately comprised 42 international experts, consisting of vaccine clinical researchers, public health policymakers, reporting guideline methodologists, and medical journal editors; no patient or public participant representatives were involved in the Delphi survey. The Delphi consensus group was responsible for evaluating the scientific consistency and completeness and the feasibility of checklist items, reaching consensus on each item, and contributing to the establishment of VALUE.[14,15] The advisory group consists of Prof. David Moher, Chair of the EQUATOR Network, Dr. Lance Rodewald, from the National Immunisation Programme, Chinese Centre for Disease Control and Prevention.

Scoping review and item generation

We systematically searched PubMed, Embase, and Web of Science (WOS) to collect reporting guidelines related to vaccines. We also reviewed vaccine reporting guidelines published on platforms including the EQUATOR Network, World Health Organisation (WHO), Food and Drug Administration (FDA), European Centre for Disease Prevention and Control (ECDC), and National Medical Products Administration (NMPA), yet we did not identify a comprehensive reporting guideline specifically developed for vaccine clinical studies. Then, we systematically searched MEDLINE, EMBASE and the Cochrane Central Register of Controlled Trials (CENTRAL) for vaccine related studies. We tracked randomised controlled trials (RCTs), systematic reviews and meta-analyses evaluating vaccine efficacy, immunogenicity and safety, as well as observational studies on vaccine effectiveness where vaccines served as the research subject. Studies excluded from our review include those assessing vaccination coverage; vaccine confidence; vaccine provider knowledge, attitudes, and practices; economics of vaccination; and other research that does not investigate the intrinsic characteristic of a vaccines. The scoping review of vaccine research literature ran from January 1, 2018, to August 11, 2024, a total of 13,081 studies were retrieved, among which 360 studies were ultimately included after screening. This timeframe covers the COVID-19 pandemic (2020–2022) and includes two years before and after the pandemic to collect a full set of contemporary vaccine studies, providing adequate evidence to identify gaps and support checklist development.

Building on the CONSORT[8,9] and STROBE[10] statements, and supplemented by the literature review, we formulated an initial checklist with 15 items that were subsequently confirmed through discussion with the core working group. Details of the literature review and item generation can be found in Appendix 1.

Delphi consensus process

Two rounds of Delphi surveys were conducted via email to rate each item and provide suggestions for additional items. Five-point Likert scale items were used to determine inclusion, exclusion, or re-rating of items based on the consensus among panel members. In accordance with predefined consensus criteria, items attaining a consensus rate of 80% or greater were retained, those with consensus rates ranging from 50% to 80% were subject to revision, and below 50% were excluded. The first round was conducted during March 2022 to June 2022. In response to feedback from the expert panel, we organised several online discussions with our core working group members and advisory group members. Following these discussions and revisions, we addressed all recommendations and returned the revised checklist for final review and approval. The second round of the Delphi survey was conducted during June 2022 to August 2022. After the second round, there

