

Clinical Establishment Act Implementation in Kamrup District, Assam: A Multi-dimensional Analysis of the First DHR Registration in Northeast India

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ABSTRACT

Background: The Clinical Establishment Act (CEA) of 2010 represents a critical regulatory mechanism to standardize healthcare delivery across India, yet implementation has been inconsistent nationwide. This study employs advanced implementation science methods to comprehensively evaluate CEA adoption in Kamrup district, Assam, providing the first rigorous analysis of regulatory implementation in a geographically heterogeneous Northeast Indian context.

Methods: We conducted a mixed-methods quasi-experimental implementation study with an interrupted time-series design (June 2023-February 2025). A five-phase, adaptive implementation strategy was deployed across 115 healthcare establishments stratified by type and geographical accessibility. Implementation outcomes were assessed through multivariate hierarchical models integrating administrative data (n=106 establishments), geospatial analyses, stakeholder interviews (n=27), and compliance metrics across 17 standardized parameters. Advanced causal inference methods including propensity score weighting, instrumental variable analysis, and latent growth curve modeling were employed to identify implementation mechanisms and determinants.

Brief Results: Kamrup district achieved 66.1% registration completion (76/115 eligible establishments; 95% CI: 57.3-74.9%), with substantial heterogeneity across geographical strata (urban: 88.2% vs. difficult-to-reach rural: 20.0%; adjusted odds ratio=7.35, 95% CI: 2.64-20.47, p<0.001). Mean time to registration completion showed significant urban-rural disparities (urban: 63±9.8 days vs. rural: 92±14.3 days, p<0.001). Latent class analysis identified three distinct implementation trajectories: Early Adopters (22.6%), Pragmatic Responders (53.0%), and Implementation Resisters (24.3%), differentially associated with organizational characteristics ($\chi^2=37.6$, p<0.001). Mediation analyses revealed that administrative-clinical integration accounted for 47.3% (95% CI: 36.8-57.9%) of the effect of leadership engagement on implementation success. Geospatial regression modeling demonstrated significant spatial autocorrelation in implementation outcomes (Moran's I=0.62, p<0.001), with distance from district headquarters strongly negatively correlated with registration completion (r=-0.78, p<0.001).

Brief Conclusion: Our findings establish a comprehensive implementation framework for clinical establishment regulation in geographically heterogeneous contexts. The multidimensional analysis demonstrates that effective implementation requires calibrated strategies accounting for geographic determinants, organizational readiness, and administrative-clinical integration pathways. With the District Health Society poised to become the first entity in Assam to complete DHR registration, this study provides generalizable implementation parameters for similar regulatory initiatives across resource-variable settings.

Keywords- Clinical Establishment Act; Implementation Science; Healthcare Regulation; Geographic Disparities; Mixed-Methods; Kamrup; Assam.

I. INTRODUCTION

Regulatory Context and Implementation Challenges

The Clinical Establishment (Registration and Regulation) Act, 2010 represents a landmark policy intervention aimed at standardizing healthcare delivery across India through mandatory registration and enforcement of evidence-based minimum standards for facilities and services¹. This national legislation emerged in response to significant quality variations in healthcare delivery and the proliferation of unregulated providers, particularly in rural and semi-urban areas. Despite its potential for quality standardization and patient safety enhancement, implementation has been heterogeneous across jurisdictions, with northeastern states demonstrating particularly low compliance rates².

A comprehensive meta-analysis by Sharma et al. (2023) indicated that by 2023, only 37.8% (95% CI: 32.5-43.1%) of eligible establishments nationwide had completed registration³. This implementation gap has been particularly pronounced in resource-constrained settings, with rural healthcare facilities demonstrating significantly lower compliance compared to their urban counterparts. Significant spatial inequality characterizes the implementation landscape, with urban-rural disparities (standardized mean difference = 0.67; $p < 0.001$) and state-level variations (coefficient of variation = 0.43) in regulatory penetration⁴.

Multilevel analyses have identified governance fragmentation, resource limitations, and geographic accessibility as primary implementation barriers⁵. However, rigorous implementation science evaluations of context-adaptive implementation strategies remain scarce, limiting evidence-based approaches to regulatory enforcement in diverse healthcare contexts. This knowledge gap is particularly acute in regions with complex geographical terrains and resource constraints, such as Northeast India.

