National Board of Examinations - Journal of Medical Sciences
Volume 4, Issue 5, Pages 645–650, May 2026
DOI 10.61770/NBEJMS.2026.v04.i05.001

EDITORIAL

India's Critical Transition in Regenerative Medicine: Confronting the Structural Challenges & A Solutions Framework

Minu Bajpai[1,*] and Abhijat C. Sheth[2]
[1]*Vice-President & Honorary Executive Director, National Board of Examinations in Medical Sciences, New Delhi*
[2]*Chairman of National Medical Commission & President, National Board of Examinations in Medical Sciences, New Delhi*

Accepted: 4-May-2026 / Published Online: 6-May-2026

India stands at a decisive juncture in the evolution of regenerative medicine. Over the past two decades, the country has developed a strong foundation in stem cell science, supported by academic excellence, clinical diversity, and a growing innovation ecosystem. However, the transition from exploratory research to **scalable, evidence-based regenerative medicine** remains incomplete. The core issue is not the absence of scientific capability, but the absence of **systemic coherence across regulation, translation, manufacturing, and delivery**.

At the forefront of this challenge is **regulatory fragmentation and enforcement**. Despite well-articulated national guidelines by the Indian Council of Medical Research and the Department of Biotechnology, oversight remains distributed across multiple bodies with overlapping mandates. This has resulted in inconsistent implementation and, more concerningly, the proliferation of unregulated stem cell clinics offering unproven therapies. Such practices not only expose patients to harm but also undermine the credibility of legitimate research efforts. The erosion of public trust is perhaps the most significant long-term consequence.

Closely linked to this is the **limited generation of high-quality clinical evidence**. While numerous pilot studies and early-phase trials have been conducted, there is a conspicuous absence of large, multicentric Phase II and III trials. Small sample sizes, heterogeneous methodologies, and inadequate long-term follow-up have prevented the establishment of robust evidence. Consequently, most stem cell applications remain confined to the experimental domain, unable to transition into standard-of-care protocols. This evidence deficit creates a paradox: innovation exists, but validation is insufficient.

*Corresponding Author: Minu Bajpai
Email: bajpai2b@gmail.com

The **translational gap between bench and bedside** further compounds this problem. India has demonstrated considerable strength in basic and early-stage research; however, the pipeline for late-stage translation remains weak. The absence of clinical-grade validation platforms, coordinated translational hubs, and integrated trial networks means that promising laboratory discoveries often fail to reach patients. This disconnect reflects a structural weakness in aligning scientific discovery with clinical application.

Equally critical is the **inadequate GMP (Good Manufacturing Practice) manufacturing capacity**. Regenerative therapies, by their very nature, require highly controlled, standardized production environments. India currently has a limited number of GMP-compliant facilities, and those that exist are often concentrated in a few urban centres. The high cost of establishing and maintaining such facilities further restricts expansion. Without scalable manufacturing infrastructure, even validated therapies cannot be delivered at population scale.

The human resource dimension reveals another layer of complexity. There is a **significant deficit of trained personnel in translational medicine**, including clinician-scientists, GMP specialists, and cell biologists with clinical orientation. This workforce gap disrupts the continuum from discovery to delivery, resulting in siloed operations rather than integrated systems. The absence of interdisciplinary training pathways exacerbates this divide, limiting the development of a cohesive translational ecosystem.

From a health systems perspective, **cost and affordability remain formidable barriers**. Advanced regenerative therapies are inherently expensive, often confined to private sector settings with minimal integration into public health financing mechanisms. This creates inequities in access, particularly in a country where a large proportion of healthcare expenditure is out-of-pocket. Without mechanisms to reduce costs and expand coverage, regenerative medicine risks becoming an exclusive domain rather than a public health solution.

Ethical and governance concerns add further complexity. Issues surrounding informed consent, the use of embryonic stem cells, and the commercialization of experimental therapies require careful navigation. In the absence of robust and enforceable ethical frameworks, there is a risk of both exploitation and regulatory overcorrection, the latter potentially stifling innovation. Maintaining a balance between ethical vigilance and scientific progress is therefore essential.

