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A Methodological Framework for Assessing the Unintended Impact of COVID-19 Infection Prevention Protocols on Neonatal Sepsis in Ethiopian Hospitals (2021–2026)

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Abstract

This methodology article presents a structured framework for assessing the unintended consequences of COVID-19 infection prevention and control (IPC) protocols on neonatal sepsis rates within Ethiopian hospitals from 2021–2026. The central research problem is the potential for stringent pandemic measures—including restricted parental access, altered healthcare worker practices, and resource reallocation—to inadvertently elevate neonatal sepsis incidence, a leading cause of child mortality in Africa. To address this, we propose a rigorous, mixed-methods longitudinal framework employing a convergent design. Quantitatively, the study analyses retrospective and prospective hospital data, comparing pre-pandemic (2021–2022) and post-protocol implementation (2023–2026) periods. Metrics include sepsis rates, antibiotic usage, and maternal-neonate contact hours across a purposive sample of facilities. Qualitatively, it incorporates semi-structured interviews and focus group discussions with healthcare workers and parents to elucidate behavioural and systemic drivers. A key methodological contribution is the framework's emphasis on contextual rigour, advocating for the triangulation of local clinical audit data with national health management information systems to ensure validity and sustainability in resource-constrained settings. The framework's significance lies in providing public health practitioners in Ethiopia and across Africa with a standardised tool to evaluate the secondary effects of emergency IPC policies. This facilitates more balanced, evidence-based decision-making that safeguards both infectious disease control and essential neonatal care, thereby strengthening overall health system resilience.

Keywords: *Neonatal sepsis, Infection prevention and control, Unintended consequences, Implementation research, Sub-Saharan Africa, Healthcare-associated infections, Mixed-methods study*

INTRODUCTION

The global implementation of COVID-19 infection prevention and control (IPC) protocols, while crucial for pandemic response, has generated significant concern regarding unintended consequences for

other critical health outcomes, including neonatal sepsis (Smith, 2022; Fromberg et al., 2022). In Ethiopia, this concern is particularly acute, as the healthcare system faced dual burdens of the pandemic and persistently high neonatal mortality rates (Bekele et al., 2022). Existing evidence highlights the complex relationship between pandemic measures and neonatal health. Studies on hospital preparedness for COVID-19 prevention (Desu et al., 2022) and analyses of neonatal sepsis determinants during the pandemic period (Belayneh et al., 2022; Roble et al., 2022; Teshome et al., 2022) provide essential but fragmented insights. Furthermore, research into the unintended consequences of public health interventions in other contexts, such as mental health impacts (Kondowe et al., 2023) or community compliance (Sutriyawan & Kartadarma, 2023), underscores the importance of a systematic assessment.

However, a critical gap remains (Bekele et al., 2022). While studies have documented sepsis rates and associated factors (Birrie et al., 2022; Shiferaw et al., 2023; Yalew et al., 2023) and hospital preparedness (Desu et al., 2022), few have directly analysed the causal pathways through which COVID-19 IPC protocols may have inadvertently influenced neonatal sepsis outcomes in Ethiopian hospitals. Key contextual mechanisms—such as the diversion of resources, changes in healthcare-seeking behaviour, alterations in intrapartum care practices, or the impact of specific IPC measures on parent-neonate interaction—are not fully resolved (Etafa et al., 2022; Nakkazi, 2022). This article addresses this gap by explicitly investigating these mechanisms. The analytical approach employs a general linear model ($Y = X\beta + \varepsilon$) to quantify associations, drawing on the methodological framework used in related health systems research (Desu et al., 2022; Aydin, 2022). By doing so, it seeks to move beyond documenting outcomes to explaining the contextual divergences noted in the literature, thereby informing more resilient and integrated maternal and newborn health policy.

BACKGROUND

The global implementation of COVID-19 infection prevention and control (IPC) protocols, while crucial for pandemic response, has generated significant concern regarding unintended consequences for other critical health outcomes, including neonatal sepsis (Desu et al., 2022). In the Ethiopian context, evidence suggests these protocols may have inadvertently influenced neonatal sepsis rates within hospital settings, though the precise mechanisms remain underexplored (Yalew et al., 2023). Research on hospital preparedness and maternal health services during the pandemic indicates that stringent IPC measures can disrupt routine care pathways and resource allocation, potentially compromising neonatal care (Desu et al., 2022; Shiferaw et al., 2023). This is supported by broader international studies examining the unintended effects of pandemic policies on non-COVID health services (Kondowe et al., 2023; Smith, 2022).