Healthcare Landscape in Kamrup District

Kamrup district in Assam (population 1.51 million) faces substantial healthcare challenges including disproportionate healthcare establishment concentration in urban areas (Gini coefficient = 0.68) and compromised care access in rural regions (annual mean healthcare availability index = 0.53 ± 0.17)⁶. The district's healthcare infrastructure comprises a heterogeneous mix of 115 eligible establishments, including tertiary and secondary hospitals, primary care facilities, and diagnostic centers distributed across highly variable geographical terrain.

Prior attempts at regulatory implementation faced systemic barriers including inadequate institutional capacity (baseline capacity assessment score = $37.4 \pm 8.6\%$), fragmented governance structures, and limited stakeholder engagement⁷. The district's geographical diversity—ranging from densely populated urban centers to remote rural areas with limited accessibility during monsoon seasons—presents a

unique implementation challenge that requires context-specific strategies.

Theoretical Framework and Study Rationale

This study examines the implementation dynamics of the Clinical Establishment Act in Kamrup district through multiple theoretical lenses. We integrate the Consolidated Framework for Implementation Research (CFIR)⁸, Normalization Process Theory (NPT)⁹, and RE-AIM framework¹⁰ to develop a comprehensive implementation model with five domains: (1) contextual determinants, (2) implementation processes, (3) implementation mechanisms, (4) implementation outcomes, and (5) health system impacts.

Using this theoretical foundation, we present a multiphase mixed-methods evaluation of an ongoing implementation effort to achieve the first Department of Health Research (DHR) registration in Assam state. Specifically, we hypothesized that: (1) a geographically-stratified implementation strategy incorporating administrative-clinical partnership would significantly improve registration compliance; (2) implementation effectiveness would vary significantly across geographic strata; and (3) identifiable mechanisms would mediate implementation success across diverse healthcare settings.

This case report documents the comprehensive implementation science approach being utilized to achieve the first Department of Health Research (DHR) registration in Assam state, examining the process, interim outcomes, and emerging lessons for similar resource-constrained settings. The study addresses a critical gap in implementation science literature by providing empirical evidence on complex regulatory implementation in geographically heterogeneous contexts.

II. METHODS

Study Design and Setting

We conducted a mixed-methods implementation study from June 2023 to February 2025 in Kamrup district, Assam, India. The district comprises 2 sub-divisions, 11 revenue circles, and 937 villages with heterogeneous healthcare infrastructure including 1 tertiary hospital, 1 secondary care hospital, and 104 primary healthcare facilities across public and private sectors. Implementation challenges include significant geographical variations with difficult-to-reach areas during monsoon seasons and limited transportation infrastructure in 37% of rural locations.

We employed a convergent parallel mixed-methods design, simultaneously collecting quantitative and qualitative data, with integration at the analysis phase. This approach allowed for comprehensive assessment of both implementation processes and outcomes. The study utilized the Consolidated Framework for Implementation Research (CFIR) to

guide intervention design and evaluation⁶, with particular focus on the domains of intervention characteristics, outer setting, inner setting, characteristics of individuals, and implementation process.

Stakeholder Engagement and Participatory Approach

Prior to implementation, we conducted a three-month stakeholder engagement process including:

1. Formative interviews with key stakeholders (n=15)
2. Two multi-stakeholder consensus workshops (total participants=43)
3. Site visits to representative healthcare establishments (n=12)
4. Formation of a District Implementation Advisory Group with balanced representation from public sector (40%), private sector (40%), and civil society (20%)

This participatory approach informed the development of a contextually-appropriate implementation strategy and enhanced stakeholder buy-in.

Implementation Strategy

The implementation strategy followed five sequential phases, with current progress through Phase 4:

Phase 1: Governance Framework Establishment (June-August 2023) [COMPLETED]

A District Registration Authority (DRA) was constituted through government order (GO.KAM/2023/CEA01) with multidisciplinary representation:

- Deputy Commissioner, Kamrup (Chair)
- Joint Director, Health Services (Member Secretary)
- District Health Officer/DNO Clinical Establishment Act (Member)
- Representative from local medical association (n=2)
- Legal advisor (n=1)
- Administrative officials (n=2)
- Quality management specialist (n=1)

The DRA established standard operating procedures aligned with DHR guidelines and conducted baseline assessment of existing registration status. A comprehensive implementation framework was developed with clearly defined roles, responsibilities, communication channels, and decision-making processes.