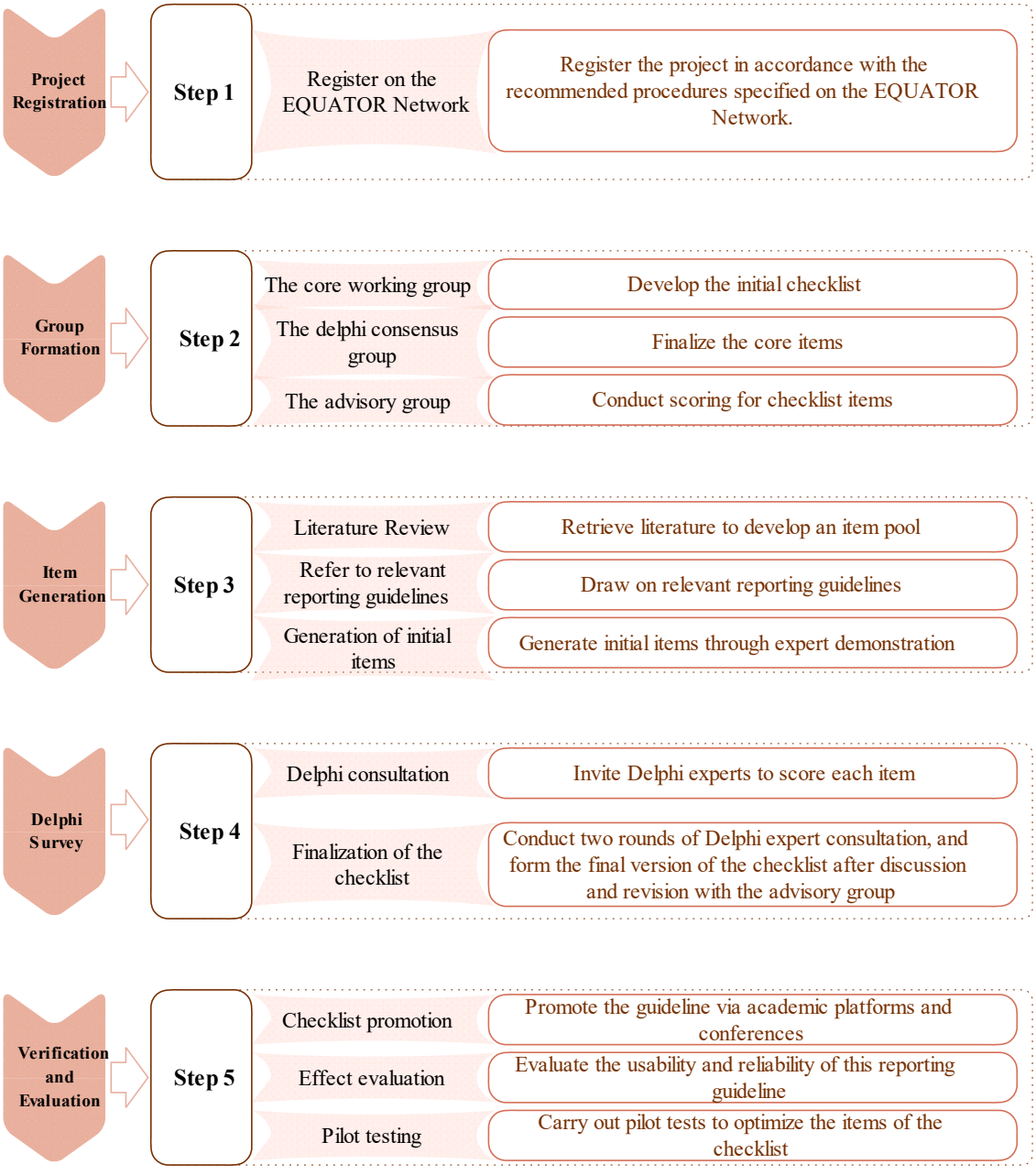


Fig. 1: Flowchart of the full development process of the VALUE guideline.

was consensus on all VALUE items. Our working group members refined and finalised the checklist after the second Delphi round, with the approval of advisory group members.

Ethics

The data for this study were obtained through a secondary integration of publicly available research literature. Therefore, no Institutional Review Board (IRB) approval or informed consent from participants were required.

Role of funders

The funders of this study had no role in study design, data collection, data analyses, interpretation, or writing of report.

Results

Item generation

We formulated a preliminary checklist for VALUE based on intrinsic characteristics of vaccines, guided by CONSORT[8,9] and STROBE[10] statements, and

supplemented by findings from the scoping review. CONSORT[8,9] and STROBE[10] statements are designed for experimental and observational studies and have well-established items in domains including title, background and rationale, objectives, and eligibility criteria for participants, interventions, sample size, and statistical analysis. Building upon these items, we tailored our list of items to align with the specific characteristics of vaccines and the focus of clinical vaccine studies. For instance, the title should emphasise that this is a vaccine clinical study and clearly specify the type of clinical research, and the background and rationale should include fundamental reason for conducting the study, supporting preclinical data, and key information regarding principles of vaccination. After the scoping review, we identified several key characteristics of vaccines that are not addressed by CONSORT[8,9] and STROBE[10] guidelines, including vaccine type, vaccine platform, dosage, adjuvant composition, as well as tolerability outcomes, and immunogenicity results. Based on literature findings, we developed new items beyond the existing guidelines to supplement the CONSORT[8,9] and STROBE[10] statement. The checklist at that point had 15 domains and 18 items. For more detailed information, please refer to Appendix 1.

Participants

Forty-two experts participated in the Delphi survey, including 21 authors of vaccine clinical trials, 21 clinical investigators, nine vaccine researcher and developers, and seven reporting guideline developers. The participants come from five continents. Most of the participants were from China, Pakistan, the United Kingdom, the United States of America, and Australia; details are shown in Table 1.