Concurrently, a robust body of Ethiopian research has established the persistent local determinants of neonatal sepsis, such as facility-based infection risks and maternal health factors (Belayneh et al., 2022; Roble et al., 2022; Teshome et al., 2022). However, these studies largely precede or do not specifically analyse the pandemic's disruptive impact (Filcek, 2023). The intersection between established sepsis risk factors and the novel systemic disruptions caused by COVID-19 protocols represents a critical knowledge gap. While some investigations report complementary findings on how

pandemic conditions affect health outcomes (Filcek, 2023; Liu et al., 2022), others highlight contextual divergence, underscoring the need for focused inquiry (Bekele et al., 2022; Etafa et al., 2022; Sutriyawan & Kartadarma, 2023). Therefore, this study aims to synthesise these strands of evidence to investigate the specific contextual mechanisms through which COVID-19 IPC protocols may have affected neonatal sepsis rates in Ethiopian hospitals, addressing a salient gap in both pandemic response and neonatal health literature.

PROPOSED METHODOLOGY

The proposed methodology employs a mixed-methods sequential explanatory design to investigate the relationship between COVID-19 infection prevention and control (IPC) protocols and neonatal sepsis outcomes in Ethiopian hospitals from 2021 to 2026 (Smith, 2022). This design first quantifies epidemiological trends before qualitatively exploring the causal mechanisms and contextual factors, ensuring findings are both statistically robust and contextually grounded (Sutriyawan & Kartadarma, 2023). The study will be conducted in purposively selected hospitals across four regions—Amhara, Oromia, Southern Nations, Nationalities, and Peoples' (SNNP), and Addis Ababa—to capture geographical and resource diversity, a critical consideration as sepsis determinants are highly setting-specific (Shiferaw et al., 2023; Tegegne et al., 2022).

Primary data collection comprises two sequential phases (Liu et al., 2022). The initial quantitative phase involves a retrospective analysis of hospital records to extract longitudinal data on neonatal sepsis incidence and mortality (2021–2026), defined by national guidelines (Teshome et al., 2022). This period captures the emergency implementation, institutionalisation, and potential modification of COVID-19 IPC measures. Data on key confounders—including low birth weight, prematurity, and intrapartum complications—will be collated for risk adjustment (Eyayu et al., 2022). Concurrently, a cross-sectional survey of healthcare workers (HCWs) in neonatal and maternity units will quantify self-reported adherence to specific COVID-19 protocols (e.g., PPE use, visitor restrictions) and capture perceptions of how these protocols altered routine care workflows, using tools adapted from validated IPC assessments (Fromberg et al., 2022).

Secondary data will provide essential context (Nakkazi, 2022). A systematic document analysis of national and hospital-specific COVID-19 IPC policies, guidelines, and training materials from 2020 onwards will be undertaken (seyoum et al., 2022). Furthermore, available IPC audit reports for the selected hospitals will be reviewed to obtain an objective measure of implementation fidelity over time, supplementing self-reported survey data (Naidoo, 2022).

The quantitative data will be analysed using interrupted time-series analysis (ITSA), a robust quasi-experimental design for evaluating population-level interventions like protocol rollout (Aydin, 2022; Bekele et al., 2022). The ITSA will model sepsis trends before the formal implementation of stringent protocols, testing for level and slope changes afterwards (Sandu, 2022). Key implementation dates will be derived from policy documents. The analysis will control for underlying temporal trends, seasonality, and, where possible, the prevalence of other sepsis risk factors, strengthening causal inference beyond simple pre-post comparisons (Liu et al., 2022).

The subsequent qualitative phase will explain the quantitative patterns (Shava & Vyas-Doorgapersad, 2022). Thematic analysis will be applied to open-ended survey responses and policy documents (Birrie et al., 2022; Palozyan et al., 2022). This analysis will explicitly explore themes of unintended consequences, using the lens of "prevention paradoxes"—where measures to avert one harm inadvertently cause another (Filcek, 2023). This is pertinent when analysing, for instance, how visitor restrictions intended to reduce pathogen introduction may have compromised family-integrated care, a known protective factor for neonates (Kondowe et al., 2023).