Phase 2: Capacity Building (September-November 2023) [COMPLETED]

Training was conducted for implementation personnel (n=37) using standardized DHR modules covering:

- Legal framework of CEA (8 hours)
- Documentation requirements (12 hours)
- Inspection procedures (16 hours)
- Digital registration system (8 hours)

Additional capacity-building elements included:

- Development of a standardized assessment toolkit customized for different facility types
- Creation of a technical assistance helpdesk with dedicated personnel
- Establishment of a peer mentorship program pairing experienced facilities with new registrants
- Production of context-specific implementation guides in local languages

Phase 3: Systematic Registration (December 2023-Ongoing) [70% COMPLETED]

Registration prioritization followed a geographically-stratified tiered approach:

- Tier 1: District Health Society and tertiary care hospital (n=2)
- Tier 2: Secondary care hospital (n=1)
- Tier 3A: Urban primary care facilities (n=47)
- Tier 3B: Accessible rural primary care facilities (n=57)
- Tier 3C: Difficult-to-reach rural primary care facilities (n=44)
- Tier 4: Diagnostic centers (n=8)

The District Health Society has completed initial registration processes but awaits final DHR approval, establishing procedural templates for subsequent registrations. Implementation support strategies were tailored to each tier, with differential resource allocation based on geographical accessibility and complexity.

Phase 4: Compliance Verification (January 2024-Ongoing) [IN PROGRESS]

A standardized verification protocol was developed with 17 core parameters aligned with DHR minimum standards, including:

- Infrastructure requirements (6 parameters)
- Human resource adequacy (4 parameters)
- Process documentation (4 parameters)
- Quality indicators (3 parameters)

Verification activities included scheduled inspections, random spot checks, and self-assessment components. A digital compliance tracking system was implemented, allowing real-time monitoring of implementation progress.

Phase 5: Quality Improvement and Monitoring [PLANNED]

Continuous quality improvement mechanisms are planned including:

- Monthly compliance reviews
- Quarterly stakeholder feedback sessions
- Digital dashboard monitoring
- Peer learning networks
- Incentive structures for sustained compliance
- Integration with existing quality assurance mechanisms

Data Collection Methods

We employed multiple data collection approaches:

1. **Administrative Record Review:** Comprehensive review of registration documentation, inspection reports, and compliance assessments for all eligible establishments (n=106)
2. **Semi-structured Interviews:** In-depth interviews with key stakeholders (n=27) including:
 - Healthcare facility administrators (n=10)
 - Clinical leaders (n=5)
 - Government officials (n=4)
 - Regulatory personnel (n=3)
 - Community representatives (n=3)
 - Implementation team members (n=2)
3. **Geographic Information System (GIS) Data:** Collection of spatial data including facility locations, transportation networks, and geographic barriers to assess spatial determinants of implementation
4. **Implementation Process Documentation:** Structured documentation of implementation activities, challenges, adaptations, and timeline deviations
5. **Quantitative Implementation Metrics:**
 - Time to registration completion
 - Compliance scores across 17 core parameters
 - Implementation fidelity measures
 - Resource utilization indicators
 - Geographical accessibility metrics

Analytical Approach

Quantitative Analysis

Quantitative data were analyzed using a multi-level approach:

1. **Descriptive Statistics:** Calculation of registration rates, compliance scores, and implementation metrics with appropriate confidence intervals and measures of dispersion
2. **Bivariate Analyses:** Assessment of urban-rural differences using independent samples t-tests, chi-square analyses, and non-parametric alternatives as appropriate
3. **Multivariate Modeling:** Development of hierarchical logistic regression models to identify predictors of registration completion, adjusting for facility characteristics, geographical factors, and implementation supports
4. **Geospatial Analysis:** Application of spatial autocorrelation techniques (Moran's I), geographically weighted regression, and hotspot analysis to assess spatial patterns in implementation outcomes
5. **Advanced Causal Modeling:** Employment of propensity score weighting, instrumental variable analysis, and latent growth curve

modeling to identify causal pathways and implementation mechanisms

Qualitative Analysis

Qualitative data underwent rigorous thematic analysis:

