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STANDARD OF CARE IN MEDICAL NEGLIGENCE: A STUDY OF INDIAN JUDICIARY WITH REFERENCE TO NAGALAND

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ABSTRACT

The concept of the *standard of care* constitutes the cornerstone of medical negligence jurisprudence in India, serving as the primary criterion for determining professional liability. Indian courts have largely relied on the *Bolam principle* and the notion of the “*reasonable medical practitioner*” to assess whether a medical professional has acted with due skill and diligence. While this framework has contributed to doctrinal clarity and consistency, its uniform application across diverse healthcare settings raises important concerns. This paper examines the judicial evolution of the standard of care in India and evaluates its applicability in the context of Nagaland, a region characterized by infrastructural constraints, limited medical resources, and geographical challenges. Through a doctrinal and analytical approach, the study highlights the gap between judicially evolved standards and the realities of healthcare delivery in resource-constrained settings. It argues that a strictly uniform standard may lead to inequitable outcomes by failing to account for systemic limitations faced by medical practitioners in such regions. The paper advocates for a context-sensitive interpretation of the standard of care that incorporates relevant factors such as availability of infrastructure, level of expertise, and situational urgency, while maintaining the core principles of accountability and patient protection. It concludes that such an approach would promote substantive fairness and enhance the effectiveness of medical negligence law in addressing regional disparities within India.

Keywords: Medical Negligence, Standard of Care, Bolam Principle, Indian Judiciary, Nagaland, Healthcare Law, Resource-Constrained Settings, Patient Rights

1 INTRODUCTION

Medical negligence constitutes a significant and evolving component of both tortious liability and consumer protection jurisprudence within the broader framework of healthcare law in India. With the increasing recognition of patients as rights-bearing individuals and the expansion of medical services under the ambit of legal scrutiny, the question of accountability in medical practice has assumed considerable importance. Central to this discourse is the concept of the “standard of care,” which serves as the foundational criterion for determining whether a medical professional has

discharged their duty with the requisite degree of skill, competence, and diligence expected in a given set of circumstances.

The determination of this standard has been shaped primarily through judicial interpretation. Indian courts, drawing from common law principles, have developed a structured approach that seeks to balance competing considerations—on the one hand, safeguarding patients from negligent treatment, and on the other, preserving the autonomy and discretion of medical practitioners in making clinical decisions. The reliance on principles such as the Bolam test reflects a preference for evaluating medical conduct against the practices accepted by a responsible body of professionals, thereby acknowledging the specialized and often uncertain nature of medical science.

At the same time, the evolution of medical negligence jurisprudence in India has been accompanied by a gradual shift towards greater patient-centricity. Issues such as informed consent, transparency in treatment, and the right to receive adequate medical care have increasingly been emphasized within judicial reasoning. This reflects a broader constitutional orientation, wherein access to healthcare is linked to the right to life and personal liberty. Consequently, the standard of care is no longer viewed solely through the lens of professional norms but also in light of patient rights and expectations.

Despite these developments, a critical challenge arises in the application of a uniform standard of care across a country characterized by significant socio-economic, geographical, and infrastructural diversity. India's healthcare landscape is marked by stark disparities between well-equipped urban hospitals and resource-constrained rural or remote regions. In states such as Nagaland, factors including difficult terrain, dispersed populations, limited availability of trained medical personnel, and inadequate healthcare infrastructure create conditions that differ substantially from those in metropolitan areas. Medical practitioners in such settings often operate under constraints that directly impact their ability to adhere to ideal or textbook standards of treatment.

The application of a uniform judicial standard in such diverse contexts raises important questions of fairness and practicality. A standard derived largely from urban, resource-rich environments may not adequately account for the limitations faced in regions with restricted access to medical facilities and technology. This, in turn, creates the risk of imposing liability in situations where deviations from ideal practices are not the result of negligence, but rather of systemic and structural constraints. At the same time, any relaxation of standards must be carefully calibrated to ensure that patient safety and rights are not compromised.

In this context, Nagaland provides a particularly relevant case study for examining the interaction between legal standards and ground realities. The state's healthcare system reflects many of the challenges associated with remote and underserved regions, thereby offering a lens through which the adequacy of existing legal principles can be critically assessed. By situating the analysis within this specific regional context, the present study seeks to move beyond abstract doctrinal discussions and engage with the practical implications of the standard of care.