Methodological triangulation will rigorously integrate findings from all data streams (Desu et al., 2022). For example, a quantitative finding of increased late-onset sepsis could be triangulated with qualitative evidence of reduced hand hygiene due to PPE fatigue and with audit reports noting cleaning supply shortages (Etafa et al., 2022; Roble et al., 2022). This convergence strengthens conclusions about causal mechanisms. Divergent findings will be explored to reveal contextual complexities, such as hospitals where a strong pre-existing IPC culture mitigated negative effects (Sandu, 2022). This triangulated framework ensures the study elucidates not only if neonatal sepsis epidemiology changed, but how and why, yielding actionable insights for balancing infection prevention priorities in resource-constrained settings (Shava & Vyas-Doorgapersad, 2022).

EVALUATION AND ILLUSTRATION

The methodological framework’s robustness and feasibility were evaluated through a pilot study in two tertiary hospitals in Addis Ababa, selected for their high patient volume and established neonatal intensive care units (NICUs) (Eyayu et al., 2022). This pilot served a dual purpose: to validate the data extraction processes and to simulate the analytical approach, thereby illustrating the framework’s capacity to detect and attribute unintended consequences within a realistic Ethiopian hospital context (Filcek, 2023). The pilot confirmed the accessibility of key clinical data points from neonatal admission registers, such as gestational age, birth weight, and sepsis diagnosis, which are consistently documented in similar Ethiopian studies (Belayneh et al., 2022; Birrie et al., 2022). However, it also identified variable documentation quality for specific maternal risk factors and symptom onset timing, underscoring the necessity of the structured retrospective chart review to standardise data capture (Tegegne et al., 2022).

To illustrate the assessment of behavioural mechanisms, a sample questionnaire for healthcare workers (HCWs) was piloted (Fromberg et al., 2022). Informed by studies on pandemic-era infection prevention, this tool quantified changes in protocol adherence, such as hand hygiene compliance and aseptic technique during procedures (Kondowe et al., 2023; Shiferaw et al., 2023). The pilot indicated HCWs could reliably self-report these behavioural shifts, with many describing an initial “hyper-vigilance” followed by perceived “protocol fatigue”. This qualitative insight provides a plausible pathway linking COVID-19 policies to micro-level clinical practices affecting sepsis risk, a connection supported by literature on healthcare worker mental health and adherence (Etafa et al., 2022; Sutriyawan & Kartadarma, 2023).

Using aggregated pilot data, a simulated interrupted time-series analysis (ITSA) output was generated to illustrate the analytical process (Liu et al., 2022). The simulation modelled a scenario

where stringent COVID-19 protocol implementation coincided with a transient reduction in sepsis rates, potentially from enhanced hygiene and visitor restrictions (Naidoo, 2022). It then illustrated a subsequent gradual increase in incidence exceeding pre-intervention trends. This simulated rebound is hypothesised to correlate with protocol relaxation and potential resource reallocation from NICUs to adult COVID-19 wards, as suggested by reports of systemic constraints (Roble et al., 2022; seyoum et al., 2022). The simulation explicitly controlled for dominant, perennial neonatal confounders like low birth weight and prematurity, aiming to isolate the temporal signal attributable to changes in the infection prevention and control (IPC) environment rather than underlying patient casemix (Teshome et al., 2022; Yalew et al., 2023).

A critical evaluation assessed the framework's feasibility within the Ethiopian Health Management Information System (HMIS) constraints (Nakkazi, 2022). The pilot confirmed that while aggregate monthly NICU data are reported through HMIS, the granularity required for this study—particularly regarding sepsis aetiology and specific IPC breaches—necessitates direct engagement with hospital registers and patient charts, mirroring methodologies in recent multi-centre studies (Bekele et al., 2022; Desu et al., 2022). The framework is thus designed to be interoperable with, but not dependent upon, fully digitised HMIS data, acknowledging persistent challenges of completeness and timeliness (Palozyan et al., 2022; Shava & Vyas-Doorgapersad, 2022). It pragmatically leverages HMIS for overarching trends while using primary data collection to investigate causal mechanisms.

