

ORIGINAL ARTICLE

Reporting quality of participant eligibility criteria in retrospective studies: A cross-sectional investigation of medical journals with high impact factors

Fuxiang Liu¹, Tongyue Du², Xingxing Ruan^{1,*}¹Center for Journal Publishing of the Third Affiliated Hospital, Sun Yat-sen University, Guangzhou 510630, Guangdong Province, China²Department of Intensive Care Unit, Second Affiliated Hospital of Nanjing Medical University, Nanjing 210003, Jiangsu Province, China**ABSTRACT**

Background: The reporting quality of participant eligibility criteria in retrospective studies significantly affects research reproducibility and result interpretation. However, standardized guidelines for writing eligibility criteria in retrospective studies are lacking. We aim to systematically evaluate the quality of eligibility criteria reporting in retrospective studies published in high-impact factor medical journals, develop evidence-based recommendations for standardization, and provide supplementary guidance for relevant reporting guidelines. **Methods:** We conducted a cross-sectional analysis of retrospective studies published in the top 40 nonreview medical journals listed in the Journal Citation Reports (JCR) from January 2023 to September 2024. We extracted article characteristics (journal, author, objective, and study type) and eligibility criteria components. Two independent reviewers did the quality assessment of literature, which focused on clarity of retrospective nature (temporal framework), purposefulness (alignment with research objectives), and logical consistency between inclusion and exclusion criteria. **Results:** Among the top 40 nonreview medical journals in the 2023 JCR rankings, 11 journals contained 78 retrospective studies that were analyzed, of which 2.6% (2/78) demonstrated unclear retrospectivity and purposefulness in eligibility criteria. Logical contradiction between exclusion and inclusion criteria was found in 11.5% (9/78) of articles. Inter-rater reliability for quality assessment was substantial ($\kappa = 0.857$). **Conclusion:** The reporting quality of participant eligibility criteria in retrospective studies published in high-impact factor medical journals was flawed. On the basis of our systematic evaluation, we propose a structured framework for formulating eligibility criteria that emphasizes temporal precision, diagnostic clarity, and logical consistency between inclusion and exclusion criteria to supplement existing research reporting guidelines.

Key words: retrospective study, research design, patient selection, guidelines, eligibility criteria, quality control

INTRODUCTION

Retrospective studies are a cornerstone of medical research methodology, offering valuable insights through the systematic analysis of previously collected

data.^[1,2] These studies form a substantial proportion of published medical literature, particularly in specialized clinical fields where randomized controlled trials may be impractical or unethical.^[3,4] As reported by Ciulla and Vivona,^[5] retrospective designs constitute 58.6% of the

***Corresponding Author:**

Xingxing Ruan, Center for Journal Publishing of the Third Affiliated Hospital, Sun Yat-sen University, No. 621 Tianhe Road, Tianhe District, Guangzhou 510630, Guangdong Province, China. Email: rxingx@mail.sysu.edu.cn; <https://orcid.org/0009-0009-9574-0522>

Received: 17 September 2025; Revised: 12 October 2025; Accepted: 13 October 2025

<https://doi.org/10.54844/ep.2025.1068>

clinical research literature indexed in MEDLINE from 2013 to 2017. In research concerning specific conditions such as performance-based outcomes following intramedullary nailing of tibial shaft fractures, retrospective studies constitute 46.4% of the published literature.^[6] The quality of participant eligibility criteria in retrospective studies directly influences their internal validity, reliability, and generalizability, serving as a critical determinant of research quality.^[7]

Retrospective studies can be observational in nature or can manifest in other research types, such as predictive model development studies. Standardized research reporting serves as a crucial indicator for evaluating study quality,^[2] with the description of the participants constituting an indispensable component of research reports. The Strengthening the Reporting of Observational Studies in Epidemiology (STROBE) statement emphasizes that detailed descriptions of the study participants help readers understand the applicability of the results, and the studies should provide the eligibility criteria, and the sources and methods of selection of the participants. Eligibility criteria may be presented as inclusion and exclusion criteria, although this distinction is not always necessary or useful.^[8,9] Similarly, the Transparent Reporting of a Multivariable Prediction Model for Individual Prognosis or Diagnosis (TRIPOD) statement specifies that study reports should describe the participant eligibility criteria.^[10]

Despite their methodological importance, the reporting of eligibility criteria in retrospective studies frequently lacks standardization and clarity.^[11] In a survey of observational stroke research, 17 of 49 reports (35%) did not specify the eligibility criteria.^[12] This inconsistency potentially compromises research reproducibility, impedes accurate interpretation of results, and complicates evidence synthesis efforts. Comprehensive and transparent reporting of eligibility criteria enables readers to assess the applicability of the findings to specific populations and contexts, which is a fundamental aspect of evidence-based practice.^[13]

