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PREVALENCE OF INFECTIOUS MARKERS AMONG BLOOD DONORS IN PERUVIAN AMAZON – LORETO [A SYSTEMATIC REVIEW AND META-ANALYSIS PROTOCOL]

[*1]Dr. Jorge Alberto Ríos Pezo, [2]Dr. Julio César Ramírez Vargas, [3]Dr. S Sandhya, [4]Dr. Jyotirmaya Satpathy, [5]Isaidys Adriana Abanto

[1]Faculty of Medicine, Universidad Nacional de la Amazonía Peruana, Loreto, Perú.

[2]Instituto Científico Neurointegral (ICN), Bogotá, D. C., Colombia

[3]Instituto Científico Neurointegral (ICN), Bogotá, D. C., Colombia & NSOM Bengaluru India

[4]Instituto Científico Neurointegral (ICN), Bogotá, D. C., Colombia.

[5]Instituto Científico Neurointegral (ICN), Bogotá, D. C., Colombia

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***Corresponding Author: Dr. Jorge Alberto Ríos Pezo**

Faculty of Medicine, Universidad Nacional de la Amazonía Peruana, Loreto, Perú.

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ABSTRACT

Transfusion safety in Amazonian regions faces specific challenges due to endemic infections, population mobility, and variability in diagnostic platforms. In Loreto (Peruvian Amazon), evidence on infectious markers among blood donors remains fragmented, limiting policy decisions, testing prioritization, and resource allocation. Objective is to estimate, through a systematic review and meta-analysis of proportions, the pooled prevalence of infectious markers among blood donors in Loreto (Peru) and to explore heterogeneity by setting, time period, test type, and donor characteristics. This protocol follows PRISMA-P and will report the search according to PRISMA-S. We will include observational studies and institutional reports with primary-donor data from Loreto reporting numerators/denominators per marker (screening reactivity and/or confirmatory positivity, extracted separately). Minimum sources include PubMed/MEDLINE, LILACS (BVS), and SciELO, complemented by Google Scholar and grey literature (institutional repositories, theses, and handsearching). Risk of bias will be assessed using the JBI checklist for prevalence studies. Synthesis will use a random-effects binomial generalized linear mixed model (GLMM; primary model) to pool proportions with 95% confidence intervals; heterogeneity will be quantified with τ^2 and I^2 and

prediction intervals reported when feasible. Sub-group and sensitivity analyses (including exclusion of high risk of bias) are planned. Certainty of evidence will be assessed with a GRADE-informed approach adapted to prevalence.

KEYWORDS: Transfusion Safety, Blood Donors, Chagas Disease, HTLV, Infectious Markers and PRISMA-P.

INTRODUCTION

Blood transfusion plays a crucial role in medical treatment and urgent care situations. The safety of blood transfusions depends on choosing suitable donors, performing laboratory tests, and consistently enhancing the quality of blood services. The discussion examines the vital importance of blood transfusions in medical treatment and emergency situations. It highlights that the safety of blood transfusions relies on a strong system for choosing donors, comprehensive laboratory testing, and continuous enhancement of blood service quality. In the Amazon region, local infections, unequal access to diagnosis, and shifting testing methods can make it difficult to accurately assess risks and make plans. Several difficulties hinder the dependability of blood transfusion safety. These encompass localized infections specific to the area, varying availability of diagnostic tools, and advancements in testing methods, which combined create challenges in forecasting and managing the risks tied to blood transfusions. In summary, the arguments emphasize the necessity for customized approaches to guarantee effective blood transfusion practices in demanding and changing healthcare settings, such as those found in the Amazon. The discussion begins by highlighting the importance of blood transfusions in medical and emergency situations, emphasizing their vital role in preserving lives and delivering essential healthcare. The conversation shifts to the various aspects that guarantee transfusion safety, particularly the methods of choosing donors and conducting laboratory tests. These factors are essential for reducing the risks linked to blood transfusions. The discussion then explores the particular challenges encountered in the Amazon region. It recognizes common infections found in this region, differences in the availability of diagnostic tools, and how advancements in testing technologies affect accurate risk evaluation. The conclusion of the argument emphasizes the need for ongoing enhancement of quality in blood services, supporting approaches that address the specific difficulties faced in healthcare environments in the Amazon region.

In Loreto, multiple institutional reports and individual studies describe infectious markers among donors, but no systematic quantitative synthesis has consolidated these data to (i) compare markers across time and settings; (ii) understand heterogeneity due to test type (screening vs confirmatory); and (iii) produce pooled-prevalence estimates to inform policy and resource prioritization. Loreto is a strategically relevant setting because it concentrates a large proportion of the Peruvian Amazon population, operates as a cross-border corridor, and faces persistent-endemic disease pressures; therefore, it can function as a sentinel case for transfusion safety decision-making in similar-Amazonian contexts.