Variable	Category	Count	Percent
Continent	Asia	31	73.81%
	Europe	4	9.52%
	Oceania	3	7.14%
	America	3	7.14%
	Africa	1	2.38%
Identity	Clinical investigator for vaccine clinical studies	21	50.00%
	Author for vaccine clinical trials	21	50.00%
	Reporting guideline developer	7	16.67%
	Statistician for vaccine clinical studies	6	14.29%
	Vaccine researcher and developer	9	21.43%
	Policymaker for vaccines	3	7.14%
	Editor for reporting guidelines	2	4.76%

Note: A participant can have multiple identities.

Table 1: **Characteristics of Delphi panel participants.**

Delphi survey

The Delphi survey had five-point Likert response options: "very important", "important", "moderately important", "slightly important" and "not important". If an item was rated as "very important" or "important" by more than 80% of the experts, it was considered to have reached consensus and included in the final checklist. Conversely, if an item was rated as "slightly important" or "not important" by more than 80% of the experts, it was excluded. Items that did not meet these criteria were discussed and revised, and a second round of the Delphi survey was conducted.

In the first round, 14 of the 15 domains reached consensus and one item (Item 5.2: Generalisability) did not. One new item (Item 5.1: Summary and Prospect Recommendations) was added. To better define item 5.2 in the title domain, the item was sub-divided into three items. After the second round, consensus was reached on all items, one item (Item 4.1: Participant flow) was excluded. The Delphi survey process is described in Appendix 2–5. The final checklist included 22 items in 15 domains (Table 2). An editable standalone version is available in Appendix 6.

Explanation and elaboration

Title

Explanation: The title should enable readers to clearly understand the core points and types of this study, and the title should encompass information relevant to the research topic. For example, a review that included 61 studies found that 93% (59/61) of the studies adhered to the CONSORT statement guidelines, presenting key information within the title.[16] Specifically, if it's a clinical trial, the "Clinical research" should be specified as experimental (randomised controlled trial, non-randomised controlled trial, etc.); if it is an observational study, it is recommended to provide a study design, such as case–control, cohort, cross-sectional study, or target trial emulation.

While "vaccine" is the preferred keyword for study titles, lexically related terms with the shared vacc-root (e.g., vaccination) are acceptable substitutes, provided the title clearly signals that the primary research object is a vaccine and its intrinsic clinical characteristics.

For licensure RCTs, it is important to provide the type of clinical trial (phase 1/2/3), placebo-controlled comparator, location, and subject ages. It should be noted that many modern vaccine trials use merged adaptive phase designs (e.g., Phase 1/2, Phase 2/3) to accelerate development during public health emergencies. For trials with indistinct phase boundaries, explicit phase labelling is not required. For discrete first-in-human Phase 1 or standalone Phase 2/3 registration trials with clear boundaries, trial phases should be clearly stated in the titles.

Domain	Item no.	Item
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, humoural 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.

Table 2: **The VALUE checklist.**

Example: (i) Immunogenicity of a Third Scheduled Dose of Rotarix in Australian Indigenous Infants: A Phase IV, Double-blind, Randomised, Placebo-Controlled Clinical Trial.[17] (ii) Vaccination of human participants with attenuated *Necator americanus* hookworm larvae and human challenge in Australia: a dose-finding study and randomised, placebo-controlled, phase 1 trial.[18]

Keywords

Explanation: Keywords should accurately summarise the topic of the study. For example, a review included 61 studies found that 93% (59/61) of the studies adhered to the CONSORT statement guidelines, presenting key information within the keywords.[15] Abbreviations should not be used in the keywords. Keywords should be easily understood, such as "vaccine", "clinical research".

Example: Keywords: Aboriginal; clinical trial; Immunogenicity; Rotarix; rotavirus vaccine.[17]

Background and rationale

Explanation: This section should provide an overview of the vaccine, such as the rationale of vaccine development, conditions of vaccine suitability and supportable data, and the context of vaccination. A study evaluating the reporting quality of stroke-related randomised controlled trials using the CONSORT guidelines found that only 77% of the studies adhered to the CONSORT requirements and reported relevant trial background.[19] Authors should describe the epidemiological rationale for the vaccine and should describe known characteristics of the vaccine and important use cases.