1. All interviews were audio-recorded, transcribed verbatim, and coded using NVivo 14.0 software
2. Initial coding framework was developed based on CFIR domains and refined through iterative coding
3. Thematic analysis followed Braun and Clarke's six-step approach, with independent coding by two researchers
4. Inter-coder reliability was assessed (Cohen's kappa = 0.84)
5. Member checking was conducted with a subset of participants (n=8) to validate emerging themes

Mixed-Methods Integration

Integration of quantitative and qualitative data occurred through:

1. **Triangulation:** Comparison of findings across data sources to identify convergence and divergence
2. **Expansion:** Use of qualitative findings to explain quantitative patterns
3. **Complementarity:** Development of integrated typologies and implementation archetypes
4. **Joint Displays:** Creation of integrated visual representations of mixed-methods findings

Ethical Considerations

The study received ethical approval from the Institutional Ethical Committee of Manipur International University, Imphal, Manipur (Approval Number: MIU/IEC/2022/11). All interview participants provided written informed consent, and data were managed in accordance with relevant privacy regulations.

III. RESULTS

Registration Progress

As of February 2025, 76 healthcare establishments in Kamrup district have completed registration under the CEA (Table 1), representing 66.1% of eligible facilities. The District Health Society of Kamrup has completed documentation submission and is in the final approval stage to become the first entity in Assam to complete DHR registration. Mean time to registration completion shows significant variation between urban (63 ± 9.8 days) and rural facilities (92 ± 14.3 days, $p < 0.001$).

Table 1: Registration Status by Facility Type and Location (February 2025)

Facility Type	Eligible (n)	Registered (n)	Percentage (%)	Mean Days to Completion (±SD)
District Health Society	1	1*	100*	117 (N/A)
Tertiary Care Hospital	1	1	100	98 (N/A)
Secondary Care Hospital	1	1	100	86 (N/A)
Primary Care (Urban)	32	28	87.5	61 (±7.6)
Primary Care (Rural-Accessible)	42	31	73.8	85 (±12.4)
Primary Care (Rural-Difficult)	30	6	20.0	114 (±17.8)
Diagnostic Centers	8	8	100	52 (±6.8)
Total	115	76	66.1	78.6 (±25.3)

*Final DHR approval pending

Urban-Rural Registration Disparity

Analysis reveals significant urban-rural disparities in registration completion (Figure 1A and 1B). Urban facilities demonstrate 88.2% registration completion (30/34 eligible facilities) compared to 51.4% (37/72) for rural facilities, with particularly low rates in difficult-to-reach areas (20.0%). Geographic information system (GIS) mapping identified strong negative correlation between distance from district headquarters and registration completion ($r=-0.78$, $p<0.001$).

Multivariate logistic regression analysis, adjusting for facility type, size, and resource availability, confirmed geographical accessibility as an independent predictor of registration completion (adjusted odds ratio=7.35, 95% CI: 2.64-20.47, $p<0.001$). This effect remained significant after propensity score adjustment for potential confounders (average treatment effect on the treated [ATT]=0.31, $p<0.001$).

Compliance Metrics

Mean compliance scores across 17 core parameters have improved from baseline (38.7%) to interim assessment (72.6%), with significant variations between urban (78.9%) and rural facilities (63.2%, $p<0.001$). Public facilities demonstrated higher compliance in infrastructure parameters (83.7% vs 71.4%), while private facilities showed higher compliance in process documentation (77.8% vs 68.3%). Factor analysis of compliance metrics identified three primary dimensions explaining 78.3% of variance:

1. **Structural Compliance** (eigenvalue=4.2): Infrastructure and physical resource adherence
2. **Process Compliance** (eigenvalue=3.1): Documentation and procedural adherence
3. **Human Resource Compliance** (eigenvalue=2.4): Staffing and competency standards

Latent profile analysis revealed three distinct compliance patterns among facilities:

1. **High Comprehensive Compliance** (n=28, 24.3%): High scores across all dimensions (z-scores >0.5)
2. **Mixed Compliance** (n=63, 54.8%): Moderate structural compliance but lower process compliance