Accordingly, this paper examines the judicial understanding of the standard of care in medical negligence under Indian law and evaluates its applicability in the context of Nagaland. It seeks to explore whether the existing framework sufficiently accommodates regional disparities or whether there is a need for a more nuanced, context-sensitive approach. The paper argues that while consistency in legal standards is essential for ensuring predictability and coherence, a contextualized interpretation of the standard of care—one that takes into account the conditions under which medical services are delivered—may better align legal expectations with practical realities. Such an approach would not dilute the principle of accountability but rather enhance substantive fairness by recognizing the diversity inherent in India's healthcare system.

2 CONCEPTUAL FRAMEWORK: UNDERSTANDING STANDARD OF CARE

The doctrine of medical negligence is anchored in the foundational principles of negligence, namely the existence of a *duty of care*, a *breach of duty*, and *damage* resulting from such breach. In the context of medical practice, these elements assume a specialized character because the relationship between a doctor and a patient is inherently fiduciary and involves a high degree of trust, skill, and professional discretion. The duty of care arises once a medical professional undertakes to treat a patient, thereby obligating the practitioner to exercise a reasonable degree of competence, knowledge, and care in the course of diagnosis and treatment.

The concept of the “*standard of care*” operates as the central evaluative tool in determining whether a breach has occurred. It refers to the level of skill and caution that a reasonably competent medical practitioner would exercise under similar circumstances. This standard does not demand perfection or guarantee successful outcomes. Instead, it requires that the practitioner act in a manner consistent with accepted medical practices and with reasonable prudence.

The inherent uncertainty and complexity of medical science are thus recognized within this framework, ensuring that liability is not imposed merely because a treatment fails or an adverse outcome occurs.

Historically, Indian courts have adopted the *Bolam principle* as the primary test for determining the standard of care in medical negligence cases. According to this principle, a medical professional is not considered negligent if the course of action taken is supported by a responsible body of medical opinion. This approach places significant reliance on professional standards and peer evaluation, thereby acknowledging that medical decisions often involve a range of acceptable alternatives. It also reflects judicial restraint in interfering with clinical judgment, particularly in areas involving technical expertise.

However, the application of the *Bolam principle* has not remained static. Over time, judicial reasoning has evolved to incorporate broader considerations that extend beyond professional acceptance. Courts have increasingly emphasized the importance of patient autonomy and the right to make informed decisions regarding treatment. The requirement of *informed consent* has emerged as a significant component of the standard of care, obligating medical practitioners to disclose relevant information about risks, alternatives, and potential outcomes. This shift indicates a movement towards a more patient-oriented understanding of medical responsibility, where the interests and rights of the patient are given greater prominence.

Despite this gradual evolution, the standard of care continues to be fundamentally grounded in the notion of the “reasonable medical practitioner.” This construct is inherently objective in nature, as it seeks to measure conduct against a generalized benchmark rather than the subjective capabilities of an individual doctor. At the same time, it is not entirely rigid, as it allows for consideration of the circumstances in which the medical professional operates. Factors such as the urgency of the situation, the information available at the time, and the level of expertise expected in a particular field may influence the assessment of reasonableness.

A critical issue that arises within this conceptual framework concerns the extent to which contextual factors should shape the determination of the standard of care. The traditional formulation tends to assume a relatively uniform level of resources and facilities, which may not reflect the realities of healthcare delivery in diverse settings. In regions with limited infrastructure, shortages of trained personnel, and restricted access to advanced diagnostic tools, medical practitioners may be compelled to make decisions under constraints that differ significantly from those in well-equipped environments.

This raises the question of whether the “reasonable practitioner” standard should be interpreted as a uniform national benchmark or whether it should be adapted to reflect variations in local conditions. A strictly uniform approach may promote consistency and predictability in legal outcomes, but it may also risk imposing unrealistic expectations in contexts where ideal standards cannot be met due to systemic limitations. Conversely, a more contextual approach may better align legal standards with practical realities, but it must be carefully structured to avoid diluting accountability or compromising patient protection.

The conceptual framework of the standard of care therefore exists at the intersection of objectivity and contextual sensitivity. It seeks to establish a common benchmark for evaluating medical conduct while also allowing room for judicial discretion in assessing the circumstances of each case. The challenge lies in ensuring that this balance is maintained in a manner that upholds both professional integrity and patient rights, particularly in a country marked by significant disparities in healthcare infrastructure and access.

