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Article

# A Systematic Framework for Investigating Algorithmic Bias as a Social Determinant of Health in Low- and Middle-Income Countries: A Research Protocol

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## Abstract

**Background/Objectives:** The rapid adoption of artificial intelligence (AI) and machine learning technologies in healthcare systems across low- and middle-income countries (LMICs) presents opportunities for improving health outcomes while introducing risks for perpetuating health inequities. Despite growing concerns about algorithmic bias in healthcare delivery, systematic methodological approaches for investigating these phenomena in LMIC contexts remain underdeveloped. This research protocol presents a comprehensive methodological framework for systematically investigating algorithmic bias as a mechanism through which social determinants of health operate in LMIC healthcare contexts. **Methods:** We propose a sequential explanatory mixed-methods research protocol implemented across three phases over 36 months. Phase 1 involves systematic evidence mapping through scoping reviews and policy landscape analysis across 15 LMICs. Phase 2 comprises primary data collection through multi-stakeholder interviews (n=125) and in-depth healthcare system case studies in five countries (Nigeria, India, Kenya, Brazil, and Bangladesh). Phase 3 focuses on framework development, validation, and refinement through pilot implementation in Ghana and Vietnam. **Results:** This protocol will yield a validated research framework for investigating algorithmic bias in LMIC healthcare systems, standardized measurement tools, evidence-based policy recommendations, and capacity building guidelines. The multi-phase approach provides balanced consideration of methodological rigor and practical implementation feasibility while maintaining sensitivity to complex LMIC contexts. **Conclusions:** By providing the first comprehensive research protocol for investigating algorithmic bias as a social determinant of health in LMICs, this work establishes the methodological foundation for future empirical studies and evidence-based policy development. Implementation requires commitment from multiple stakeholder communities to ensure that digital health transformation promotes rather than undermines health equity.

**Keywords:** algorithmic bias; social determinants of health; digital health; health equity; low- and middle-income countries; research methodology; artificial intelligence

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## 1. Introduction

The global health landscape is experiencing an unprecedented digital transformation, with artificial intelligence (AI) and machine learning (ML) technologies increasingly integrated into healthcare delivery systems worldwide [1]. This technological revolution is particularly pronounced in low- and middle-income countries (LMICs), where digital health innovations offer opportunities to leapfrog traditional healthcare infrastructure limitations [2]. Mobile health platforms, AI-powered

diagnostic tools, and algorithmic clinical decision support systems are being rapidly deployed across diverse LMIC contexts.

However, this rapid technological adoption occurs within complex socioeconomic environments characterized by significant health inequities, limited regulatory frameworks, and varying degrees of digital literacy [3]. Unlike high-income countries where AI implementation typically occurs within well-established healthcare systems with robust oversight mechanisms, LMICs often lack the institutional capacity to adequately evaluate, monitor, and mitigate potential algorithmic biases [4].

Algorithmic bias in healthcare encompasses systematic and unfair discrimination embedded within computational systems that affects clinical decision-making, resource allocation, and health service delivery [5]. These biases can manifest through various mechanisms, including biased training data, inappropriate algorithmic design choices, and inadequate consideration of population diversity during system development and deployment [4].

The intersection between algorithmic bias and social determinants of health represents a critical area of investigation that remains theoretically underdeveloped and empirically understudied [6]. Social determinants of health encompass the conditions in which people are born, grow, live, work, and age, including the broader set of forces and systems that shape daily life conditions [7]. Algorithmic bias in healthcare may function as a novel mechanism through which traditional social determinants of health operate in digitalized healthcare systems [8].

Current evidence regarding algorithmic bias in healthcare derives predominantly from high-income country contexts, with limited empirical data available from LMIC settings [9]. Existing research methodologies may be inadequately suited for LMIC contexts, where data availability, regulatory frameworks, and healthcare delivery models differ substantially [10]. Investigating algorithmic bias in LMIC healthcare systems presents unique methodological challenges requiring specialized research approaches.

The primary aim of this work is to develop a comprehensive, replicable methodological framework for systematically investigating algorithmic bias as a mechanism affecting health equity in LMIC healthcare systems. This framework will provide standardized approaches for identifying, measuring, and analyzing algorithmic bias while maintaining sensitivity to diverse cultural, economic, and healthcare system contexts.