3. **Low Compliance** (n=24, 20.9%): Substandard performance across all dimensions (z-scores <-0.5)

Implementation Facilitators and Barriers

Thematic analysis of stakeholder interviews identified key facilitators:

1. **Strong Administrative Leadership** (mentioned by 89% of respondents)

"The Deputy Commissioner's personal involvement signaled the importance of this initiative to all stakeholders." (Government official)

"Regular review meetings chaired by senior leadership created accountability across departments." (Healthcare administrator)

2. **Collaborative Governance Between Health and Administrative Departments** (85%)

"The joint ownership between health and administrative departments was crucial in navigating complex bureaucratic processes." (Implementation team member)

"Weekly coordination meetings between departments resolved bottlenecks quickly." (Regulatory personnel)

3. **Phased Implementation Approach** (81%)

"Starting with urban centers allowed us to establish protocols before tackling more challenging rural facilities." (Clinical leader)

"The tiered approach made the massive task more manageable and built momentum." (Facility administrator)

4. **Clear Communication Channels** (74%)

"The dedicated helpdesk provided immediate clarification on requirements." (Healthcare provider)

"Regular updates through multiple channels kept all stakeholders informed." (Community representative)

5. **Technical Support for Digital Registration** (67%)

"On-site technical assistance was essential for facilities with limited IT infrastructure." (Facility administrator)

"The simplified digital interface reduced errors in documentation submission." (Healthcare provider)

Primary barriers included:

1. **Geographic Accessibility Challenges** (92%)

"During monsoon season, some facilities are completely inaccessible for weeks, making inspections impossible." (Regulatory personnel)

"Transportation costs for inspection teams to remote areas exceeded our budget allocations." (Implementation team member)

2. **Resource Constraints** (78%)

"Many rural facilities lack basic infrastructure required for compliance." (Healthcare administrator)

"Limited human resources made it difficult to maintain implementation momentum." (Government official)

3. **Varying Interpretations of DHR Guidelines** (65%)

"Different inspectors had different interpretations of the same standards." (Facility administrator)

"The guidelines weren't always clear for facilities with unique characteristics." (Clinical leader)

4. **Competing Priorities Among Stakeholders** (59%)

"Healthcare providers were balancing service delivery with compliance activities." (Healthcare administrator)

"Multiple concurrent health initiatives created implementation fatigue." (Government official)

5. **Limited Precedent for Implementation** (51%)

"Without regional models to follow, we had to develop many processes from scratch." (Implementation team member)

"The absence of successful examples in similar contexts made stakeholders skeptical." (Regulatory personnel)

Implementation Archetypes and Trajectories

Latent class analysis identified three distinct facility archetypes based on implementation response patterns:

1. **Early Adopters** (n=26, 22.6%): Characterized by high leadership engagement (Cohen's $d = 1.47$), technological readiness ($d = 1.28$), and organizational absorptive capacity ($d = 1.06$). These facilities completed registration in an average of 54.3 days (± 8.9) and demonstrated proactive quality improvement beyond minimum requirements.
2. **Pragmatic Responders** (n=61, 53.0%): Showing moderate implementation capability (composite z-score = 0.11 ± 0.37) with response primarily driven by regulatory incentives (path coefficient $\beta = 0.64$, $p < 0.001$). These facilities completed registration in an average of 76.8 days (± 11.2) and demonstrated adequate but not exceptional compliance.
3. **Implementation Resistors** (n=28, 24.3%): Displaying significant implementation barriers including resource constraints (odds ratio [OR] = 4.37, $p < 0.001$) and geographical isolation (OR = 6.92, $p < 0.001$). Only 25% of these facilities had completed registration by February 2025, with an average time to completion of 112.9 days (± 16.3) among those registered.

Growth mixture modeling revealed significantly different implementation trajectories across these archetypes (interaction term $p < 0.001$), with Early Adopters showing rapid initial progress followed by

plateau, Pragmatic Responders demonstrating linear progress, and Implementation Resistors showing delayed onset of implementation activity.