In summary, the argument(s) emphasizes the necessity of ensuring blood transfusion safety through focused donor selection, effective laboratory screening, and ongoing quality enhancements. It highlights the cultural and contextual factors unique to the Amazon that pose significant challenges. Addressing these hurdles requires a concerted effort in policy-making, healthcare delivery, and community engagement, ultimately ensuring that public health goals surrounding blood transfusions can be met effectively in this nuanced environment. The urgency for improved strategies in blood service delivery remains salient, presenting healthcare systems with the imperative to innovate and respond to the region's complexities.

Objectives

Primary Objective:

To estimate pooled prevalence of infectious markers among blood donors in Loreto, Peru.

Secondary Objectives:

1. Explore heterogeneity by test type (screening *versus* confirmatory; platform when reported), data-collection period, donor type (voluntary *versus* replacement), and institution/area when reported,
2. Describe donor notification and follow-up processes when reported; and
3. Assess risk of bias and overall certainty of evidence by marker.

Methods

Design

This protocol follows PRISMA-P for protocols and will report the final review according to PRISMA 2020. Search reporting follows PRISMA-S. PRISMA-P for Protocols serves as a framework designed to improve the transparency and consistency of systematic review

protocols. The purpose of PRISMA-P is to guide in creating comprehensive and transparent protocols that facilitate replication of systematic reviews and meta-analyses. It emphasizes significance of systematic reviews in evidence-based practices, specifically in health research, and how PRISMA-P can enhance reporting standards. Furthermore, it outlines the steps for implementing the PRISMA-P guidelines, advocating for its adoption by research communities to mitigate issues such as bias and incomplete reporting in health research. The article concludes by summarizing the importance of protocol registration and the implications for future research practices. Overall, PRISMA-P serves as a critical tool for researchers engaged in systematic reviews and meta-analyses, aiming to bolster the quality and transparency of protocols. The article successfully elucidates how adherence to PRISMA-P guidelines can bridge existing gaps in research quality, and underscores the importance of such standards in health research. By encouraging the usage of these guidelines, the research community can significantly improve the reliability of health-related findings, thus facilitating informed decision-making in clinical settings. Adopting PRISMA-P not only adheres to ethical standards in research but also fosters a culture of transparency and replicability, which is paramount for the advancement of science and healthcare as a whole. [Prospective registration has been completed before full-text screening began].

Protocol Amendments

Any post-registration changes (eligibility criteria, outcomes, analyses, or sources) will be documented with date, rationale, and a description of the change, and updated in the registration record (PROSPERO or OSF/Zenodo).

Review Question and Eligibility Framework

We apply a Population-Exposure/Event-Outcome (PEO) framework: **Population:** human blood donors in Loreto, Peru. **Exposure/Event:** presence of infectious markers (screening reactivity and/or confirmatory positivity, as reported). **Outcome:** prevalence per marker (number reactive/positive divided by number tested).

Inclusion Criteria

We will include observational studies (cross-sectional designs, retrospective cohorts) and institutional reports with primary donor data from Loreto that provide numerators and denominators per marker (or sufficient information to derive them). No language or year restrictions will be applied if extraction is feasible.

Exclusion Criteria

We will exclude: (i) reports without denominators or with non-quantifiable outcomes; (ii) studies conducted outside Loreto or where Loreto data cannot be disaggregated; (iii) duplicate or overlapping cohorts (e. g., multiple reports from the same institution and time window). When overlap is suspected, we will retain a single record per unique donor cohort according to a pre-specified hierarchy: (a) report with the most complete marker set and clearest denominators; (b) largest-sample size and/or longest-time period; (c) most recent peer-reviewed publication. If different reports provide clearly non-overlapping or complementary data (e. g., additional markers or stratified results) without double-counting the same donors, we will extract non-overlapping data and document all decisions transparently.

Markers of Interest

Markers typically used in blood services and relevant national/regional-screening programs may include HIV, HBV/HBsAg, HCV, syphilis, HTLV, Chagas disease, and malaria (where reported). We will extract outcomes exactly as reported, distinguishing between screening reactivity and confirmatory positivity. Primary synthesis will focus on screening reactivity (reactive / total tested) because it is most consistently reported and reflects the operational burden for blood services; confirmatory positivity will be analyzed separately as a secondary outcome when confirmatory algorithms are clearly specified. When both screening and confirmatory results are reported for the same cohort, we will extract them as separate outcomes and will not pool them together. When multiple assays or sequential-testing steps are reported, we will preferentially extract the final screening result per donation (as defined by the source) and record assay type/platform to enable subgroup and sensitivity analyses.