## 2. Materials and Methods

### 2.1. Overall Study Design

This research protocol employs a sequential explanatory mixed-methods design implemented across three interconnected phases over 36 months. The methodology combines systematic evidence synthesis, primary data collection, and framework development to generate comprehensive understanding of algorithmic bias manifestation and impact in LMIC healthcare contexts.

The research design incorporates a multi-country comparative framework encompassing diverse LMIC contexts representing different geographical regions, economic development levels, and healthcare system structures. Quality assurance mechanisms include regular methodology review meetings, external expert consultation, and systematic documentation of methodological decisions.

### 2.2. Theoretical Framework

The social determinants of health framework, as conceptualized by the World Health Organization, provides the theoretical foundation for understanding how algorithmic bias may function as a mechanism affecting health equity [7]. This framework identifies structural determinants including socioeconomic stratification, governance systems, and cultural norms as fundamental drivers of health inequities.

This research protocol proposes a novel theoretical framework conceptualizing algorithmic bias as an emergent social determinant of health that operates through direct and indirect pathways to

influence health outcomes in LMIC contexts. The conceptual model identifies three primary pathways: (1) direct discrimination through systematic differential treatment recommendations; (2) indirect discrimination through perpetuation of existing healthcare disparities; and (3) systemic exclusion through underrepresentation in algorithmic system development processes.

### 2.3. Phase 1: Systematic Evidence Mapping

#### 2.3.1. Scoping Review Protocol

The systematic evidence mapping begins with a comprehensive scoping review following the PRISMA-ScR framework [11]. The literature search strategy encompasses multiple electronic databases including PubMed, Embase, Scopus, IEEE Xplore, and Web of Science, plus regional databases and grey literature sources.

Search terms combine concepts related to algorithmic bias, healthcare applications, and LMIC contexts. The temporal scope covers publications from 2015 to present. Inclusion criteria encompass peer-reviewed articles, conference papers, and reports addressing algorithmic bias in healthcare AI applications within LMIC settings.

Data extraction utilizes standardized forms capturing study characteristics, AI application details, bias assessment methods, findings, and policy implications. Two independent reviewers conduct screening and data extraction with disagreements resolved through consensus discussion.

#### 2.3.2. Policy Landscape Analysis

The policy landscape analysis provides systematic examination of existing AI governance frameworks across selected LMIC contexts. Country selection employs purposive sampling ensuring representation across geographical regions, economic development levels, and healthcare system types across 15 LMICs.

Data sources encompass government websites, ministry publications, regulatory documents, national AI strategies, and reports from international organizations. The analytical framework employs systematic content analysis using standardized coding schemes addressing policy scope, governance mechanisms, and implementation provisions.

### 2.4. Phase 2: Primary Data Collection

#### 2.4.1. Multi-Stakeholder Interview Protocol

Primary data collection employs semi-structured interviews with diverse stakeholders across multiple LMIC contexts. Participant recruitment employs purposive sampling with maximum variation ensuring representation across stakeholder groups, geographical locations, and organizational types.

Target participant categories include health system administrators and policymakers (n=30), healthcare providers (n=50), AI researchers and health informatics specialists (n=25), and patient advocacy representatives (n=20) across five countries: Nigeria, India, Kenya, Brazil, and Bangladesh.

Data collection employs secure video conferencing with provisions for telephone interviews where connectivity is limited. Interview guides address stakeholder experiences with AI in healthcare, perceptions of algorithmic bias, organizational practices for AI evaluation, and policy recommendations. Thematic analysis employs the framework approach with both deductive and inductive themes [12].

#### 2.4.2. Healthcare System Case Studies

In-depth case studies provide detailed examination of algorithmic bias manifestation within specific healthcare system contexts. Case study methodology follows established principles for explanatory case study research [13]. Each case study employs multiple data sources including

administrative health data, policy documentation, stakeholder interviews, and technical system documentation.

Analytical procedures employ cross-case pattern matching and explanation building to identify common mechanisms and context-specific factors [14]. The selected countries represent diverse healthcare system characteristics and varying levels of AI implementation in healthcare delivery.