However, specific guidance tailored to the unique temporal characteristics and methodological nuances of retrospective studies remains insufficient. Previous research has identified various challenges in reporting the eligibility criteria of diagnostic accuracy studies, including incomplete content, inconsistent placement of criteria in the text, and an overlap between inclusion and exclusion criteria.^[14] These deficiencies also exist in retrospective observational studies, which can lead to difficulty in study replication, potential selection bias, and limited assessment of result generalizability.^[15,16] White *et al.*^[17] highlighted that retrospective studies utilizing routinely collected healthcare data present distinct reporting challenges that warrant specialized

guidance beyond existing reporting frameworks. Existing guidelines, such as the STROBE and TRIPOD statements, merely indicate that participant eligibility criteria should be provided in research reports, without offering clear instructions on how these criteria should be formulated,^[18,19] thus representing a significant limitation of current reporting standards. However, comprehensive assessments specifically targeting eligibility criteria reporting in retrospective studies remain scarce. Understanding the current landscape of reporting practices is essential for developing targeted interventions to enhance methodological rigor in this research domain.^[20]

This study aims to (1) systematically evaluate the quality of eligibility criteria reporting in retrospective studies published in high-impact factor medical journals, (2) develop evidence-based recommendations for standardizing eligibility criteria reporting in retrospective research, and (3) provide supplementary guidance for relevant reporting guidelines. By addressing these objectives, we seek to contribute to improved methodological transparency and research reproducibility in medical literature.

METHODS

Study design and sample size

On the basis of the 2023 Journal Citation Reports (JCR), we collected a total of 11 journals from the top 40 nonreview medical journals and then conducted a cross-sectional analysis of retrospective studies published in those journals. Previous survey results on observational studies showed that 35% of reports did not specify the participant eligibility criteria.^[12] On the basis of this information, we calculated the sample size. We used the formula for prevalence studies with a precision of 11% (we selected a precision of 11% based on preliminary literature search results and resource considerations. Given that our study was limited to retrospective studies published in high-impact factor journals [IF > 20], the total number of eligible articles was restricted. Adopting a precision of 11% allowed us to achieve a statistically meaningful sample size in this specific journal subset while meeting project timeline requirements), expected proportion of adequate reporting of 65%, and confidence level of 95%, yielding a minimum required sample of 73 articles. The final sample of 78 articles met this minimum requirement.

Inclusion criteria

Retrospective research articles meet all of the following criteria: (1) publication in the following journals: *The Lancet* specialty journals (*Neurology*, *Diabetes & Endocrinology*, *Oncology*, *Infectious Disease*, *Gastroenterology & Hepatology*, *Psychiatry*, and *Digital Health*), *Journal of Clinical Oncology*, *Intensive Care Medicine*, *Journal of Hepatology*, and

Gut; (2) publication period: 2023-2024; and (3) explicit mention of "retrospective" in the title.

Exclusion criteria

We excluded five types of publications: conference abstracts, letters, editorials, corrections, and commentaries. We also excluded bidirectional studies (both retrospective and prospective) and literature that merely described retrospective study results without participant enrollment details.

Search strategy

Our literature search utilized the Web of Science Core Collection database (Science Citation Index Expanded, 1999-present). The specific steps are as follows: (1) on the Web of Science literature search page, select "Web of Science Core Collection" in the "Search in" field, and choose "Science Citation Index Expanded (SCI-Expanded), 1999-present" in the Editions section; (2) select "Advanced search", choose "Publication Titles" for the search term, enter the journal name, and add it to the query preview. Then, select "Title", enter "retrospective", choose "And", and add it to the query preview. Finally, generate the search query "(SO = [journal name]) AND TI = (retrospective)", click "Search", and retrieve 6991 articles; and (3) select 2024 and 2023 under "Publication Years"; we obtained 930 articles. Then, under "Document Types", select "Article" (thus excluding document types such as meeting abstracts, letters, editorial materials, corrections, and reviews), resulting in 83 articles. After retrieving search results, we conducted a comprehensive full-text review of each article, excluding those involving retrospective and prospective two-way studies and articles that merely describe the results of retrospective studies (only summarizing the results of previous studies without mentioning subject enrollment), ultimately yielding 78 articles. This is shown in Figure 1.