3 JUDICIAL APPROACH IN INDIA

Indian jurisprudence on medical negligence has evolved through a series of landmark judicial pronouncements that have progressively clarified the contours of the *standard of care*. The courts have played a central role in balancing professional autonomy with patient rights, while also ensuring that liability is imposed only in cases of clear and demonstrable negligence.

3.1 Landmark Judicial Decisions in India

One of the most significant decisions in this domain is *Jacob Mathew v. State of Punjab* (**Jacob Mathew v. State of Punjab, (2005) 6 SCC 1**). In this case, the Supreme Court authoritatively affirmed the applicability of the *Bolam principle* within the Indian legal system. The Court held that a medical professional would not be held liable if their conduct conformed to a practice accepted by a responsible body of medical practitioners skilled in that particular field. Importantly, the Court distinguished between civil and criminal negligence, observing that criminal liability requires a much higher threshold, namely *gross negligence* or *recklessness*. The judgment emphasized that an error of judgment or an accident is not proof of negligence, thereby safeguarding medical professionals from unwarranted prosecution.

Another foundational case is *Indian Medical Association v. V.P. Shantha* (**Indian Medical Association v. V.P. Shantha, (1995) 6 SCC 651**), wherein the Supreme Court brought medical services within the ambit of the Consumer Protection Act. This decision marked a significant shift by recognizing patients as *consumers* and medical services as *services*, thereby enabling patients to seek redressal through consumer forums. The judgment strengthened accountability while also expanding access to justice in cases of medical negligence.

In *Kusum Sharma v. Batra Hospital* (**Kusum Sharma v. Batra Hospital & Medical Research Centre, (2010) 3 SCC 480**), the Supreme Court laid down detailed guidelines for determining medical negligence. The Court reiterated that the standard of care must be judged from the perspective of a *reasonable and competent practitioner* and cautioned against the tendency to attribute negligence merely because of an unsuccessful outcome. It emphasized that courts should not substitute their own views for that of medical experts and must rely on credible medical evidence. The judgment further reinforced judicial restraint and the importance of context in evaluating professional conduct.

Similarly, in *Samira Kohli v. Dr. Prabha Manchanda* (**Samira Kohli v. Dr. Prabha Manchanda, (2008) 2 SCC 1**), the Court elaborated on the doctrine of *informed consent*. It held that performing a medical procedure without the patient's consent, except in emergencies, would amount to negligence. This case marked a shift towards a more patient-centric approach by recognizing the autonomy and decision-making rights of patients within the treatment process.

Collectively, these decisions illustrate that Indian courts have consistently upheld the *Bolam principle* while simultaneously incorporating elements of patient rights, accountability, and procedural fairness. The judiciary has also acknowledged that medicine is not an exact science and that differences in professional opinion or adverse outcomes do not automatically establish negligence. At the same time, courts have maintained that liability arises when there is a clear and unreasonable deviation from accepted medical practice resulting in harm.

3.2 Cases and Judicial Trends in Nagaland

In contrast to the relatively well-developed jurisprudence at the national level, there is a limited body of reported case law specifically arising from Nagaland on medical negligence. This absence is not necessarily indicative of a lack of incidents, but may instead reflect factors such as limited litigation, low levels of legal awareness, infrastructural constraints, and reliance on informal or community-based dispute resolution mechanisms.

Medical negligence cases from Nagaland, when they do arise, are typically adjudicated either through consumer forums or fall within the jurisdiction of the Gauhati High Court, which exercises jurisdiction over the state. As a result, the legal principles applied in such cases are largely derived from the broader framework of Indian jurisprudence rather than region-specific judicial developments.

An observable trend is that courts dealing with cases from the region continue to apply the same *standard of care* as articulated in leading Supreme Court judgments, without explicit modification to account for local constraints. This suggests a reliance on uniform legal standards, even in contexts where healthcare delivery conditions differ significantly from those in urban centres.

At the same time, the scarcity of reported judgments highlights a gap in both legal scholarship and judicial engagement with region-specific issues in medical negligence. The absence of localized precedents means that questions relating to the applicability of the "*reasonable medical practitioner*" standard in resource-constrained settings remain largely unexplored in formal judicial discourse.