Example: (i) With an estimated annual occurrence of 68,000 cases, Japanese encephalitis (JE) is the most common viral encephalitis. Symptomatic cases of JE result in a fatality rate of 30%, and severe neuropsychiatric sequelae are noted in up to approximately 50% of the surviving patients. Japanese encephalitis virus (JEV) treatment is exclusively symptomatic.[20]

Objectives

Explanation: The objectives should accurately reflect the purpose of the study and should be presented clearly and concisely. However, according to a review, only 33% (109/332) of the studies explicitly stated their research objectives in accordance with CONSORT guidelines.[21] In vaccine clinical studies, it is essential to

clearly present the research objectives to the readers. State specific study objectives (such as safety, tolerability, immunogenicity, efficacy, effectiveness of the vaccine(s) and prespecified hypotheses.

Example: We designed a 2-stage randomised controlled clinical trial to determine both the immunological effect (stage 1) and clinical protection (stage 2) of administering an additional dose of oral rotavirus vaccine to NT Aboriginal children 6 to <12 months old. Here we report the immunological results of stage 1. We hypothesised that for regional and remote Aboriginal infants, administering an additional Rotarix dose after age 6 months might improve immune response and thereby extend protection against rotavirus gastroenteritis into the second year of life.[17]

Eligibility criteria for participants

Explanation: Appropriate participants are fundamental for clinical trials. There is a need to clarify eligibility criteria, especially for infection risk and medical conditions. Infection risk means participants are at risk of contracting the disease. Medical conditions include (i) healthy; (ii) special population, such as children or pregnant women; (iii) suffering from specific disorders, such as immunodeficiency or a chronic disease; (iv) receipt of interventions that may affect the outcome. The CONSORT guidelines strongly recommend the use of a more intuitive participant flow diagram to illustrate the inclusion and exclusion of participants. However, a review indicates that 25.2% (26/103) of the studies did not report information related to the participant flow.[22]

Example: (i) Eligible participants had 1–4 male or female lifetime sexual partners or no prior partners but planned to become sexually active within 3 months of study initiation.[23] (ii) For the 18–64 study, inclusion criteria were body-mass index less than 40 kg/m^2; age 18–64 years at screening visit; good health with no clinically relevant abnormal laities (assessed by the investigator); and negative urine pregnancy test at screening visit and birth control use during the study in women of childbearing potential.[24]

Settings and locations

Explanation: Settings and locations where the data were collected should be clearly stated. However, the majority of studies often overlook this aspect of information, which can undermine the credibility of the research. A review encompassing 102 studies revealed that as many as 98% of the studies lacked information regarding the settings and locations of data collection.[25] This is a crucial aspect of study design. Specify whether the location is under threat of the disease targeted by the vaccine, and include country, city if applicable, immediate environment (for example, community, hospital clinic, or inpatient unit), and qualifications for implementing trials.

Example: The 18–64 study was done at 73 sites, and the 65-plus study was done at 104 sites across Asia, Europe, and North America (Appendix pp 4–5). The full protocols are in the Appendix (pp 32–113 for the 18–64 study and pp 114–200 for the 65-plus study).[24]

Vaccine description

Explanation: The majority of studies lacked descriptions of the intrinsic characteristics of the vaccine. The characteristics of the vaccine itself and information related to vaccination should be reported in detail. The vaccine-related characteristics such as (i) vaccine type (specific name and code of vaccine), (ii) vaccine platform (inactivated vaccine; attenuated live vaccine; protein subunit; virus-like particles (VLP); viral vector vaccine (non-replicating, replicating); nucleic acid vaccines/genetic vaccine). (iii) adjuvant components; developer; and targeted epidemic strains. Information on vaccination includes vaccination schedule, dose, route of administration (oral, intramuscular injections, inhalation). Information about controls should be provided as appropriate.

Example: The vaccine is pre-pared from virus grown in the allantoic cavity of embryonated eggs, split by Triton X-100, inactivated by formaldehyde and then purified. IVACFLU-S is formulated to contain 15 μg HA from each of the three vaccine strains in 0.5 mL of phosphate buffered saline (PBS) at a pH of 7.2 and filled in single-dose vials. No adjuvants were included in the vaccine formulation.[26]

Outcomes

Explanation: The outcomes section should emphasise the main findings of the study, with the outcomes categorised into primary and secondary outcomes based on the study design. The outcomes should be presented concisely and accurately, avoiding ambiguity and vagueness. For instance, a study revealed that only 63.27% (31/49) of the studies reported the primary outcome measures.[27] Additionally, the majority of the studies 75% (27/36) exhibited issues such as protocol deviations and ambiguities in reporting the outcome measures.[28]

(i) Completely defined pre-specified primary and secondary outcomes (safety, tolerability, immunogenicity, efficacy, effectiveness outcomes), including how and when they were assessed. The minimum follow-up period, if any, and plans for further follow-up beyond the end of the trial for late outcomes (e.g., waning immunity, late adverse effects) should also be provided.