Data extraction and quality assessment

We extracted article characteristics (journal, author, objective, and study type) and eligibility criteria components. Two independent reviewers did the quality assessment of the eligibility criteria of the study participants. Quality assessment focused on clarity of retrospective nature (temporal framework), purposefulness (alignment with research objectives), and logical consistency between inclusion and exclusion criteria. Clear retrospectivity was defined as the absence of prospective elements in the eligibility criteria, properly reflecting the characteristics of the retrospective research design. Clear purposiveness was defined as eligibility criteria that aligned with the research objectives and were capable of addressing the research questions. Regarding the relationship between the inclusion and exclusion criteria, we examined whether the exclusion criteria appropriately supplemented the inclusion criteria or whether they were contradictory—a logical fallacy

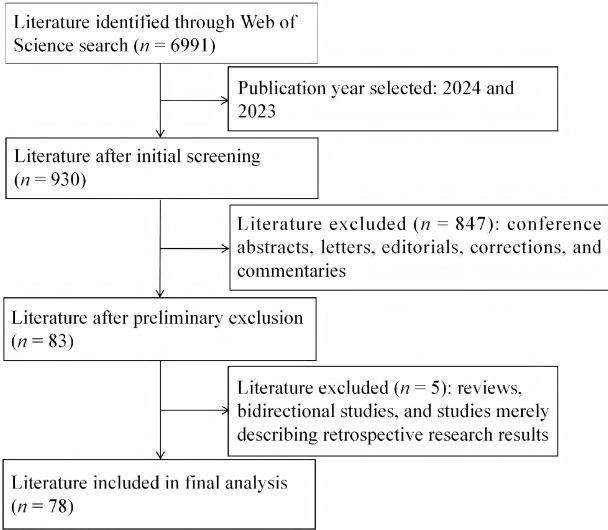


Figure 1. Flowchart of literature selection for retrospective studies.

where studies excluded participants who did not meet the inclusion criteria. This is shown in Table 1.

Both reviewers hold master’s degrees in clinical medicine and have solid backgrounds in clinical research. If a disagreement between their assessments occurs, a third reviewer will make the final evaluation.

Statistical analysis

We calculated the frequencies and proportions for the categorical variables. Inter-rater reliability was assessed using Cohen’s kappa coefficient. Subgroup analyses were performed using chi-square test or Fisher’s exact test to compare the quality differences in participant eligibility criteria across different research types. SPSS 16.0 was used for analysis, with $P < 0.05$ considered statistically significant.

RESULTS

Journal and literature characteristics

The impact factors of the 11 journals in 2023 ranged from 23.0 to 46.5. Among the 11 journals, 7 (63.6%) were The Lancet specialty journals. Of all of the 78 retrospective studies, sources from *The Lancet Digital Health* were the most common (35.9%), followed by *The Lancet Oncology* (25.6%). Eight journals had fewer than five articles. This is shown in Table 2. Among 78 retrospective studies, 51 were observational studies and 27 were artificial intelligence (AI) model development studies.

Quality of participant eligibility criteria in retrospective studies

Among the 78 retrospective studies, all of them

Table 1: Quality assessment checklist for participant eligibility criteria in retrospective studies

Item	Yes	No	Specific details
Were eligibility criteria for study participants provided?			
If provided, did the criteria clearly specify which patients were ultimately included?			
If provided, was the enrollment timeline clearly delineated? That is, did the criteria maintain retrospective consistency (e.g., cases where patients had already completed surgical treatment yet inclusion criteria referenced the need to satisfy surgical indications)?			
If provided, did the study population align appropriately with the research objectives (purposefulness)?			
If provided, were there contradictions between exclusion and inclusion criteria? That is, did the exclusion criteria identify populations that were not already included?			

Table 2: Characteristics of participant eligibility criteria in retrospective studies

Journal	2023 impact factor	Number of retrospective studies (n)	Eligibility criteria were provided (n)	Unclear retrospectivity and purposiveness (n)	Contradictory exclusion and inclusion criteria (n)
<i>The Lancet Neurology</i>	46.5	3	3	0	0
<i>The Lancet Diabetes & Endocrinology</i>	44.0	3	3	0	0
<i>Journal of Clinical Oncology</i>	42.1	2	2	0	1
<i>The Lancet Oncology</i>	41.6	20	20	0	4
<i>The Lancet Infectious Disease</i>	36.4	12	12	0	1
<i>The Lancet Gastroenterology & Hepatology</i>	30.9	1	1	1	0
<i>The Lancet Psychiatry</i>	30.8	2	2	0	0
<i>Intensive Care Medicine</i>	27.1	3	3	1	1
<i>Journal of Hepatology</i>	26.8	1	1	0	0
<i>The Lancet Digital Health</i>	23.8	28	28	0	2
<i>Gut</i>	23.0	3	3	0	0

provided the eligibility criteria of the participants and 67 (85.9%) had no obvious problems and clearly expressed the eligibility criteria. Two main types of deficiencies were identified: unclear retrospectivity and purposiveness (2.6%), and logical contradictions between the inclusion and exclusion criteria (11.5%). This is shown in Table 2.

Two studies with unclear retrospectivity and purposiveness existed (Table 3). More prevalent were studies with logical contradiction between the inclusion and exclusion criteria, where the exclusion criteria specified groups that had not been included, with nine articles having this issue (Table 4).

Inter-rater reliability was assessed using Cohen’s kappa coefficient based on the independent evaluation of all 78 articles conducted by two reviewers. The analysis showed excellent agreement between reviewers ($\kappa = 0.857$), with disagreement on only 3 out of 78 articles. All disagreements were resolved through consultation with the third reviewer to obtain the final result.