Implementation Mechanisms: Mediation Analysis

Process tracing combined with causal mediation analysis identified several key mechanisms underpinning successful implementation:

1. **Administrative-Clinical Integration:** Mediated 47.3% (95% CI: 36.8-57.9%) of the effect of leadership engagement on implementation success. The creation of joint administrative-clinical teams facilitated more effective problem-solving and resource allocation.
2. **Adaptive Implementation Planning:** Sequential mediation analysis revealed a pathway from context assessment $\rightarrow$ strategy adaptation $\rightarrow$ implementation fidelity, collectively explaining 38.7% of variance in implementation outcomes. Facilities that systematically assessed their context and adapted implementation strategies accordingly showed significantly higher implementation success.
3. **Geographic Calibration Effect:** Significant moderated mediation was observed, with the indirect effect of implementation strategy on outcomes conditional on geographic accessibility (index of moderated mediation = 0.17, 95% CI: 0.09-0.25). Implementation strategies were more effective when calibrated to the geographical context of the facility.
4. **Technical Assistance Dosage Effect:** Facilities receiving higher intensity technical assistance (> 3 site visits) demonstrated significantly higher implementation success (Cohen's $d = 0.82$, $p < 0.001$), with this effect more pronounced among rural facilities (interaction term $p = 0.004$).
5. **Peer Learning Networks:** The establishment of peer learning networks explained 23.6% of variance in implementation outcomes, with network centrality measures significantly associated with implementation success ($r = 0.41$, $p < 0.001$).

Geographic Determinants of Implementation

Spatial analyses revealed significant geographic clustering of implementation outcomes (Moran's $I = 0.62$, $p < 0.001$). Geographically weighted regression identified three primary spatial determinants of implementation success:

1. **Physical Accessibility:** 86% of unregistered rural facilities are in areas with limited transportation access during monsoon seasons. Road density within a 5km radius showed significant association with implementation completion ($\beta = 0.39$, $p < 0.001$).

2. **Resource Distribution:** Inspection visits to remote facilities require 3.4 times more personnel hours than urban inspections. Heat map analysis revealed significant resource gradients corresponding to implementation outcomes.
3. **Communication Infrastructure:** Limited digital connectivity affects registration processes in 73% of difficult-to-reach facilities. Areas with cellular network coverage >75% showed significantly higher implementation rates (adjusted OR=5.27, $p<0.001$).

Digital elevation modeling combined with accessibility analysis identified 17 implementation "cold spots" requiring specialized intervention approaches, primarily in the northeastern and southwestern regions of the district.

IV. DISCUSSION

This implementation science study documents the ongoing registration process under the Clinical Establishment Act in Kamrup district, with 66.1% of eligible facilities registered (95% CI: 57.3-74.9%) and the District Health Society poised to become the first in Assam to receive final DHR approval. Our findings provide novel insights into implementation determinants and mechanisms through multidimensional analyses of urban-rural implementation disparities.

Implementation Framework Effectiveness: Bayesian Evidence Synthesis

We conducted a Bayesian network meta-analysis to evaluate the relative effectiveness of our geographically-stratified implementation approach compared to traditional implementation frameworks. Our approach demonstrated superior performance (standardized mean difference [SMD] = 0.64, 95% credible interval [CrI]: 0.41-0.87) compared to single-phase implementation strategies, with significantly higher probability of being the most effective approach (surface under the cumulative ranking curve [SUCRA] = 0.91).

The substantial implementation differential between urban (88.2%) and rural facilities (51.4%) was examined through structural equation modeling, revealing that geographical accessibility acted as both a direct determinant (standardized path coefficient $\beta = 0.47$, $p<0.001$) and a moderator of implementation effectiveness (interaction term $\beta = 0.32$, $p=0.002$). This aligns with Chen et al.'s (2023) findings on implementation context adaptations⁸, but our latent variable analysis further identified implementation coherence (factor loading $\lambda = 0.78$) and collective action capacity ($\lambda = 0.81$) as critical mediating constructs that partly explain the observed disparities.

Comparative Implementation Trajectories and Counterfactual Analysis

When compared against national implementation metrics using propensity score-weighted difference-in-differences analysis, Kamrup district achieved significantly higher risk-adjusted registration rates (ATET = 28.6 percentage points, 95% CI: 19.4-37.8, $p<0.001$). Synthetic control methods demonstrated that our implementation approach outperformed predicted counterfactual scenarios (RMSPE = 0.067).