### 2.5. Phase 3: Framework Development and Validation

#### 2.5.1. Integrated Analytical Framework

Framework development synthesizes evidence from all previous phases using established methodological approaches including framework synthesis and meta-ethnography [15]. The synthesis process begins with systematic extraction of key findings using standardized templates.

Framework construction involves iterative development of conceptual models integrating empirical findings with existing theoretical frameworks. The resulting analytical framework encompasses theoretical models, operational definitions, methodological guidelines, and implementation strategies for different healthcare system contexts.

#### 2.5.2. Protocol Validation and Refinement

The final phase involves validation and refinement through pilot implementation in Ghana and Vietnam. Pilot implementation focuses on protocol feasibility, cultural appropriateness, and methodological robustness.

Validation employs established criteria including reliability assessment, validity evaluation, and practicality assessment. Refinement processes incorporate stakeholder feedback and pilot findings to optimize protocol components for broader implementation.

### 2.6. Ethical Considerations

The ethical framework prioritizes justice, beneficence, respect for persons, and cultural sensitivity while addressing specific challenges associated with algorithmic bias research in LMIC contexts [16]. Justice considerations encompass fair participant selection, equitable benefit distribution, and protection of vulnerable populations.

Institutional Review Board approval strategies involve comprehensive multi-country ethics review processes. Data protection measures comply with international standards including relevant GDPR provisions and national data protection laws. All participants will provide informed consent, and data will be anonymized to protect participant confidentiality.

### 2.7. Data Analysis

Quantitative data analysis will employ descriptive statistics and comparative analysis across countries and stakeholder groups. Qualitative data analysis will utilize thematic analysis following established frameworks [12]. Mixed-methods integration will employ joint displays and meta-inferences to synthesize findings across data types.

Cross-case analysis will identify patterns and variations across different LMIC contexts. Framework development will employ systematic synthesis techniques to integrate findings into coherent theoretical and methodological frameworks.

## 3. Results

### 3.1. Expected Methodological Contributions

This research protocol will generate several significant methodological contributions including a comprehensive, validated research protocol specifically designed for LMIC contexts, standardized measurement tools and indicators, best practices for cross-cultural research implementation, and frameworks for policy-relevant research design.

The systematic evidence mapping will provide the first comprehensive assessment of existing knowledge regarding algorithmic bias in LMIC healthcare contexts. This will identify critical evidence gaps and inform priority areas for future research investment.

### *3.2. Anticipated Empirical Findings*

Multi-stakeholder interviews will generate understanding of diverse perspectives and experiences regarding algorithmic bias in healthcare delivery. This will include healthcare provider experiences, patient advocacy concerns, policy maker priorities, and researcher perspectives on methodological challenges.

Healthcare system case studies will provide detailed evidence regarding specific mechanisms through which algorithmic bias affects health outcomes. Comparative analysis will identify common patterns and contextual variations enabling generalizable findings while recognizing important contextual factors.

### *3.3. Framework Development Outcomes*

The integrated analytical framework will provide theoretical models linking algorithmic bias to health equity outcomes in LMIC contexts. This will include operational definitions suitable for empirical research, measurement indicators adaptable across diverse healthcare systems, and implementation guidelines accounting for resource constraints.

Validation processes will demonstrate framework reliability, validity, and practical applicability across different LMIC contexts. Refinement activities will optimize framework components based on pilot implementation experiences and stakeholder feedback.

## **4. Discussion**

This research protocol addresses critical methodological gaps in algorithmic bias research within LMIC healthcare contexts. The multi-phase, mixed-methods approach provides balanced consideration of methodological rigor and practical implementation feasibility while maintaining sensitivity to complex cultural, economic, and healthcare system factors.

The significance extends beyond immediate research contributions to encompass broader implications for global health equity, international development, and technology governance. As AI technologies become increasingly integrated into healthcare delivery systems worldwide, ensuring equitable access while protecting vulnerable populations from algorithmic discrimination represents a fundamental challenge for global health and social justice.

### *4.1. Methodological Innovations*

The proposed framework introduces several methodological innovations specifically designed for LMIC research contexts. The integration of systematic evidence mapping with primary data collection provides comprehensive understanding combining existing knowledge with novel empirical insights.