DISCUSSION

Our systematic evaluation of eligibility criteria reporting in retrospective studies revealed that quality issues exist even in high-impact factor medical journals. Although the majority (85.9%) of the articles demonstrated acceptable reporting quality, we identified specific deficiencies that affect reproducibility and result interpretation. The most prevalent issues included logical contradictory inclusion and exclusion criteria (11.5%) and unclear retrospectivity and purposiveness (2.6%). These findings align with previous research highlighting challenges in standardization of methodological reporting in medical literature.^[7] Unclear retrospectivity in eligibility criteria can lead to temporal ambiguity, potentially compromising internal validity.^[32] Similarly, logical inconsistencies between inclusion and exclusion criteria create confusion regarding the actual study population, limiting the assessment of external validity and generalizability.^[33,34] Participants being excluded must be from the included population (Figure 2). Our findings provide quantitative evidence supporting the need for enhanced guidance in reporting eligibility criteria in retrospective studies.

Table 3: Retrospective studies with unclear retrospectivity and purposiveness in participant eligibility criteria

Study	Type of study	Objective	Inclusion criteria of participants	Exclusion criteria of participants	Unclear retrospectivity and purposiveness in detail
Eikenboom et al. ^[21]	Observational study	To assess the risk of metachronous colorectal cancer after partial colectomy and extensive colectomy in carriers of Lynch syndrome with different pathogenic variants	People who were confirmed carriers of Lynch syndrome and who had colorectal cancer	Individuals for whom the type of surgery or mismatch repair gene was not specified in the database	Study participants were required to not only have a confirmed diagnosis of Lynch syndrome, colorectal cancer, but also a history of either partial colonic resection or extensive colectomy
Levy et al. ^[22]	Observational study	To investigate whether systemic thrombolysis prior to VA-ECMO treatment in PE patients results in higher bleeding risk and alters patient prognosis	Patients referred from June 2012 to June 2023 with suspected or confirmed high-risk PE, requiring VA-ECMO support	Patients who received ECMO after surgical embolectomy or catheter-directed thromboaspiration	The study population comprised patients with active VA-ECMO support, rather than those merely requiring or eligible for VA-ECMO intervention

VA-ECMO, veno-arterial extracorporeal membrane oxygenation; PE, pulmonary embolism.

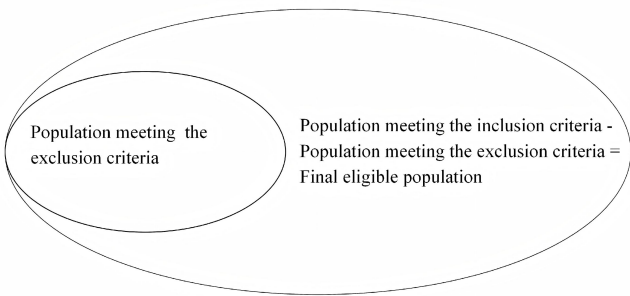


Figure 2. Principles for establishing participant eligibility criteria (first include and then exclude from those already included).

On the basis of our findings and experience, we propose a four-step process for developing participant eligibility criteria in retrospective studies. First, researchers should explicitly acknowledge the retrospective nature of the study, recognizing that it utilizes existing data for analysis. When investigating treatment effects, inclusion criteria should focus on patients who have already received the treatment rather than discuss treatment indications and contraindications. Second, preliminary inclusion criteria should be established based on research objectives. For example, in a study examining the predictive value of cervical cytology and high-risk human papillomavirus (HPV) testing for recurrent cervical intraepithelial neoplasia grade 2 or higher (including recurrent cervical cancer) after fertility-preserving surgery, the basic population would include patients with early cervical cancer (International Federation of Gynecology and Obstetrics [FIGO] 2009, stage IA1 to IB1) who have undergone fertility-preserving procedures. Initial inclusion criteria might be the following: (1) confirmed diagnosis of early cervical cancer (FIGO 2009, stage IA1 to IB1) and (2) previous fertility-preserving surgery (large loop excision of the transformation zone, conization, and vaginal or radical trachelectomy). Third, inclusion criteria should be optimized by considering potential confounding factors

such as age range and treatment timeframe. For instance, the criteria might be refined to the following: (1) age 18-40 years; (2) confirmed diagnosis of early cervical cancer (FIGO 2009, stage IA1 to IB1); and (3) fertility-preserving surgery performed between January 1, 2000, and December 31, 2020. Following these steps, appropriate exclusion criteria should be developed to eliminate individuals with characteristics that could potentially influence the study results (the fourth step), such as patients who underwent hysterectomy, radiotherapy, or chemoradiotherapy within three months after fertility-preserving surgery and those with incomplete follow-up information. This structured approach to developing eligibility criteria promotes clarity in retrospective study design and helps in avoiding the common pitfalls identified in our analysis. The three-step process is shown in Figure 3.