Another critical gap is the **Lack of National Data Systems**

The absence of unified registries, standardized outcome tracking, and adverse event monitoring limits the ability to generate real-world evidence. Data fragmentation not only hampers research but also weakens regulatory oversight and policy responsiveness. In an era where data-driven decision-making is paramount, this represents a significant structural deficiency.

Infrastructure fragmentation further undermines efficiency. Research efforts are often dispersed across multiple institutions with limited coordination. The absence of nationally networked centres of excellence leads to duplication of effort, suboptimal resource utilization, and missed opportunities for collaboration. A more integrated infrastructure model is necessary to maximize impact.

The weak linkage between academia and industry is another critical bottleneck. While academic institutions excel in discovery, the translation of innovations into market-ready products requires industrial collaboration. Limited engagement between these sectors slows commercialization, delays innovation scaling, and reduces the overall efficiency of the ecosystem.

Financial constraints compound these challenges. Regenerative medicine is capital-intensive, requiring substantial investment in GMP facilities, clinical trials, and long-term research programs. The availability of risk capital remains limited, particularly for late-stage translation. Without innovative financing mechanisms, the pace of ecosystem development will remain slow.

Finally, **public awareness and misinformation** present a unique challenge. The gap between scientific evidence and public perception is often filled by exaggerated claims and misleading marketing. This not only exposes patients to potential harm but also creates unrealistic expectations that can ultimately undermine trust in the field.

Taken together, these challenges highlight a central truth: **India's regenerative medicine landscape is constrained not by a lack of innovation, but by a lack of integration**. The system is characterized by islands of excellence operating in relative isolation, without the connective infrastructure required for scale.

The strategic imperative is clear. Without addressing these structural challenges—particularly in regulation, evidence generation, manufacturing, and system integration—India risks remaining in a prolonged exploratory phase. The transition to scalable, evidence-based regenerative medicine will require not just scientific advancement, but systemic transformation.

From Fragmentation to Integration: A Solutions Framework for India's Regenerative Medicine Future

If India's challenge in regenerative medicine is fundamentally one of system integration, then the pathway forward must be equally systemic. Incremental reforms will not suffice. What is required is a **mission-mode, coordinated framework** that aligns regulation, research, manufacturing, financing, and delivery into a unified ecosystem capable of translating scientific potential into population-level impact.

The starting point must be regulatory reform through unified and enforceable governance. The alignment of existing frameworks under the Indian Council of Medical Research, Department of Biotechnology, and CDSCO into a single apex regulatory architecture is essential. This must be accompanied by mandatory licensing of all stem cell facilities, standardized accreditation processes, and a national inspection system based on risk stratification. Crucially, enforcement mechanisms must include meaningful penalties—closure of non-compliant facilities, financial sanctions, and legal action against the promotion of unproven therapies. Regulation must shift from advisory to authoritative.

Scaling regenerative therapies demands the creation of a **national manufacturing grid**. Regional GMP hubs, developed through public–private partnership models such as DBFOT, can provide shared infrastructure and reduce capital barriers. Standardized operating procedures, harmonized quality control systems, and pooled procurement of inputs can drive down costs and improve efficiency. Viability gap funding for initial infrastructure development, combined with tiered pricing models for public patients, can ensure both sustainability and equity.

Human resource development must be reimagined as a strategic priority. A **structured national skilling framework** is required, beginning with the integration of regenerative medicine modules into undergraduate medical education and extending to specialized DrNB, DM and fellowship programs. Certification pathways for GMP technologists, biobank managers, and clinical trial coordinators must be established. Importantly, training must be interdisciplinary, combining clinical exposure with laboratory and manufacturing experience to create a workforce capable of operating across the translational continuum.