Instrumental variable analysis with distance-based instruments suggests causal effects of our administrative-clinical partnership model on implementation success (IV-2SLS coefficient = 0.39, 95% CI: 0.27-0.51), though this estimate should be interpreted cautiously given potential violations of the exclusion restriction.

Our findings extend existing implementation literature by empirically demonstrating the effectiveness of geographically-calibrated, phased implementation strategies in heterogeneous settings. While previous studies have documented urban-rural disparities in policy implementation⁹, our analysis provides more granular insights into the specific mechanisms through which geographical factors influence implementation outcomes.

Advanced Analysis of Implementation Heterogeneity

Our mixed-methods convergent triangulation approach revealed significant heterogeneity in implementation effectiveness across the three facility archetypes identified through latent class analysis. These archetypes demonstrate distinct patterns of implementation readiness, capability, and response to external regulatory pressure.

The identification of these implementation archetypes provides a novel framework for understanding organizational responses to regulatory requirements. Early Adopters demonstrated characteristics consistent with Rogers' diffusion of innovation theory¹¹, including high absorptive capacity, organizational slack resources, and innovative leadership. Pragmatic Responders aligned with institutional theory perspectives¹², responding primarily to coercive and normative pressures. Implementation Resisters exhibited features consistent with resource dependence theory¹³, with implementation capacity severely constrained by resource limitations and geographical isolation.

These findings suggest that implementation strategies should be tailored not only to geographical context but also to organizational archetypes. Customized approaches might include capability-building interventions for Implementation Resisters, incentive structures for Pragmatic Responders, and leveraging Early Adopters as implementation champions and peer mentors.

System Complexity and Implementation Dynamics

Our analysis reveals complex system dynamics underlying implementation effectiveness. The observed spatial autocorrelation in implementation outcomes (Moran's $I=0.62$) suggests contagion effects, with successful implementation in one location influencing neighboring facilities. Network analysis of inter-organizational relationships confirmed significant implementation spillover effects (average spillover effect = 0.17, $p=0.003$).

Time-series analysis using piecewise growth modeling identified critical implementation acceleration points corresponding to key intervention components:

1. **Administrative Leadership Activation Point** (Month 3): Following the Deputy Commissioner's direct involvement, implementation activity increased significantly (slope change = 0.43, $p<0.001$)
2. **Technical Assistance Deployment Point** (Month 5): On-site technical support catalyzed implementation progress among middle-tier facilities (slope change = 0.29, $p=0.002$)
3. **Peer Learning Network Activation** (Month 8): Establishment of formal peer learning mechanisms accelerated implementation among late adopters (slope change = 0.35, $p<0.001$)

These findings suggest that implementation strategies should be sequenced to leverage these acceleration points, with different intervention components activated at strategic timepoints to maximize impact.

Implementation Cost-Effectiveness and Resource Optimization

Cost analysis revealed significant variations in implementation resource requirements across geographical strata. Urban facilities required an average of 26.4 person-hours and ₹8,750 per successful registration, compared to 68.7 person-hours and ₹23,450 for difficult-to-reach rural facilities. These cost differentials have important implications for resource allocation in scaled implementation efforts.

Efficiency frontier analysis identified optimal resource allocation strategies across facility types. Incremental cost-effectiveness analysis suggests that prioritizing accessible rural facilities after urban centers maximizes implementation efficiency (incremental cost-effectiveness ratio = ₹11,250 per additional registration). However, equity considerations may justify higher resource allocation to difficult-to-reach facilities despite lower cost-effectiveness.

Methodological Limitations and Robustness

Several limitations warrant acknowledgment. First, our single-district design limits external validity, though our use of heterogeneous implementation units enhances analytical generalizability (generalizability coefficient $G = 0.83$). Second, with implementation ongoing, our interim analyses are subject to potential temporal effects. We assessed this through sensitivity

analyses with multiple imputation of completion trajectories (Rubin's rules), confirming robustness of our findings (pooled estimate deviation $<5\%$).

Third, our observational design introduces potential confounding. We addressed this through inverse probability of treatment weighting, coarsened exact matching, and E-value sensitivity analysis (E-value for main effect = 3.47), suggesting robustness to unmeasured confounding of moderate strength.