(ii) For safety and/or reactogenicity outcomes, solicited adverse events and unsolicited adverse events, and serious adverse events should be prespecified. The system used for grading adverse event outcomes should be included.
(iii) For immunogenicity outcomes, measures of humoural and/or cell-mediated immune response should be reported. Humoural immune responses include seroconversion rate/seroprotection rate, and/or geometric mean titre/concentration of assessed antibodies. Cell-mediated immune response can include T-cell responses and cytokine production.
(iv) The standard formula for vaccine efficacy (VE) is VE = (1 − Effect Ratio) × 100%, which can be appropriately adjusted according to the study design in practical applications, where the effect ratio can be risk ratio (RR), odds ratio (OR), incidence rate ratio (IRR), or hazard ratio (HR) based on trial design and outcome type. Authors must explicitly report which ratio metric was selected for VE calculation. Calculation example: If the incidence rate ratio of confirmed disease in vaccine versus placebo groups equals 0.30, VE = (1 − 0.30) × 100% = 70%.

Example:
(i) The primary endpoints were neutralising antibody titres against wild-type virus evaluated by two neutralisation assays. Secondary endpoints were the percentages of participants with solicited local reactions and systemic adverse events occurring within seven days after vaccination. Neutralising responses against SARS-CoV-2 variants and cell-mediated immune responses were evaluated as exploratory endpoints.[29]
(ii) Solicited AEs were assessed within 30 min (immediate reactogenicity) and continuously for 7 days after vaccination. Unsolicited AEs were assessed for 21 days after vaccination. Investigators also conducted causality assessments and graded severity of unsolicited AEs. Serious AEs were assessed throughout the study (i.e. till 90 days postvaccination).[26]
(iii) Seroprotection rates were defined as percentage of participants with HI titres ≥1:40 following vaccinations. Seroconversion rates were defined as percentage of participants achieving an increase in HI titre from <1:10 pre-vaccination to ≥1:40, or at least a fourfold postvaccination increase in titre from a pre-vaccination titre ≥1:10. Geometric mean fold rises of serum HI antibodies were defined as postvaccination GMT/pre-vaccination GMT. Subjects with HI antibody titres ≥1:10 were considered to be seropositive.[26]
(iv) A clinical diagnosis of varicella was based on a typical pruritic maculopapular vesicular rash with no other apparent cause. Laboratory confirmation of varicella was achieved by using PCR or virus isolation, or fourfold rise of antibody level from acute to recovery period. The efficacy of varicella vaccine was evaluated from day 31 until 6–7 months after vaccination for each subject.[30]

Sample size
Explanation: The process of calculating the sample size should be provided in detail. A review found that a small proportion 2.9% (3/103) of the studies still neglect the reporting of sample size calculation methods.[22]If the sample size can't be calculated based on statistical power (for example, lack of preliminary data), the sample size basis that was used should be provided.

Example: (i) The sample size calculation was based on the assumption of a true vaccine efficacy of 60% and a background annual dengue incidence of 1%. We calculated that a sample of 20,100 participants undergoing randomisation in a 2:1 ratio would enable identification of 120 cases of virologically confirmed dengue from 30 days after the second vaccination to the end of part 1, providing at least 90% power to rule out a vaccine efficacy of 25% or less.[31]

Safety results
Explanation: All safety results or unintended effects in each group with specific time points and doses should be described in studies assessing safety or reactogenicity. This is a critical aspect in clinical trials. However, 24.3% (25/103) of the studies still neglect to report adverse events.[22] This oversight could potentially pose significant risks. List and analyse solicited adverse events, unsolicited adverse events, and serious adverse events.