This gap presents an opportunity for academic inquiry and policy consideration. By examining Nagaland as a case study, it becomes possible to assess whether existing legal principles adequately address the realities of healthcare delivery in such regions or whether there is a need for a more context-sensitive judicial approach.

4 STANDARD OF CARE IN RESOURCE-CONSTRAINED SETTINGS: THE CASE OF NAGALAND (WITH DATA SUPPORT)

Nagaland presents a distinct and contextually significant setting for examining the application of the *standard of care* in medical negligence law. The state is characterized by difficult geographical terrain, dispersed rural populations, and a predominantly tribal demographic structure. Districts such as Kohima and Dimapur serve as relatively better-equipped urban centres, while regions such as Mon, Tuensang, Longleng, Kiphire, and Phek reflect more pronounced infrastructural and accessibility challenges. This uneven distribution of healthcare facilities creates a layered healthcare reality within the state itself.

The healthcare infrastructure in Nagaland continues to face multiple structural constraints. There exists a persistent shortage of trained medical professionals, particularly specialists, which directly affects the quality and range of services

that can be provided. Recent estimates indicate that the doctor-to-population ratio in Nagaland is approximately **1:4000**, which is significantly below the World Health Organization's recommended ratio of 1:1000. This shortage is further compounded by uneven distribution, with rural districts experiencing greater scarcity than urban centres.

In addition to human resource limitations, infrastructural constraints remain a major concern. According to Rural Health Statistics and related assessments, Nagaland has faced **shortfalls in Primary Health Centre infrastructure**, being identified as one of the states with insufficient PHC facilities relative to population needs. Further, available data indicate that healthcare institutions in rural areas often serve large populations and multiple villages, placing additional strain on limited resources.

District-level data further illustrates these disparities. For instance, Phek district alone has around **70 health units**, including one district hospital, three community health centres, and several primary health centres and sub-centres, which are unevenly distributed across geographically challenging terrain. Such distribution patterns highlight the gap between institutional presence and actual accessibility.

Referral systems, which are critical to effective healthcare delivery, are also affected by logistical challenges. Patients requiring specialized treatment are often referred to higher-level institutions located in Kohima, Dimapur, or even outside the state. These referrals involve not only financial costs but also delays due to transportation barriers and limited connectivity. In emergency situations, such delays may significantly impact patient outcomes, complicating the attribution of responsibility in cases of alleged negligence.

Within this framework, medical practitioners are frequently required to make clinical decisions under conditions of uncertainty, limited resources, and time constraints. The absence of advanced equipment or specialist consultation may necessitate reliance on basic clinical evaluation and experiential judgment. In such circumstances, decisions that may appear inadequate when evaluated against urban standards may, in reality, represent the most reasonable course of action available within the given constraints.

An additional dimension that merits consideration is the role of customary tribal practices and community-based systems of dispute resolution in Nagaland. The state operates under a unique constitutional framework that recognizes customary laws and practices of its tribal communities. In many rural areas, disputes, including those relating to harm or perceived wrongdoing, may be addressed through village councils or customary institutions rather than formal legal mechanisms. While medical negligence as a formal legal concept may not always be articulated within these systems, notions of responsibility, compensation, and reconciliation are nonetheless present.

This coexistence of formal legal frameworks and customary systems has implications for the enforcement and interpretation of the *standard of care*. It may influence both the likelihood of litigation and the expectations placed upon medical practitioners. The relatively low number of reported medical negligence cases from Nagaland may partly reflect these socio-legal dynamics, in addition to infrastructural and awareness-related constraints.

Against this backdrop, the application of a uniform "*standard of care*", largely shaped by judicial interpretations grounded in urban and resource-rich environments, raises important concerns. A strict and unqualified application of such a standard risks overlooking the systemic limitations within which medical professionals in Nagaland operate. It may lead to the imposition of liability in situations where deviations from ideal medical procedures are not the result of individual negligence but arise from structural deficiencies.

At the same time, the lack of contextual sensitivity in legal standards may create a disincentive for medical professionals to serve in remote or underserved regions. The possibility of being judged against standards that do not adequately reflect ground realities may discourage practitioners from working in districts such as Mon or Kiphire, where healthcare needs are often the greatest.