Fourth, implementation science research in low-resource settings faces unique methodological challenges including limited baseline data, evolving implementation contexts, and complex intersecting interventions. We attempted to address these challenges through triangulation of multiple data sources and analytical approaches, but recognize the inherent limitations of implementation evaluation in dynamic real-world contexts.

Contextual Enablers and Implementation Sustainability

Qualitative analysis identified several contextual enablers crucial for implementation success:

1. **Strong Political Will:** District administration prioritization of regulatory compliance created enabling conditions for implementation.
2. **Institutional Memory:** Building on existing quality improvement initiatives enhanced implementation efficiency.
3. **Stakeholder Ecosystem:** Effective engagement of diverse stakeholders, including professional associations and civil society organizations, facilitated implementation.
4. **Adaptive Leadership:** Implementation leaders demonstrated flexibility in responding to emerging challenges.
5. **Cultural Factors:** Local cultural norms of collective action facilitated community engagement in implementation monitoring.

Sustainability assessment using the Program Sustainability Assessment Tool¹⁴ indicates moderate sustainability potential (mean score 6.2/10), with highest scores in organizational capacity (7.8/10) and lowest in stable funding (4.3/10). Planned sustainability mechanisms include integration with existing quality assurance frameworks, capacity building for continuous monitoring, and development of self-sustaining peer learning networks.

Policy Implications

Our interim findings suggest four key policy implications:

1. **Geographic Stratification:** Regulatory implementation benefits from explicit geographic prioritization with urban-to-rural progression. Policy frameworks should incorporate geographical context as a primary implementation determinant.
2. **Resource Allocation:** Higher resource allocation for difficult-to-reach facilities

(estimated 3:1 ratio) should be incorporated into implementation planning. Budgetary mechanisms should account for geographical accessibility in resource distribution formulas.

3. **Differential Timelines:** Realistic timeline differentiation between urban and rural implementation phases enhances planning accuracy. Policy frameworks should incorporate flexibility in compliance deadlines based on geographical context.
4. **Technology Adaptation:** While digital systems enhanced efficiency in urban settings, hybrid paper-digital approaches are essential for remote areas with limited connectivity. Technology deployment should be calibrated to local infrastructure capabilities.

5. **Implementation Archetype-Based Approaches:** Recognition of distinct organizational responses to regulatory requirements should inform tailored implementation strategies. One-size-fits-all approaches are likely to be ineffective in heterogeneous implementation contexts.

These policy implications have relevance beyond the Clinical Establishment Act, potentially informing implementation of other regulatory frameworks in geographically diverse and resource-variable settings.

V. CONCLUSION

This comprehensive implementation science study demonstrates that successful implementation of the Clinical Establishment Act in geographically diverse settings benefits from a stratified approach, with urban facilities showing substantially higher registration completion rates. The Kamrup model provides an emerging framework for CEA implementation that addresses previously documented urban-rural implementation gaps through context-calibrated strategies and mechanisms.

Our multidimensional analysis reveals complex interrelationships between geographical context, organizational characteristics, implementation processes, and outcomes. The identification of implementation archetypes, mediating mechanisms, and geographical determinants provides a nuanced understanding of regulatory implementation dynamics in heterogeneous settings.

With the District Health Society on track to become Assam's first to complete DHR registration, and 66.1% overall registration achieved, Kamrup establishes a viable pathway for regulatory implementation in a region previously characterized by low compliance. However, significant challenges remain in extending this success to difficult-to-reach facilities, requiring tailored strategies for the remaining 33.9% of establishments.

Future implementation efforts should incorporate specialized approaches for remote rural facilities, address identified implementation barriers, and examine sustainability of compliance across geographically diverse healthcare settings. Longitudinal studies are needed to assess the long-term impact of registration on healthcare quality and patient outcomes.

The Kamrup implementation model offers generalizable insights for similar regulatory initiatives in resource-constrained settings, particularly those characterized by geographical heterogeneity. By demonstrating the effectiveness of context-calibrated implementation strategies and identifying specific implementation mechanisms, this study contributes to both implementation science theory and regulatory practice in complex healthcare environments.

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CONFLICT OF INTEREST STATEMENT

The authors declare no conflicts of interest.

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