Several limitations should be considered when interpreting our findings. First, our sample was limited to high-impact factor journals, which may not represent reporting practices across the broader medical literature. Second, although our evaluation focused on specific quality indicators, other aspects of eligibility criteria reporting may warrant examination. Third, our cross-sectional design provides a snapshot of current practices but cannot capture temporal trends in reporting quality. The substantial inter-rater agreement ($\kappa = 0.857$) strengthens our findings' reliability but cannot eliminate potential subjectivity in quality assessment. The high inter-rater reliability can be attributed to the following: (1) the use of clearly defined binary evaluation criteria, (2) thorough pre-evaluation training and discussion of assessment standards between reviewers, and (3) the relatively straightforward nature of the evaluation items. In addition, our analysis did not explore factors influencing reporting quality, such as author expertise, journal-specific guidelines, and peer review processes.^[35–37]

Future research should explore the implementation of

Table 4: Summary of studies with contradictory exclusion and inclusion criteria for participants

Study	Type of study	Objective	Inclusion criteria of participants	Exclusion criteria of participants	Contradictory situation between exclusion and inclusion criteria
Kittai <i>et al.</i> ^[23]	Observational study	To explore the efficacy and safety of anti-CD19 CAR-T for RT patients	RT patients (RT was defined as patients with LBCL with preceding or concurrently diagnosed CLL)	Patients with Hodgkin's lymphoma or other subtypes of RT	Among the population meeting the inclusion criteria, Hodgkin lymphoma patients did not exist, making it impossible to exclude this group
Arthur <i>et al.</i> ^[24]	AI model development study	To develop and independently validate a CT-based radiomics classification model for the prediction of histological type and grade in retroperitoneal leiomyosarcoma and liposarcoma	(1) Histologically confirmed retroperitoneal liposarcoma or leiomyosarcoma, (2) baseline venous phase contrast-enhanced CT, and (3) minimum clinical dataset required for radiomic model development available	(1) Other histological types, (2) baseline or venous phase contrast-enhanced CT scans unavailable, and (3) missing clinical data	Among the population meeting the inclusion criteria, patients meeting the exclusion criteria did not exist, making it impossible to exclude this group
Wang <i>et al.</i> ^[25]	Observational study	To explore the impact of molecular features associated with TMB-H on the tumor immune microenvironment and the survival benefit of immune checkpoint inhibitor treatment in MSS gastrointestinal tumors	(1) Samples with pathologically confirmed gastrointestinal cancer and (2) samples with known TMB and microsatellite stability status	(1) International cases and tumors of nongastrointestinal cancer types and (2) cases that were tested for TMB and microsatellite stability status but yielded no informative results	Among the population meeting the inclusion criteria, patients meeting the exclusion criteria did not exist, making it impossible to exclude this group
Zeng <i>et al.</i> ^[26]	AI model development study	To develop an AI model able to estimate ABRs expression directly from histological slides and to evaluate if model predictions were associated with progression-free survival	(1) Unequivocal diagnosis of hepatocellular carcinoma by two liver pathologists, (2) available digital histological slides (haematein-eosin stained) from FFPE materials, and (3) available gene expression profiling (RNA sequencing)	(1) Existence of equivocal histological features (morphological areas suggestive of a diagnosis of combined hepatocellular cholangiocarcinoma), (2) absence of whole-slide images from FFPE material and (3) absence of RNA sequencing data	Among the population meeting the inclusion criteria, patients meeting the exclusion criteria did not exist, making it impossible to exclude this group
Karpinski <i>et al.</i> ^[27]	Observational study	To compare the prognostic value of PSMA-PET by PROMISE (PPP) stage with established clinical nomograms in a large prostate cancer dataset with follow-up data for overall survival	Male patients with histologically proven prostate cancer at any disease stage	Missing pathology report for prostate cancer	Patients with histologically proven prostate cancer did not include those whose pathology reports are missing, making it impossible to exclude this group
Wong <i>et al.</i> ^[28]	Observational study	To identify the incidence of viral burden rebound and associated risk factors and clinical outcomes	In hospitalized adult patients (age ≥ 18 years) with non-oxygen-dependent COVID-19 in public hospitals in Hong Kong	Those aged younger than 18 years	Among the population meeting the inclusion criteria, those aged younger than 18 years did not exist, making it impossible to exclude this group
Ehmann <i>et al.</i> ^[29]	Observational study	To determine the association between intravenous CM administration and persistent AKI in patients with pre-existing AKI	Patients (≥ 18 years old) who met KDIGO sCr-based criteria for AKI stage 1 or greater (an absolute increase in sCr of at least 3 mg/L or relative increase of at least 1.5 times over baseline sCr) at the time of ED arrival	Patients who did not meet criteria for AKI on ED arrival	Among the population meeting the inclusion criteria, patients who did not meet criteria for AKI on ED arrival did not exist, making it impossible to exclude this group
Saux <i>et al.</i> ^[30]	AI model development study	To develop a model using machine learning to provide individual preoperative prediction of 5-year weight loss trajectories after surgery	Patients submitted for the first time to RYGB, sleeve gastrectomy, and AGB	Patients with a previous history of bariatric surgery	Among the population meeting the inclusion criteria, patients with a previous history of bariatric surgery did not exist, making it impossible to exclude this group
Häggström <i>et al.</i> ^[31]	AI model development study	To train a deep learning artificial intelligence algorithm to classify [18 F] FDG-PET-CT scans of patients with lymphoma with or without hypermetabolic tumor sites	(1) Patients with biopsy-proven [18 F] FDG-avid lymphomas according to the Lugano guideline and (2) who had undergone whole-body [18 F] FDG-PET-CT for routine purposes (staging and treatment response assessment)	(1) Other cancers in addition to lymphoma and (2) non-[18 F] FDG-avid or variably [18 F] FDG-avid lymphomas for which [18 F] FDG-PET-CT is not recommended	Among the population meeting the inclusion criteria, patients meeting the exclusion criteria did not exist, making it impossible to exclude this group