This context underscores the need to examine whether the existing legal framework governing medical negligence sufficiently accommodates the realities of healthcare delivery in regions like Nagaland. It also highlights the importance of developing a more context-sensitive approach that aligns legal standards with infrastructural realities while maintaining the core objective of ensuring safe and accountable medical care.

5 CRITICAL ANALYSIS

A central tension in the law of medical negligence lies in reconciling the ostensibly objective nature of the *standard of care* with the inherently variable and situational realities of medical practice. The legal framework seeks to apply a uniform benchmark based on the conduct of a "*reasonable medical practitioner*", thereby ensuring consistency, predictability, and fairness in adjudication. However, this objectivity, while doctrinally sound, may not always account

for the diversity of conditions under which medical services are delivered, particularly in a country marked by significant regional disparities.

Uniform standards serve an important normative function. They establish a baseline of acceptable medical conduct, ensure that patient rights are uniformly protected, and prevent arbitrary or subjective determinations of negligence. They also reinforce public trust in the healthcare system by affirming that medical professionals are accountable to a consistent legal standard. However, the application of such uniformity without adequate regard to context risks producing outcomes that may be formally equal but substantively inequitable.

In resource-constrained settings, the gap between ideal standards and actual practice conditions becomes particularly pronounced. Medical practitioners in such environments are often required to operate with limited infrastructure, inadequate diagnostic tools, and insufficient specialist support. They may be compelled to make critical decisions in the absence of complete information or without access to optimal treatment options. Evaluating such decisions against standards derived from well-equipped urban hospitals may impose an unrealistic burden on practitioners and fail to reflect the constraints within which they function.

This disjunction has broader implications for healthcare delivery. The imposition of liability based on idealized standards may discourage medical professionals from working in remote or underserved regions, thereby exacerbating existing disparities in access to healthcare. It may also contribute to the practice of defensive medicine, wherein practitioners prioritize legal safety over clinical judgment. Such practices can lead to unnecessary referrals, over-prescription of diagnostic tests, or avoidance of high-risk cases, ultimately affecting the quality and accessibility of healthcare.

At the same time, the argument for contextual sensitivity must be approached with caution. A dilution of the *standard of care* under the guise of contextualization could undermine patient rights and weaken mechanisms of accountability. Patients in resource-constrained settings are equally entitled to protection from negligent treatment, and the law must ensure that contextual factors do not become a justification for substandard care or professional complacency.

The challenge, therefore, lies in striking a principled balance between uniformity and flexibility. The current judicial approach in India, while nuanced in its recognition of professional discretion and the complexities of medical science, does not explicitly articulate a structured framework for incorporating regional or infrastructural disparities into the assessment of negligence. Courts have acknowledged that circumstances matter, yet they have not systematically defined how such circumstances should influence the determination of the *standard of care*.

This lack of explicit guidance creates ambiguity and leaves room for inconsistent application of principles. Different courts may adopt varying approaches when confronted with similar factual situations, leading to uncertainty for both patients and medical practitioners. It also limits the ability of the legal system to respond effectively to the realities of healthcare delivery in diverse contexts.

A more clearly articulated framework, grounded in both legal principle and practical reality, would enhance coherence in judicial reasoning and promote fairness in outcomes. Such a framework would not undermine the integrity of the *standard of care* but would instead refine its application to ensure that it remains both just and contextually relevant.

6 NEED FOR CONTEXTUALIZED STANDARD OF CARE

The foregoing analysis indicates a compelling need for a more context-sensitive interpretation of the *standard of care* within Indian medical negligence law. Such an approach does not imply a lowering or dilution of standards. Rather, it involves adapting the application of existing legal principles to reflect the conditions under which medical services are actually delivered. The objective is to ensure that the assessment of negligence remains fair, realistic, and aligned with the operational environment of medical practice.

A contextualized standard would retain the core principle of evaluating conduct against that of a “*reasonable medical practitioner*”, but would interpret reasonableness in light of relevant situational factors. This would require courts to adopt a more nuanced inquiry that considers not only what ought ideally to have been done, but also what could reasonably have been done within the constraints faced by the practitioner.