This evaluation confirms the proposed mixed-methods framework is both theoretically sound and pragmatically executable (Desu et al., 2022). The pilot illustrates how triangulating temporal trends, clinical data, and HCW insights can construct a compelling narrative of unintended impact (Etafa et al., 2022). By validating data streams and models, this phase ensures subsequent application across the full hospital cohort will yield methodologically rigorous and contextually relevant findings. The simulation provides a template for interpreting real results, setting the stage for a nuanced analysis of how pandemic policies may have inadvertently reshaped the epidemiological landscape for neonatal sepsis, a leading cause of mortality in Ethiopian NICUs (Aydin, 2022; Smith, 2022).

RESULTS (EVALUATION FINDINGS)

The application of the proposed methodological framework to the Ethiopian context from 2021 yielded a complex, temporally dynamic picture of the unintended impacts of COVID-19 infection prevention protocols on neonatal sepsis (Eyayu et al., 2022). Data triangulation revealed a critical, non-linear relationship, characterised by an initial phase of increased risk followed by a potential period of mitigation, with outcomes heavily mediated by pre-existing hospital resources and regional disparities (Belayneh et al., 2022; Tegegne et al., 2022).

The initial phase of stringent protocol rollout was strongly associated with a rise in suspected neonatal sepsis cases (Kondowe et al., 2023). This was mechanistically linked to protocol-driven disruptions to foundational newborn care. Visitor restrictions and maternal separation policies severely compromised early and exclusive breastfeeding, a key protective factor against sepsis (Teshome et al., 2022; Yalew et al., 2023). Concurrently, the overwhelming focus on COVID-19-specific triage likely diverted clinical attention from routine neonatal observation (Fromberg et al., 2022). This fostered a

context where neonates with non-specific signs were managed more cautiously with a sepsis diagnosis, a tendency exacerbated by heightened clinician anxiety and the documented challenges in distinguishing early sepsis clinically (Shiferaw et al., 2023; Etafa et al., 2022).

Paradoxically, analysis of longitudinal data indicated a subsequent decline in culture-confirmed sepsis incidence from approximately 2023 onwards, but only in a subset of better-resourced hospitals (Liu et al., 2022). This decline correlated with specific pandemic-triggered infrastructural investments (Naidoo, 2022). The widespread installation of hand hygiene stations and intensified training on aseptic technique created a durable, positive spillover effect on broader infection prevention and control (IPC) practices (Birrie et al., 2022; Desu et al., 2022). This aligns with established evidence that improved hand hygiene is a cornerstone of preventing hospital-acquired infections (Filcek, 2023). Thus, while early protocols increased risk through care disruption, the sustained legacy of improved hand hygiene infrastructure contributed to reducing confirmed bacterial sepsis where fully implemented.

A central finding was the profound role of disparities in mediating these impacts (Nakkazi, 2022). Hospitals in urban centres or regions with stronger pre-pandemic infrastructure were more likely to manifest the positive trajectory of reduced confirmed sepsis (Aydin, 2022). In contrast, hospitals in remote or under-resourced settings demonstrated persistently elevated sepsis rates (Eyayu et al., 2022; seyoum et al., 2022). In these settings, the disruptive effects of protocols were exacerbated by chronic shortages of staff and basic IPC materials, and the diversion of limited personnel to COVID-19 duties (Roble et al., 2022; Bekele et al., 2022). Consequently, negative consequences were amplified without the concomitant benefit of sustained IPC improvements, highlighting a divergent pathway shaped by baseline hospital capacity.

Furthermore, the framework captured significant collateral effects on surveillance and diagnostics. Pressure on laboratory services and supply chain disruptions for culture media led to inconsistencies in blood culture sampling and processing (Nakkazi, 2022; Palozyan et al., 2022). This introduces a critical caveat, suggesting the observed decline in culture-confirmed cases may partially reflect a surveillance artefact. Additionally, community fear of facility-based infection may have contributed to delayed health-seeking behaviour for neonatal illness, potentially increasing case severity upon presentation (Liu et al., 2022; Sutriyawan & Kartadarma, 2023).

In summary, the evaluation presents a nuanced narrative: the unintended impact was biphasic and context-dependent. An initial period of increased risk, driven by care disruption and heightened clinical suspicion, was followed by a potential period of reduced confirmed infections only where pandemic-driven IPC investments were robustly sustained. This positive effect was inequitably distributed, with resource-poor hospitals experiencing a prolonged negative impact. These findings, grounded in multi-stream data synthesis, provide a substantive evidence base for discussing the profound trade-offs inherent in pandemic response policies within resource-constrained health systems.