The correct approach is to exclude from the included population; this table only lists the contradictory inclusion and exclusion criteria, not all content mentioned in each article. CAR-T, chimeric antigen receptor T-cell therapy; RT, Richter transformation; LBCL, large B-cell lymphoma; CLL, chronic lymphocytic leukemia; AI, artificial intelligence; TMB-H, high tumour mutational burden; MSS, microsatellite stable; ABRs, atezolizumab-bevacizumab response signature; FFPE, formalin-fixed paraffin-embedded; KDIGO, Kidney Disease Improving Global Outcomes; sCr, serum creatinine; AKI, acute kidney injury; ED, emergency department; RYGB, Roux-en-Y gastric bypass; AGB, adjusted gastric banding; FDG, fluorodeoxyglucose; PET, positron emission tomography; CT, computed tomography.

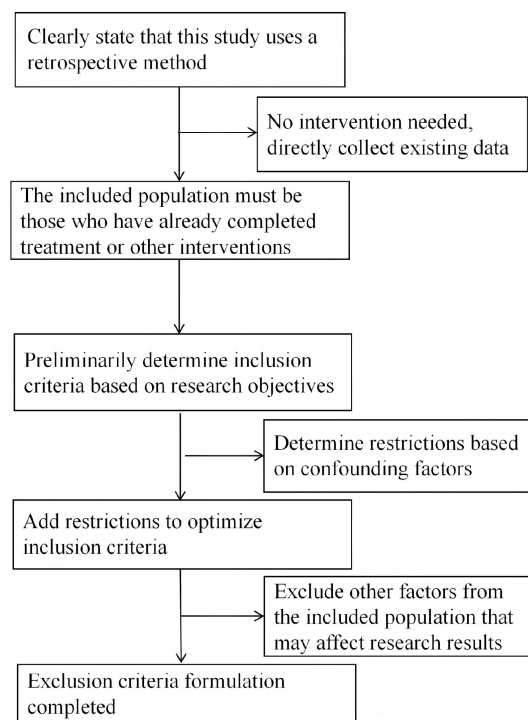


Figure 3. Approach for establishing participant eligibility criteria in retrospective studies.

structured frameworks for eligibility criteria reporting in retrospective studies. The development of specialized checklists or extensions to existing reporting guidelines would provide concrete guidance to researchers, journal editors, and peer reviewers. Such tools should emphasize temporal precision, diagnostic clarity, and logical consistency between inclusion and exclusion criteria. Similar to advancements in systematic review methodology, automated tools for checking logical consistency in eligibility criteria could enhance reporting quality during manuscript preparation. Incorporating natural language processing techniques could help in identifying common reporting deficiencies before publication, thereby improving the overall research transparency.^[38] Longitudinal evaluation of reporting quality following guideline implementation would provide valuable insights into the effectiveness of the standardization efforts and identify areas requiring further attention.

CONCLUSION

The lack of standardized guidance for writing eligibility criteria in retrospective studies represents a notable gap in current research reporting frameworks. While existing guidelines such as STROBE and TRIPOD emphasize the importance of reporting eligibility criteria, they provide limited practical instruction on how these criteria should be formulated, particularly considering

the unique temporal characteristics inherent to retrospective studies.

Our proposed structured framework addresses these limitations by emphasizing three core principles: temporal precision that clearly delineates the retrospective nature of participant selection, diagnostic clarity that ensures alignment with research objectives, and logical consistency that eliminates contradictions between inclusion and exclusion criteria. Implementation of these recommendations can enhance methodological transparency, facilitate study replication, and improve the quality of retrospective study reporting. These recommendations serve as a practical supplement to existing reporting guidelines and provide researchers, reviewers, and editors with concrete strategies to strengthen the methodological rigor of retrospective studies.