The multi-stakeholder approach ensures diverse perspectives are incorporated throughout the research process. This participatory methodology recognizes that algorithmic bias affects multiple stakeholder groups and requires inclusive investigation approaches.

### *4.2. Implementation Considerations*

Successful implementation requires substantial investment in local research capacity and institutional partnerships [17]. The capacity building strategy recognizes that sustainable research implementation requires long-term collaborative relationships with academic institutions, government agencies, and healthcare systems.

Resource requirements for this 36-month research protocol total approximately \$2.5 million, including personnel costs, travel expenses, data collection costs, and capacity building activities.

Cost-effectiveness optimization strategies maximize research impact through collaborative approaches and resource sharing agreements.

#### 4.3. Policy Implications

The research will generate evidence-based recommendations for AI governance frameworks tailored to LMIC healthcare contexts, implementation guidelines for bias mitigation strategies, capacity building frameworks, and international cooperation strategies facilitating knowledge sharing and collaborative development.

These policy contributions will support evidence-based decision making regarding AI implementation in healthcare while promoting equitable access and protection of vulnerable populations.

#### 4.4. Limitations

This research protocol acknowledges several important limitations including resource constraints, data availability variations, cultural and linguistic barriers, rapidly evolving technology landscape, and regulatory approval challenges that may affect implementation feasibility and findings generalizability.

The focus on selected LMIC contexts may limit generalizability to other settings. However, the multi-country comparative approach and framework validation processes are designed to maximize transferability while recognizing contextual variations.

## 5. Conclusions

This research protocol presents the first comprehensive methodological framework specifically designed for investigating algorithmic bias as a social determinant of health in LMIC healthcare contexts. By addressing critical evidence gaps and methodological limitations, this protocol establishes the foundation for systematic, rigorous, and culturally appropriate investigation across diverse global health settings.

Through systematic evidence mapping, comprehensive stakeholder engagement, detailed case study analysis, and collaborative framework development, this protocol generates the methodological tools and empirical evidence necessary for evidence-based policy development.

Implementation requires commitment from multiple stakeholder communities including academic institutions, funding organizations, policy makers, healthcare leaders, and civil society organizations. The collaborative approach reflects recognition that addressing algorithmic bias requires sustained international cooperation, knowledge sharing, and capacity building initiatives.

This protocol represents a call for international collaboration and coordinated action to ensure that the digital health transformation occurring across LMICs promotes rather than undermines health equity and social justice. Through systematic investigation, evidence-based policy development, and collaborative capacity building, the global health community can work together to harness AI benefits while protecting vulnerable populations from algorithmic discrimination.

**Supplementary Materials:** The following supporting information can be downloaded at: [URL], Interview guides; Policy analysis framework; Data extraction forms.

**Informed Consent Statement:** Informed consent was obtained from all subjects involved in the study.

**Data Availability Statement:** Data supporting reported results can be found at [https://drive.google.com/file/d/1pMObedK0PaKixA9-i9Vtke2CujEy32vK/view?usp=drive\\_link](https://drive.google.com/file/d/1pMObedK0PaKixA9-i9Vtke2CujEy32vK/view?usp=drive_link). And [https://docs.google.com/document/d/13JkYnQuKLGg9V3U-DafF5RkLvoOjhJpJ/edit?usp=drive\\_link&ouid=102837271023250039326&rtpof=true&sd=true](https://docs.google.com/document/d/13JkYnQuKLGg9V3U-DafF5RkLvoOjhJpJ/edit?usp=drive_link&ouid=102837271023250039326&rtpof=true&sd=true). Interview data will be made available upon reasonable request following appropriate ethical approval and data sharing agreements.

**Conflicts of Interest:** The authors declare no conflicts of interest. The funders had no role in the design of the study; in the collection, analyses, or interpretation of data; in the writing of the manuscript; or in the decision to publish the results.

## Abbreviations

The following abbreviations are used in this manuscript:

AI	Artificial Intelligence
ML	Machine Learning
LMIC	Low- and Middle-Income Countries
WHO	World Health Organization
PRISMA-ScR	Preferred Reporting Items for Systematic Reviews and Meta-Analyses extension for Scoping Reviews

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