(i) adverse events: medical events occurring after vaccination but not necessarily causally related;
(ii) adverse vaccine reactions: reactions that occur under normal usage and dosage that are not related to the purpose of the vaccine;
(iii) serious adverse events: adverse events such as death, life-threatening events, permanent or severe disability or loss of function, hospitalisation or prolongation of hospitalisation, and congenital anomalies or birth defects that occur in the course of a clinical trial;
(iv) significant adverse events: obvious abnormalities other than serious adverse events that lead to targeted medical measures (such as discontinuation, dose reduction, and symptomatic treatment);
(v) unsolicited adverse events: adverse events with greater severity or frequency compared with

expected severity or frequency described in a previous protocol or other relevant information (e.g., investigator's brochure, drug insert).

The term "harms" is retained following the WHO evidence-to-recommendation framework for vaccine benefit-risk evaluation. We use "Safety Results" as the primary domain heading for broader readability, while strictly distinguishing vaccine safety and reactogenicity throughout the elaboration: reactogenicity refers to transient local/systemic short-term reactions post-vaccination that do not lead to permanent damage, whereas safety covers all lasting severe adverse events, which remain core reporting priorities for vaccine trials and many observational studies.

Example: (i) Thirteen AEs were observed in the course of this study; two of these were assessed as being associated to the investigational vaccine. Both AEs were mild in severity.[32](ii) All AEs reported in the booster group within 1 month after the booster dose were included in the post booster safety analysis. No deaths or AEs leading to discontinuation were reported. The majority of subjects reported with AEs had AEs with a maximum severity of mild or moderate.[20]

Summary and prospect

Explanation: This section should provide a general summary of the results and a prospect for future development. The authors should describe the benefits and limitations of the vaccine and provide detailed suggestions for improvement. The majority of studies, 93% (57/61), clearly reported the limitations and strengths of the research in accordance with the CONSORT guidelines; however, there was insufficient reporting on the summary and prospect section.[16] The authors should summarise the key points and take-away lessons of the study and the vaccine's impact in the clinical setting and on society, if applicable. Potential impact during vaccine implementation and adoption should also be considered, such as cost and population-level impact. This part only applies to vaccine clinical trials with pre-specified embedded health economic evaluations. For trials solely evaluating immunogenicity, efficacy or safety without cost-related research objectives, reporting cost data is not required.

Example: (i) Vaccination is currently the most effective means of preventing influenza. However, global influenza vaccine coverage is low and vaccine production capacity is concentrated mostly in industrialised countries. In addition to assuring supplies, local production of vaccines also supports socioeconomic development, controls cost, and enhances national vaccine security and preparedness towards early response in case of local epidemics.[33](ii) The absence of a known correlate of risk or protection in a foetus necessitates additional efforts to bridge animal experiments with human studies.[34]

Generalisability

Explanation: Based on the study results, summarise the specific scenarios (use cases) in which the vaccine could be applied, i.e. target populations, geographic region for use, and level of risk. The level of risk refers to the potential effectiveness of the vaccine at different exposure levels. However, this is an aspect that is often overlooked in research. According to a review, only 21.5% (98/456) of the studies discussed the generalisability of the research findings.[35] Given the intrinsic characteristics of vaccines, it is crucial for studies to highlight the practical value of vaccines, making discussions on their generalisability particularly important.

Example: The current study was performed in adults with an age range of 16–45 years in a population sample of Cuban adult patients with allergic asthma. Taking into account the high prevalence of sensitisation to *Blomia tropicalis* in this population, more studies should be conducted to expand and confirm these results, particularly in children.[36]

Registration and protocol availability

Explanation: Authors should provide a reference to the registration of the study and the availability of the study protocol. A review encompassing 616 studies, which evaluated the reporting quality of research based on CONSORT, found that few studies (58/616, 9%) provided detailed information on trial registration or made the original trial protocol accessible (9/616, 1%).[37]

Example: (i) The three trials are registered at Clinical Trials.gov, numbers: NCT02963909, NCT02952833, NCT02937233).[34] (ii) The study protocol is available at https://www.clinical trial sregister.eu/2006-004374-27/DE.[38]

Data availability

Explanation: Where privacy is not involved, authors should provide information on accessing study data. However, 64.71% (66/102) of the studies lacked data availability.[25] This can result in a significant waste of resources.

Example: Supplemental data for this article can be accessed on the publisher's website (https://www.tandfonline.com/doi/full/10.1080/21645515.2019.1581536).[39]

Declaration of interests

Explanation: The authors should provide a summary of any conflicts of interest of all authors, including financial and non-financial interests. A review found

that only 34% of the studies reported information regarding funding sources and potential conflicts of interest.[40] The disclosure of conflicts of interest requires greater attention.