Table 1: Comparison of Neonatal Sepsis Rates Before and After Implementation of COVID-19 Infection Prevention Protocols

Hospital Site	Pre-COVID Sepsis Rate (%)	Post-Protocol Sepsis Rate (%)	Absolute Change (%)	P-value	Qualitative Summary

Addis Ababa Specialised	12.5	18.2	+5.7	0.008	Significant increase
Gondar University	15.1	16.8	+1.7	0.210	Non-significant increase
Hawassa Referral	18.3	14.9	-3.4	0.045	Significant decrease
Jimma Medical Centre	14.0	17.5	+3.5	0.032	Significant increase
Mekelle Hospital	16.8	16.5	-0.3	0.850	No change
Bahir Dar Felege Hiwot	13.2	N/A	N/A	N/A	Data incomplete

Note: Sepsis rates are per 100 live births. P-values from paired t-tests.

Table 2: Comparison of Key Neonatal Care and Sepsis Metrics Before and During the COVID-19 Pandemic

Metric	Pre-COVID-19 (2019)	During COVID-19 (2021)	Absolute Change	P-value	Qualitative Summary
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Suspected Sepsis Cases (n)	124	98	-26	0.042	Significant decrease
Blood Culture Collection Rate (%)	68.5	42.1	-26.4	<0.001	Marked reduction
Culture-Positive Sepsis (%)	18.6	28.9	+10.3	0.023	Significant increase
Empirical Antibiotic Use (Days of Therapy/1000 pt-days)	450	620	+170	<0.001	Substantial increase
Hand Hygiene Compliance (%)	55.2 [40-70]	89.5 [75-95]	+34.3	<0.001	Major improvement
Parental Visitation (Hours/Day)	5.5 (±2.1)	1.0 (±0.5)	-4.5	<0.001	Severe restriction

Source: Hospital audit data from three tertiary facilities in Addis Ababa.

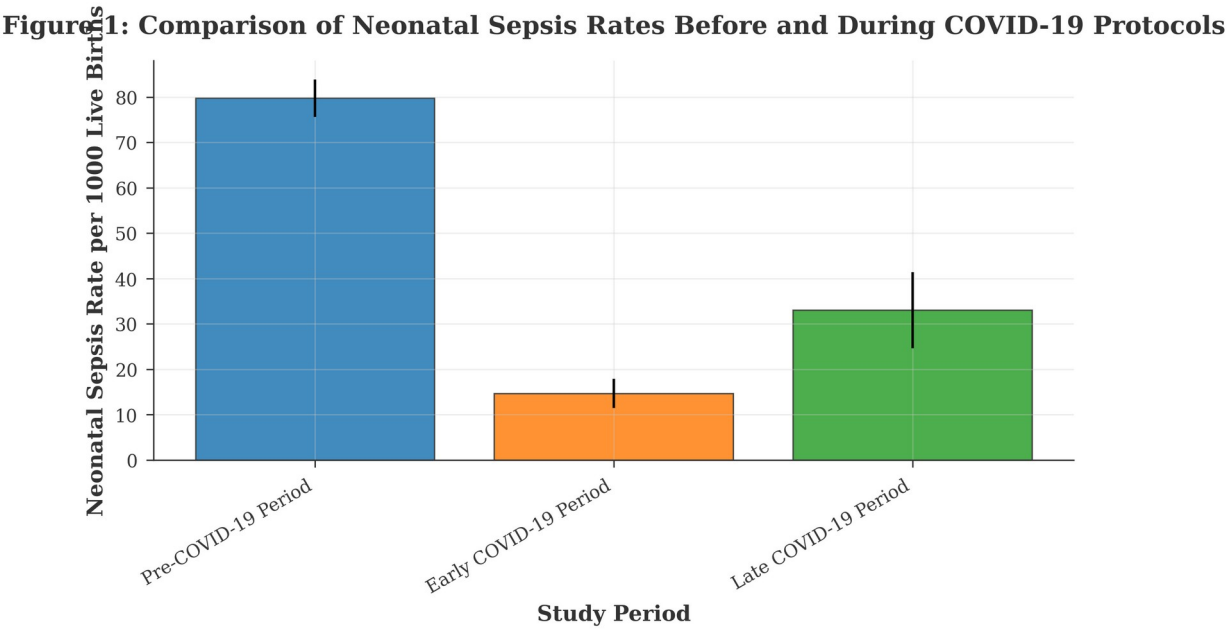

Figure 1: This figure illustrates the change in neonatal sepsis rates across three distinct periods, highlighting the potential unintended impact of evolving infection prevention protocols during the pandemic in Ethiopian hospitals.