DECLARATIONS

Acknowledgement
None.

Author contributions
Liu F: Conceptualization, Formal analysis, Methodology, Writing—Original draft, Writing—Review and Editing. Du T: Formal analysis, Writing—Review and Editing. Ruan X: Conceptualization, Methodology, Writing—Review and Editing. All authors have read and approved the final version.

Source of funding
This work was supported by the Academic Journals Working Committee for Universities and Colleges of Guangdong Higher Education Association (Project No. 20240404), with the grant recipient being Liu FX. The funders had no role in study design, data collection and analysis, decision to publish, or preparation of the manuscript.

Ethical approval
Not applicable.

Informed consent
Not applicable.

Conflict of interest
The authors have no conflicts of interest to declare.

Use of large language models, AI, and machine learning tools
During the preparation of this work the authors used Claude Sonnet 3.5 in order to translate the initial Chinese draft of this article into English. After using this tool, the authors reviewed and edited the content as

needed and take full responsibility for the content of the published article.

Data availability statement

The data used to support the findings of this study are available from the corresponding author.

REFERENCES

- Hess DR. Retrospective studies and chart reviews. *Respir Care*. 2004;49(10):1171-1174.
- Glasziou P, Vandenbroucke JP, Chalmers I. Assessing the quality of research. *BMJ*. 2004;328(7430):39-41.
- Mathes T, Pieper D. Study design classification of registry-based studies in systematic reviews. *J Clin Epidemiol*. 2018;93:84-87.
- Baumgartner PC, Haynes RB, Hersberger KE, Arnet I. A systematic review of medication adherence thresholds dependent of clinical outcomes. *Front Pharmacol*. 2018;9:1290.
- Ciulla MM, Vivona P. Time arrow in published clinical studies/trials indexed in MEDLINE: a systematic analysis of retrospective *vs* prospective study design, from 1960 to 2017. *PeerJ*. 2019;7:e6363.
- Thwaites S, Abrahams J, Thewlis D, Rickman M. The absence of reporting standards and a lack of objective, performance-based outcomes following intramedullary nailing of tibial shaft fractures: findings from a scoping review into 179 articles. *Eur J Trauma Emerg Surg*. 2024;50(1):59-70.
- Wang SV, Pinheiro S, Hua W, et al. STaRT-RWE: structured template for planning and reporting on the implementation of real world evidence studies. *BMJ*. 2021;372:m4856.
- von Elm E, Altman DG, Egger M, Pocock SJ, Gøtzsche PC, Vandenbroucke JP. STROBE Initiative. The Strengthening the Reporting of Observational Studies in Epidemiology (STROBE) statement: guidelines for reporting observational studies. *Int J Surg*. 2014;12(12):1495-1499.
- Vandenbroucke JP, von Elm E, Altman DG, et al. STROBE Initiative. Strengthening the Reporting of Observational Studies in Epidemiology (STROBE): explanation and elaboration. *Int J Surg*. 2014;12(12):1500-1524.
- Collins GS, Reitsma JB, Altman DG, Moons KG. Transparent reporting of a multivariable prediction model for individual prognosis or diagnosis (TRIPOD): the TRIPOD statement. *BMJ*. 2015;350:g7594.
- Khozin S, Blumenthal GM, Pazdur R. Real-world data for clinical evidence generation in oncology. *J Natl Cancer Inst*. 2017;109(11):10.
- Tooth L, Ware R, Bain C, Purdie DM, Dobson A. Quality of reporting of observational longitudinal research. *Am J Epidemiol*. 2005;161(3):280-288.
- Negrini S, Armijo-Olivo S, Patrini M, et al. The randomized controlled trials rehabilitation checklist: methodology of development of a reporting guideline specific to rehabilitation. *Am J Phys Med Rehabil*. 2020;99(3):210-215.
- Tan DT, Liang H, Yu YB, et al. Quality evaluation of reports on inclusion and exclusion criteria in diagnostic tests. *Hunan Univ J Chin Med*. 2022;42(11):1916-1921.
- Lobos E, Catanzariti A, McMillen R. Critical analysis of retrospective study designs: cohort and case series. *Clin Podiatr Med Surg*. 2024;41(2):273-280.
- Ruan XX, Huang ZY, Liu FX, et al. Clinical research paper writing based on the perspective of doctors in diagnosing and treating patients. *Chin J Endourol (Electronic Edition)*. 2024;18(4):397-401.
- White RG, Hakim AJ, Salganik MJ, et al. Strengthening the Reporting of Observational Studies in Epidemiology for respondent-driven sampling studies: "STROBE-RDS" statement. *J Clin Epidemiol*. 2015;68(12):1463-1471.