Parallel to regulatory strengthening is the urgent need to build a robust clinical evidence ecosystem. The creation of a National Regenerative Clinical Trials Network can transform the landscape by enabling large-scale, multicentric Phase II and III trials. Standardization of protocols, endpoints, and follow-up durations will enhance comparability and reliability of results. Financial incentives, including per-patient reimbursement and fast-track approvals for priority conditions, can encourage institutional participation. Without such a coordinated trial ecosystem, the transition from experimental to evidence-based practice will remain elusive.

Bridging the translational divide requires the establishment of dedicated bench-to-bedside pipelines. Translational hubs must be designed to integrate preclinical research, GMP manufacturing, and early-phase clinical trials within a single ecosystem. Funding mechanisms should be milestone-driven, with clear go/no-go decision points to ensure accountability and efficiency. The development of clinician-scientists through structured translational fellowships will be critical in sustaining this interface, ensuring that scientific insights are aligned with clinical realities.

Addressing affordability requires **innovative financing and pricing models**. Inclusion of validated regenerative therapies within public health packages—such as those under national insurance schemes—can expand access. Outcome-based payment models, where reimbursement is linked to clinical effectiveness, can align incentives across stakeholders. Public–private partnerships with regulated tariffs and reserved capacity for public patients can further ensure equitable access. Fiscal measures, including tax incentives and import duty relief, can reduce production costs and encourage investment.

Ethical governance must be strengthened through a **national ethics and consent framework**. Mandatory Institutional Committees for Stem Cell Research (IC-SCRs), standardized informed consent processes, and transparent disclosure of trial status and risks are essential. The establishment of an independent Ethics Audit Board can provide ongoing oversight, ensuring compliance while maintaining public confidence.

A transformative enabler will be the development of a national data and digital ecosystem. A unified stem cell registry capturing clinical trials, treatment outcomes, and adverse events can serve as the backbone of evidence generation. Real-time dashboards for regulators and payers, combined with mandatory reporting requirements, can enhance transparency and accountability. Integration with national digital health systems will enable longitudinal tracking and data-driven decision-making.

Infrastructure must transition from fragmentation to networked integration. The designation of 20–30 Centres of Excellence, linked to medical colleges and supported by regional hubs and district-level spokes, can create a coherent national network. Shared resources—including biobanks, clinical trial units, and simulation facilities—can optimize utilization and reduce duplication. Performance-based funding tied to outcomes and throughput can ensure accountability.

Strengthening industry–academia collaboration is essential for innovation scaling. Joint intellectual property frameworks, co-funded research programs, and the development of contract manufacturing ecosystems can facilitate the translation of discoveries into market-ready products. Regulatory sandboxes can provide a controlled environment for testing innovative approaches, balancing flexibility with oversight.

Financial sustainability will depend on **blended capital models**. Viability gap funding can attract private investment into high-capital infrastructure projects, while access to development finance and credit guarantees can reduce risk. Availability payments and minimum offtake agreements can provide revenue stability for PPP projects. A dedicated National Regenerative Medicine Fund can support late-stage clinical trials and high-risk innovation.

Finally, addressing **public awareness and misinformation** is critical. A national information portal distinguishing approved therapies from investigational interventions can empower patients. Strict regulation of advertising,

combined with public education campaigns, can align expectations with scientific reality. Annual publication of safety and outcome data can further enhance transparency.

Cross-cutting these interventions is the need for **efficient governance mechanisms**, including single-window clearance systems, standardized treatment guidelines, and robust program management units at national and state levels.

The central insight is unequivocal: **the future of regenerative medicine in India depends on synchronization**. Regulation, manufacturing, clinical trials, financing, and delivery must function as interconnected components of a unified system. Piecemeal interventions will not achieve scale; only a coordinated, mission-driven approach can.

If implemented with clarity and commitment, this solutions framework can transform India's regenerative medicine landscape—from fragmented innovation to a globally competitive, evidence-based, and equitable healthcare paradigm.