Several factors may be relevant in this regard. The availability and adequacy of medical infrastructure is a primary consideration, as it directly influences the range of diagnostic and treatment options accessible to a practitioner. The level of expertise and specialization available in a particular setting is equally important, particularly in regions where general practitioners are required to perform functions that would ordinarily be handled by specialists. The urgency of the situation must also be taken into account, as emergency conditions often necessitate rapid decision-making with

limited information. Additionally, the accessibility of alternative facilities, including referral centres, plays a critical role in determining the reasonableness of the course of action adopted.

Incorporating these factors into the assessment of negligence would enable a more realistic evaluation of medical conduct without compromising the underlying objective of accountability. It would also align the legal standard with the principle of substantive equality, which recognizes that identical treatment of unequal situations may result in inequitable outcomes. By acknowledging contextual differences, the law can ensure that fairness is achieved not merely in form, but in substance.

At the same time, it is important that such contextualization operates within clearly defined limits. The core expectations of competence, diligence, and good faith must remain non-negotiable. Contextual factors should inform the application of the standard, not excuse conduct that falls below a minimum threshold of acceptable care. In this sense, contextualization should function as a tool for refining, rather than weakening, the legal framework.

A structured approach to contextualizing the *standard of care* would also enhance predictability and consistency in judicial decision-making. By explicitly recognizing relevant factors and articulating their role in the evaluation process, courts can provide clearer guidance to both medical practitioners and patients. This, in turn, would contribute to a more balanced and equitable system of medical liability, one that is responsive to the diversity of healthcare conditions across different regions of the country.

Ultimately, the adoption of a context-sensitive approach reflects an evolution in legal reasoning, one that seeks to harmonize doctrinal principles with social realities. In doing so, it strengthens the capacity of the law to deliver justice in a manner that is both principled and pragmatic.

7 CONCLUSION

The concept of the *standard of care* occupies a central position in the determination of medical negligence under Indian law. Judicial interpretation has, over time, developed a coherent framework grounded in the *Bolam principle* and the notion of the “reasonable medical practitioner.” This framework has sought to balance patient rights with professional autonomy while ensuring that liability is imposed only in cases of clear and demonstrable negligence.

However, as this paper has demonstrated, the application of a uniform standard across diverse healthcare settings raises important concerns. In regions such as Nagaland, where medical practitioners operate under significant infrastructural and logistical constraints, the strict application of standards derived from resource-rich environments may lead to outcomes that are formally consistent but substantively inequitable. The absence of explicit judicial guidance on incorporating contextual factors further contributes to ambiguity and inconsistency in the application of legal principles.

At the same time, any move towards contextualization must be carefully calibrated to ensure that it does not dilute the fundamental objective of protecting patients from negligent treatment. The challenge lies in developing a balanced approach that recognizes contextual realities while preserving the core principles of accountability, competence, and diligence.

In this regard, the following suggestions are proposed:

- Judicial Clarification:
- Courts may explicitly recognize relevant contextual factors in determining the *standard of care*, particularly in cases involving rural or resource-constrained settings. Such recognition would enhance transparency and consistency in judicial reasoning.
- Guidelines for Application
- There is a need for the development of judicial or regulatory guidelines that clearly outline the factors to be considered in assessing negligence across different contexts. This would assist courts in applying the law in a structured and predictable manner.
- Capacity Building
- Training and awareness programs may be undertaken to enhance legal literacy among medical practitioners, particularly in regions such as Nagaland. This would enable practitioners to better understand their legal obligations and rights.
- Infrastructure Development
- Strengthening healthcare infrastructure is essential to reducing the gap between expected standards and actual practice conditions. Investments in medical facilities, equipment, and human resources would contribute to improving both healthcare delivery and legal compliance.

- Policy Intervention
- Healthcare and legal policy frameworks may incorporate regional considerations, recognizing the diversity of conditions across different parts of the country. This would facilitate a more equitable approach to regulation and accountability.
- Documentation Practices
- Medical practitioners may be encouraged to maintain proper documentation of clinical decisions, resource constraints, and treatment processes. Such documentation can play a crucial role in the fair adjudication of negligence claims.
- In conclusion, a context-sensitive interpretation of the *standard of care* represents not a departure from established legal principles, but an evolution of them. By aligning legal standards with practical realities, the law can better achieve its dual objectives of fairness and accountability, particularly in diverse and resource-variable settings such as Nagaland.

STATEMENTS ON COMPLIANCE WITH ETHICAL STANDARDS

Disclosure of conflict of interest

The authors declare no conflicts of interest regarding this manuscript.

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