- Sounderajah V, Ashrafi H, Aggarwal R, et al. Developing specific reporting guidelines for diagnostic accuracy studies assessing AI interventions: The STARD-AI Steering Group. *Nat Med*. 2020;26(6):807-808.
- Blanco D, Altman D, Moher D, Boutron I, Kirkham JJ, Cobo E. Scoping review on interventions to improve adherence to reporting guidelines in health research. *BMJ Open*. 2019;9(5):e026589.
- Aggarwal R, Ranganathan P. Study designs: part 2—descriptive studies. *Perspect Clin Res*. 2019;10(1):34-36.
- Eikenboom EL, Moen S, van Leerdam ME, et al. Metachronous colorectal cancer risk according to Lynch syndrome pathogenic variant after extensive versus partial colectomy in the Netherlands: a retrospective cohort study. *Lancet Gastroenterol Hepatol*. 2023;8(12):1106-1117.
- Levy D, Saura O, Passarelli MT, et al. Thrombolysis before venoarterial ECMO for high-risk pulmonary embolism: a retrospective cohort study. *Intensive Care Med*. 2024;50(8):1287-1297.
- Kittai AS, Bond D, Huang Y, et al. Anti-CD19 chimeric antigen receptor T-cell therapy for Richter transformation: an international, multicenter, retrospective study. *J Clin Oncol*. 2024;42(17):2071-2079.
- Arthur A, Orton MR, Emsley R, et al. A CT-based radiomics classification model for the prediction of histological type and tumour grade in retroperitoneal sarcoma (RADSARC-R): a retrospective multicohort analysis. *Lancet Oncol*. 2023;24(11):1277-1286.
- Wang J, Xiu J, Farrell A, et al. Mutational analysis of microsatellite-stable gastrointestinal cancer with high tumour mutational burden: a retrospective cohort study. *Lancet Oncol*. 2023;24(2):151-161.
- Zeng Q, Klein C, Caruso S, et al. Artificial intelligence-based pathology as a biomarker of sensitivity to atezolizumab-bevacizumab in patients with hepatocellular carcinoma: a multicentre retrospective study. *Lancet Oncol*. 2023;24(12):1411-1422.
- Karpinski MJ, Hüsing J, Claassen K, et al. Combining PSMA-PET and PROMISE to re-define disease stage and risk in patients with prostate cancer: a multicentre retrospective study. *Lancet Oncol*. 2024;25(9):1188-1201.
- Wong CKH, Lau KTK, Au ICH, et al. Viral burden rebound in hospitalised patients with COVID-19 receiving oral antivirals in Hong Kong: a population-wide retrospective cohort study. *Lancet Infect Dis*. 2023;23(6):683-695.
- Ehmann MR, Mitchell J, Levin S, et al. Renal outcomes following intravenous contrast administration in patients with acute kidney injury: a multi-site retrospective propensity-adjusted analysis. *Intensive Care Med*. 2023;49(2):205-215.
- Saux P, Bauvin P, Raverdy V, et al. Development and validation of an interpretable machine learning-based calculator for predicting 5-year weight trajectories after bariatric surgery: a multinational retrospective cohort SOPHIA study. *Lancet Digit Health*. 2023;5(10):e692-e702.
- Häggström I, Leithner D, Alvé J, et al. Deep learning for [¹⁸F] fluorodeoxyglucose-PET-CT classification in patients with lymphoma: a dual-centre retrospective analysis. *Lancet Digit Health*. 2024;6(2):e114-e125.
- Cragg WJ, McMahon K, Oughton JB, Sigsworth R, Taylor C, Napp V. Clinical trial recruiters' experiences working with trial eligibility criteria: results of an exploratory, cross-sectional, online survey in the UK. *Trials*. 2021;22(1):736.
- Porzsolt F, Wiedemann F, Becker SI, Rhoads CJ. Inclusion and exclusion criteria and the problem of describing homogeneity of study populations in clinical trials. *BMJ Evid Based Med*. 2019;24(3):92-94.
- Patino CM, Ferreira JC. Inclusion and exclusion criteria in research studies: definitions and why they matter. *J Bras Pneumol*. 2018;44(2):84.
- Cobo E, Cortés J, Ribera JM, et al. Effect of using reporting guidelines during peer review on quality of final manuscripts submitted to a biomedical journal: masked randomised trial. *BMJ*. 2011;342:d6783.
- Gonzalez P, Wilson GS, Purvis AJ. Peer review in academic publishing: Challenges in achieving the gold standard. *J Uni Teach Learn Pract*. 2022;19(5):1.

37. Bruce R, Chauvin A, Trinquart L, Ravaud P, Boutron I. Impact of interventions to improve the quality of peer review of biomedical journals: a systematic review and meta-analysis. *BMC Med.* 2016;14(1):85.
38. Paliya N, Jha SS. Quality indicators for academic journals: What makes a journal trust worthy? *IP Indian J Anat Surg Head, Neck Brain.* 2024;10(4):83-91.