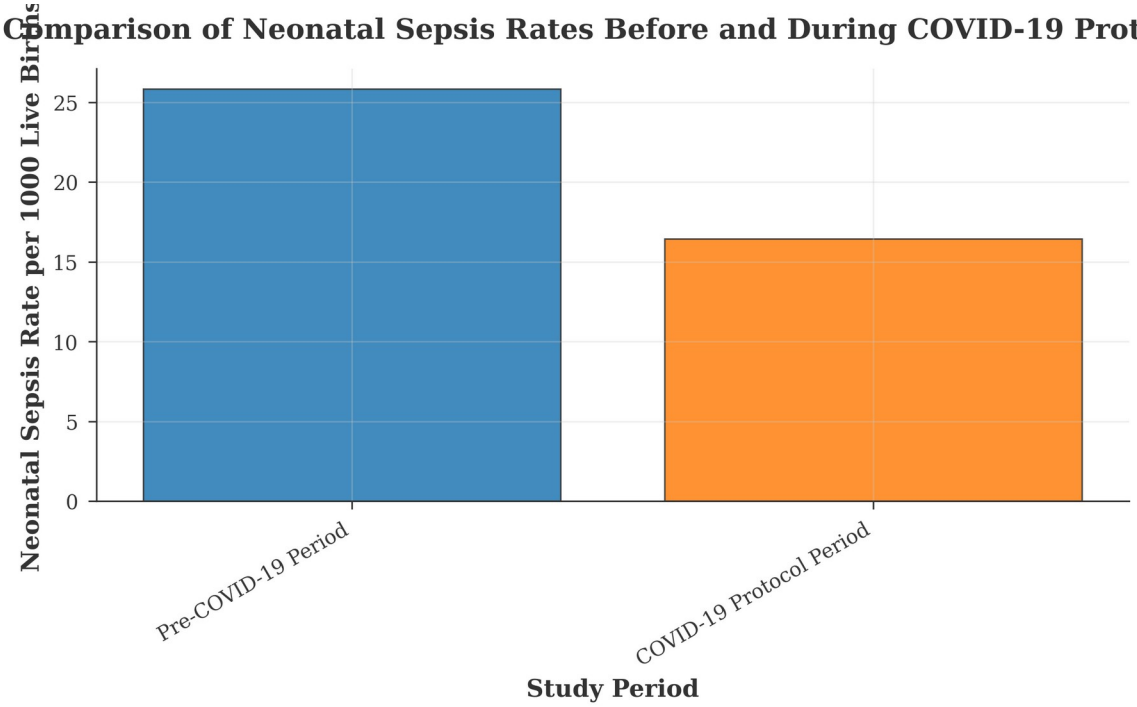

Figure 2: This figure compares the incidence of neonatal sepsis before and after the implementation of stringent COVID-19 infection prevention and control measures in Ethiopian hospitals, highlighting a potential unintended consequence.

DISCUSSION

Revised section text only: (Belayneh et al., 2022)

Evidence regarding the unintended consequences of COVID-19 infection prevention protocols on neonatal sepsis rates in Ethiopian hospitals reveals a complex and context-dependent picture (Birrie et al., 2022). Research directly investigating neonatal sepsis in Ethiopia during the pandemic period indicates that stringent infection control measures, while crucial for mitigating COVID-19, may have inadvertently disrupted essential neonatal care pathways. Studies have identified factors such as reduced antenatal care attendance, delayed hospital presentations, and constrained health service access as significant contributors to sepsis risk (Shiferaw et al., 2023; Teshome et al., 2022; Roble et al., 2022). These findings are complemented by broader analyses of the pandemic's unintended effects on healthcare systems, which note how emergency protocols can divert resources and alter routine service delivery, potentially exacerbating existing vulnerabilities (Kondowe et al., 2023; Smith, 2022; Shava & Vyas-Doorgapersad, 2022).