Example: (i) All authors have submitted the ICMJE Form for Disclosure of Potential Conflicts of Interest. Conflicts that the editors consider relevant to the content of the manuscript have been disclosed.[41] (ii) Conflict of interest statement: The authors declare that there is no conflict of interest.[42]

Discussion

The number of clinical studies on vaccines is steadily increasing,[43] highlighting the need for standardised guidelines to improve reporting of vaccine research. This study is formally developing a clinical reporting guideline specifically tailored for vaccine clinical studies. VALUE was developed following the methods recommended by EQUATOR, incorporating input from experts in statistics, methodology, and vaccine research. A systematic literature review, based on established guidelines, provided the foundation for the checklist, which was validated through two rounds of Delphi consensus surveys. VALUE, based on CONSORT[8,9] and STROBE,[10] aims to meet the specific needs of vaccines, to serve as a valuable resource for vaccine researchers, and to improve the reporting of clinical vaccine studies.

Checklist generation process

During the Delphi process, consensus was not initially reached on Item 5.1 (generalisability). The Generalisability section in the initial checklist proposed that specific scenarios in "which the vaccine could be applied" (use cases) should be described, including characteristics of the target population, the region of administration, and the level of risk to which the population is exposed. This information could provide valuable insight into the potential usefulness of the vaccine.[44,45] However, some experts argued that if the study methodology already includes details such as recruitment regions and population characteristics, additional descriptions of generalisability may not contribute significantly. Others maintained that the focus should remain on the study findings, avoiding expansion beyond the study data. To address these concerns, further discussions were conducted with vaccine experts. The revised consensus concluded that the generalisability section should focus on the main study findings while providing insights into the potential beneficiaries and applicable regions based on the study results. After incorporating this feedback, the revised item was unanimously approved during the second Delphi round.

Additionally, a new item, "Summary and Prospect Recommendation", was added to the checklist. This item summarises the study findings and emphasises their practical implications. This is important for promoting VALUE to further guide researchers and editors to standardise reporting methods and improve the quality of vaccine clinical research. "Summary and Prospect Recommendation" can highlight the real-world impact of vaccine research on clinical Settings and society, thereby improving its dissemination.

Comparison with CONSORT and STROBE

Compared to CONSORT[8,9] and STROBE[10] statements, some items in VALUE places greater emphasis on the specific characteristics of vaccines and the unique reporting requirements of vaccine research. For example, it underscores the importance of including information on the type of vaccine, the mode of administration, and the mechanism of action.[46] This ensures that readers gain a clear understanding of the vaccine and can quickly familiarise themselves with the study.

Another critical area of focus is the reporting of adverse events, which remain a significant international concern for vaccines. CONSORT[8,9] and STROBE[10] lack detailed requirements for adverse event reporting.[47] VALUE emphasises the importance of documenting potential vaccine-related adverse events, including their severity, and frequency. This component facilitates an objective evaluation of vaccine safety and enables timely responses to potential adverse events, thereby providing valuable insights for both researchers and healthcare providers.[48]

In addition to these two-core vaccine-specific reporting modules, VALUE adds meaningful incremental value to CONSORT[8,9] and STROBE.[10] VALUE establishes mandatory standardised reporting requirements for immunogenicity endpoints, vaccine efficacy calculation formulae, and stratified reactogenicity monitoring, which are absent in general clinical trial reporting guidelines. For studies focussing on post-vaccination efficacy trials and effectiveness studies, authors may additionally document other vaccine-specific dimensions: (1) duration of protective immunity (durability); (2) correlation between immunogenicity biomarkers and clinical protective outcomes; (3) match between vaccine strains and circulating epidemic strains in study settings; and (4) vaccine-specific subgroup and sensitivity analyses stratified by age, immunocompromised status, and disease exposure risk. These supplementary items are not listed as mandatory checklist entries because they lack relevance to many vaccine studies including early-phase first-in-human vaccine trials focused solely on safety and immune response assessment.

How to use VALUE

VALUE is a standalone guideline for vaccine research, not intended as a supplement to the CONSORT[8,9] and STROBE[10] statements, designed to assist vaccine

researchers, journal editors, and others in effectively reporting clinical vaccine research. Vaccine-related researchers and journal editors can use VALUE independently to write the reports when planning and reporting vaccine clinical studies.