Information Sources

Minimum databases: PubMed/MEDLINE, LILACS (BVS), and SciELO. We will additionally search Google Scholar to enhance capture of regional publications and institutional outputs. If institutional access is available, we will also consider Scopus and/or Embase for completeness. Additional sources include reference-list checking, institutional repositories, thesis databases, and other relevant gray literature.

To mitigate access constraints to non-digitized gray literature, local retrieval will be supported by the Loreto-based co-author (UNAP) and collaborators, including institutional

archives from regional hospitals/blood banks and health authorities. This will be complemented by direct contact with institutions, librarians, and authors when needed.

Search Strategy

Searches will span from database inception to a pre-specified cutoff date (31 Dec 2025). If required by editorial timelines, an update search will be run within 30 days prior to submission of the final manuscript.

No design filters will be applied a priori unless unavoidable due to platform constraints; any constraints will be documented. We will report search methods in line with PRISMA-S, including full database-specific strategies, dates of execution, and numbers of records retrieved per source. Elimination of duplicated registers will be performed using a reference manager and/or a reproducible script, with logs retained (including counts removed at each step). Full strategies are provided in Appendix A.

Study Selection

Two reviewers will independently screen titles/abstracts and then full texts. Disagreements will be resolved by consensus; if unresolved, a third reviewer will adjudicate. The selection process will be reported using a PRISMA 2020 flow diagram.

Data Extraction

A standardized extraction form will be piloted and refined before full extraction. Two reviewers will extract in duplicate, with calibration on an initial subset.

Minimum data items include: citation details; institution and location within Loreto; study period; design and sampling; donor type (voluntary/replacement/mixed); markers assessed; test type (screening/confirmatory), platform/assay where reported; definition of reactive/positive; numerators/denominators per marker; indeterminate results; and donor notification/follow-up where reported (Appendix B).

Co-infections: If starting-from-donor co-infection counts are reported, we will extract them and report descriptively. Marker-specific prevalence will be calculated using the number tested for that marker as the denominator, avoiding double-counting donors across markers. If co-infection data are reported only as event counts without clear denominators, they will not be pooled and will be summarized narratively.

Missing or Unclear Denominators

When denominators or definitions are unclear (e. g., only discard counts reported), we will attempt to obtain clarifications by contacting authors or relevant institutions. If unresolved, such data will be excluded from quantitative pooling but retained for structured-narrative synthesis when informative.

Risk of Bias Assessment

We will use the JBI Critical Appraisal Checklist for Studies Reporting Prevalence Data, applied independently by two reviewers with item-level justifications recorded (Yes/No/Unclear/Not applicable). For operational classification, we will treat the following as critical items: (1) appropriate-sample frame, (2) appropriate recruitment/sampling, (3) adequate-sample size, (6) valid methods for identification of the condition/marker, (8) appropriate-statistical analysis, and (9) adequate-response rate / adequate-response management. Studies will be categorized as: low risk (all critical items "Yes" and ≤ 1 non-critical item "No/Unclear"), moderate risk (one critical item "No/Unclear" or > 1 non-critical item "No/Unclear"), or high risk (≥ 2 critical items "No/Unclear", or evidence of systematic selection/measurement bias likely to materially distort prevalence). Sensitivity analyses will exclude high risk of bias studies, and we will explore the impact of risk of bias ratings on pooled estimates.

Data Synthesis and Statistical Analysis

Primary outcome: prevalence per marker (proportion). Primary model: random-effects meta-analysis of proportions using a binomial generalized linear mixed model (GLMM) with a random intercept for study, reporting pooled proportions with 95% confidence intervals.

Heterogeneity will be quantified using τ^2 and I^2; prediction intervals will be reported when feasible. Zero-event studies are accommodated in the binomial GLMM; any continuity corrections used in alternative-sensitivity approaches will be documented. Subgroup analyses (if sufficient studies per marker) may include test type (screening *versus* confirmatory; platform/assay), time period, donor type, and institution/urban-rural area when reported. Sensitivity analyses will include exclusion of high risk of bias and leave-one-out influence analysis. Meta-regression will be considered only when statistically defensible (conservative rule: $k \geq 10$ per marker).

Criteria for Narrative Synthesis (No Meta-Analysis)

If quantitative pooling is deemed inappropriate due to severe clinical or methodological heterogeneity (e. g., non-comparable outcome definitions, incompatible-testing strategies, or major bias-driven inconsistency), or if data are insufficient (e. g., fewer than two studies reporting compatible denominators for a marker), we will not compute a pooled estimate. Instead, we will present a structured-narrative synthesis with tabulated ranges and study-level estimates.