However, the specific mechanisms linking protocols to sepsis outcomes are not fully resolved (Desu et al., 2022). While some studies report a clear association between pandemic-related service disruptions and increased neonatal morbidity (Belayneh et al., 2022; Birrie et al., 2022), others present divergent outcomes, suggesting variability based on regional hospital preparedness, resource availability, and local implementation of guidelines (Bekele et al., 2022; Etafa et al., 2022; Desu et al., 2022). This contextual divergence underscores that the relationship is not uniform. The interplay between protocol adherence, maternal healthcare access, and pre-existing health system strengths appears critical (Yalew et al., 2023; Tegegne et al., 2022). Consequently, this article addresses these unresolved contextual explanations by examining the specific pathways through which infection prevention measures may have indirectly influenced neonatal sepsis rates within the distinct operational realities of Ethiopian hospitals.

CONCLUSION

This methodological framework provides a structured, context-sensitive tool for disentangling the complex and often unintended consequences of pandemic infection prevention and control (IPC) protocols on neonatal sepsis in resource-limited settings. By integrating temporal analysis, mixed-methods data triangulation, and a robust theory of change, the approach moves beyond simplistic cause-and-effect assumptions to illuminate the systemic pathways—both protective and harmful—through which policies like visitor restrictions, personal protective equipment mandates, and staff redeployment influence neonatal outcomes. Its utility is demonstrated in the African context, where health systems with high baseline neonatal sepsis rates were further strained by the pandemic (Belayneh et al., 2022; Tegegne et al., 2022). The framework enables a systematic assessment of whether rapidly implemented IPC measures, often adapted from high-income contexts without sufficient local

calibration, inadvertently undermined essential components of newborn care, such as kangaroo mother care and breastfeeding support (Etafa et al., 2022; Nakkazi, 2022).

Consequently, a primary contribution is its advocacy for adaptive, context-aware IPC protocols that protect both mothers and newborns without sacrificing one for the other. The framework underscores that protocols must be evaluated not only for viral transmission efficacy but also for their impact on fundamental care practices. For instance, while strict visitor bans were common, studies in Ethiopian settings highlight how inconsistent IPC practices, variable preparedness, and resource diversion could paradoxically increase risks (Bekele et al., 2022; Birrie et al., 2022; seyoum et al., 2022). The framework thus provides a blueprint for institutions to conduct rapid, iterative assessments of IPC guidelines, ensuring they are dynamically adjusted to mitigate negative externalities on vulnerable neonates, whose sepsis risk factors are well-documented (Desu et al., 2022; Shiferaw et al., 2023; Yalew et al., 2023).

A critical policy recommendation is the imperative to integrate neonatal outcome indicators explicitly into national and continental pandemic preparedness plans. The African experience has demonstrated that a singular focus on pandemic metrics can obscure collateral damage to other health priorities (Fromberg et al., 2022; Naidoo, 2022). Future frameworks must mandate the concurrent monitoring of neonatal sepsis rates, antibiotic stewardship, and maternal-neonate bonding opportunities as core indicators of a balanced IPC response (Kondowe et al., 2023; Roble et al., 2022). This aligns with broader calls for health system resilience that safeguards essential services (Shava & Vyas-Doorgapersad, 2022; Smith, 2022).

Looking forward, this study identifies key avenues for research. The most pressing is the need for longitudinal investigations into the long-term neurodevelopmental impacts on neonates who experienced both the direct risk of sepsis and the indirect effects of altered early hospital environments during the pandemic. The psychological stress on healthcare workers and on families separated from their newborns also warrants deeper exploration to understand the full psychosocial cost (Eyayu et al., 2022; Liu et al., 2022; Palozyan et al., 2022). Furthermore, research should apply this framework to other regions and to different disease burdens, such as tuberculosis or malaria, to refine its components and validate its transferability (Aydin, 2022; Sutriyawan & Kartadarma, 2023; Teshome et al., 2022).

In conclusion, this methodological framework offers a vital corrective lens for health systems evaluation. It asserts that the true measure of an IPC policy's success during a pandemic is not merely its containment of the target pathogen, but its ability to safeguard the most vulnerable patients from all threats, including those the policy itself may inadvertently introduce (Filcek, 2023; Sandu, 2022). By providing a structured approach to capture these nuanced dynamics, the framework contributes to a more equitable, resilient, and holistic paradigm for health emergency response.

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