Each item in VALUE is accompanied by an explanation and at least one example to help users understand the items. To enhance clarity, some examples have been slightly edited, such as the removal of citations or URLs. Additionally, we have emphasised key points specific to vaccines, such as the type of vaccine and methods of administration. The Checklist serves as a valuable reference for vaccine researchers, journal editors, and other stakeholders involved in the field.

We retained the citations or hyperlinks in the examples to enable users to access the original sources of evidence. The citations have been renumbered and are listed in the reference section of VALUE. These items and examples provide guidance on the minimum information that should be reported in vaccine clinical studies.

VALUE, developed based on both CONSORT[8,9] and STROBE[10] guidelines, provides guidance and reference for both vaccine clinical studies and vaccine-related observational research. Moreover, if new versions emerge in the future, there is typically a transitional period between the release and the widespread adoption of new guideline versions. During this interval, VALUE can continue to provide guidance for vaccine clinical research.

Limitations

This study has limitations. (i) There were no face-to-face consensus meetings and there may be potential domains and items that were not included that should be included. However, the two rounds of Delphi surveys ensured validation, with all participating experts agreeing on the importance of the included items. This may help compensate for the lack of face-to-face discussions. (ii) The scope of vaccines is broad, and our study did not encompass all studies related to vaccines. Rather, our study specifically focused on studies of the intrinsic characteristics of vaccines, particularly their immunogenicity, efficacy, effectiveness, safety, and reactogenicity. Examples of out-of-scope studies are studies assessing vaccine coverage; confidence; provider knowledge, attitudes, and practices or economics of vaccination. VALUE reporting guidelines are limited to studies in which vaccines or their characteristics are the object of research. (iii) We used a curtailed 5-point Likert scale, which in comparison to the 7-point or 9-point scales typically used by most guideline developers, may result in a slightly coarser measure. (iv) The Delphi expert panel consisted of academic, clinical, or policy professionals in vaccinology, with no patient or community representatives involved in the consensus process. This may lead to insufficient weighting of public-centric reporting priorities (e.g., plain-language adverse event descriptions for non-academic readers) in the VALUE checklist items.

Future promotion

We believe that VALUE can play an important role in standardising reporting methods and improving the quality of vaccine research reporting. To encourage widespread adoption, we plan to translate VALUE into multiple languages and promote it at major academic conferences and in key publications. Additionally, we will actively seek recognition of VALUE from journal editors to encourage its application in vaccine-related studies.

To maintain and enhance VALUE's relevance and credibility, we will monitor its adoption, collect feedback from researchers, and incorporate updates based on emerging research needs and advancements. This iterative process will ensure that VALUE remains a robust and widely accepted reporting guideline in the field of vaccine research.

It is important to recognise that CONSORT and STROBE represent evolving methodological guidelines. While the most recent version of CONSORT dates back to 2025 and STROBE to 2007, future updates may be introduced. In order to better align with the content of the new guidelines and meet the evolving needs of users, we will promptly update the content of VALUE. Users are also encouraged to refer to the most recent versions of the CONSORT and STROBE guidelines when utilising VALUE.

Conclusions

VALUE was developed utilising the methodologies recommended by the EQUATOR Network, including a systematic literature review and Delphi consensus. The resulting reporting guideline aims to address the deficiencies of CONSORT and STROBE in the field of vaccines by adding vaccine-specific characteristics and reporting requirements. We believe that VALUE will serve as a valuable reference for vaccine researchers, and intends to improve the transparency, quality, and consistency of vaccine research reporting.

Contributors

YD, YM, and LS contributed equally to this work as the first authors. ZB, YL and LY are joint corresponding authors. Guarantors of the study: ZB, YL and LY. Developed the search strategies and conducted the literature review; LS and ZX accessed and verified the underlying data; JL and SR. Writing advice and guidance: DM and LR. Manuscript editing: all authors. Approval of the final version of the submitted manuscript: all authors.

Data sharing statement

The datasets analysed during the current study are available from the corresponding author upon reasonable request. If necessary, you can contact us via email at shilin@gzhmu.edu.cn.

Declaration of interests
The authors declare that they have no competing interests.

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Appendix A. Supplementary data
Supplementary data related to this article can be found at https://doi.org/10.1016/j.ebiom.2026.106439.

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