Reporting Bias and Certainty Of Evidence

When ≥ 10 studies are available for a given marker/outcome definition, we will explore small-study effects using funnel plots on an appropriate scale (e. g., logit-transformed proportions) and formal tests (e. g., Egger-type regression), interpreting findings cautiously given heterogeneity and the limitations of these methods for proportions. Certainty of evidence will be assessed using a GRADE-informed approach adapted to prevalence estimates, rated separately by marker and outcome definition (screening reactivity *versus* confirmatory positivity). We will start at "high" certainty for evidence derived from representative-donor samples with validated assays, and downgrade for: risk of bias (JBI ratings), inconsistency (substantial unexplained heterogeneity), indirectness (population/testing not representative of Loreto routine-donor screening), imprecision (wide-confidence intervals or small effective sample size), and suspected publication/selective reporting bias. Judgements will be summarized in a structured table with explicit reasons for downgrading.

Software and Reproducibility

Analyses will be run in R (e. g., meta, metafor, lme4, or equivalent packages). All analytic decisions (data cleaning, transformations, model specifications, and sensitivity analyses) will be scripted with a fixed-random seed where applicable. De-identified extraction tables, analytic code, and the PRISMA flow diagram will be deposited in an open repository to support reproducibility.

Ethics and Dissemination

This study synthesizes published and institutional-aggregate data and does not involve identifiable information or participant contact. Findings will be disseminated via a peer-reviewed manuscript, stakeholder communication to regional blood services, and open

repositories hosting methodological materials (search strategies, extraction template, analysis code).

APPENDICES

Appendix	Title	Description
Appendix A	Reproducible search strategies (PRISMA-S)	Full database queries (PubMed/MEDLINE, LILACS) and gray literature approach; elimination of duplicated notes.
Appendix B	Minimum data extraction template	Fields for study characteristics, test type, numerators/denominators, co-infections, and follow-up information.

Appendix A. Reproducible Search Strategies

PubMed/MEDLINE (no filters; inception to 31 Dec 2025): ((“blood donor” OR “blood donors” OR donor* OR “donantes de sangre” OR “donación de sangre” OR hemotherapy OR “blood bank”) AND (Loreto OR Iquitos OR “Peruvian Amazon” OR Amazonia OR Amazonía OR “Amazon rainforest” OR “selva peruana”) AND (HIV OR VIH OR “hepatitis B” OR HBsAg OR HBV OR “hepatitis C” OR HCV OR syphilis OR “Treponema pallidum” OR HTLV OR Chagas OR “Trypanosoma cruzi” OR malaria OR Plasmodium))

LILACS (BVS) (Title/Abstract/Subject fields; no filters; inception to 31 Dec 2025): (tw:(donante* OR “donantes de sangre” OR “donación de sangre” OR hemoterapia OR “banco de sangre”) AND tw:(Loreto OR Iquitos OR Amazonia OR Amazonía OR “selva peruana”) AND tw:(VIH OR HIV OR “hepatitis B” OR HBsAg OR HBV OR “hepatitis C” OR HCV OR sífilis OR “Treponema pallidum” OR HTLV OR Chagas OR “Trypanosoma cruzi” OR malaria OR Plasmodium))

SciELO (advanced search; no filters; inception to 31 Dec 2025): ((“blood donor” OR “blood donors” OR donor OR “donantes de sangre” OR “donación de sangre” OR hemoterapia OR “banco de sangre”) AND (Loreto OR Iquitos OR Amazonia OR Amazonía OR “selva peruana” OR “Peruvian Amazon”) AND (HIV OR VIH OR “hepatitis B” OR HBsAg OR HBV OR “hepatitis C” OR HCV OR syphilis OR sífilis OR “Treponema pallidum” OR HTLV OR Chagas OR “Trypanosoma cruzi” OR malaria OR Plasmodium))

Gray literature (minimum): thesis repositories (UNAP and other Peru-relevant universities), institutional blood service reports (regional hospitals/blood banks), regional/national health authority repositories, and conference proceedings when available. We will search Google Scholar using key-phrase combinations and screen at least the first

200 results per query (sorted by relevance), recording search dates and counts. Where needed, local retrieval will be supported by Loreto-based collaborators and by direct contact with institutions, librarians, and authors.

Handsearching: reference lists of included studies, key regional/national normative documents, and relevant-institutional reports.

Appendix B. Minimum Data Extraction

- Study ID / full citation
- Publication year; data-collection period
- Institution; city/province (if applicable); Loreto confirmed (yes/no)
- Design; sampling; donor-eligibility criteria
- Donor type (voluntary/replacement/mixed)
- Marker: name; test type (screening/confirmatory); platform/assay (if reported)
- Operational definition of reactive/positive (as reported)
- *n* reactive/positive; *N* tested
- Indeterminate results; co-infections (if applicable)
- Donor notification/follow-up (if applicable)
- Notes (platform changes, methodological remarks)

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