Advanced International Journal for Research (AIJFR)
E-ISSN: 3048-7641 ● Website: www.aijfr.com ● Email: editor@aijfr.com

Regenerating Hope in India: Stem Cell Innovations for Premature Ovarian Insufficiency

Dr. Niharika Sharma

Sr. Consultant Obs/Gynae. And IVF specialist, Accord Hospital, Faridabad

Abstract

Background: Premature ovarian insufficiency (POI)—loss of ovarian activity before age 40 with oligo/amenorrhea, elevated FSH, and low estradiol—affects **~1–4% of women <40** and **~1 in 1,000 under 30** globally. In India, multiple analyses of NFHS/LASI datasets suggest **notable burdens of premature/early menopause with rural and socioeconomic gradients**, magnifying cardiometabolic and psychosocial risks. As patients and clinics increasingly seek "ovarian rejuvenation," **stem cell–based strategies** (mesenchymal stem cells [MSCs], menstrual blood–derived cells, amniotic/umbilical sources, cell-free exosomes) and **adjacent biologics** (platelet-rich plasma, PRP) have entered the conversation—often ahead of robust evidence. Indian law is clear that **any clinical use of stem cells (beyond approved HSCT indications) must occur only within regulated clinical trials**. (PubMed)

Objective: To synthesize global scientific progress on stem cell innovations for POI and **translate** it to Indian realities—clinical, social, regulatory, and financing—so that clinicians, policymakers, researchers, and affected communities can make informed, ethical decisions.

Methods: Targeted narrative review (2020–2025 prioritized) of peer-reviewed studies, systematic reviews/meta-analyses, registered trials, Indian and international guidelines (ESHRE/ASRM/IMS; ICMR/DBT; CDSCO/NDCTR; ART Act/Rules), plus **credible educational podcasts/webinars** and **media/press releases**. We triangulated **biological/technical evidence** with **India-specific policies and health-system data**. (ESHRE)

Key findings:

1. **Promise with caveats:** Preclinical and early clinical signals suggest MSCs and **cell-free exosomes** can **improve ovarian function markers** in POI, yet **high-quality human evidence remains limited**; safety, durability, and live-birth impact are **unsettled**. (PMC)

2. **India's regulatory line is bright: NGSCR 2017** and ICMR's evidence compendium state **clinical stem cell use is experimental** (outside HSCT) and must be **in approved trials only**. **Commercial "rejuvenation" outside trials is unethical**. (Department of Biotechnology)

3. **Care gaps: Costly IVF**, limited public fertility services, and **uneven counseling in local languages** drive **out-of-pocket (OOP)** medicalization and vulnerability to unproven offerings. (HTAIn)

4. **Roadmap:** India can **lead ethically** by: (a) multicenter POI-stem cell registries; (b) **GMP-grade** trials (menstrual/amnion/umbilical MSCs or exosomes) with **patient-centric, multilingual consent**; (c) coverage pilots following **HTAIn** costing; and (d) national communication campaigns to **counter misinformation**. (HTAIn)

Conclusions: Stem cell–based innovation for POI is **scientifically compelling but not clinic-ready**. India needs **rigorous trials**, **transparent regulation**, and **equitable financing** to ensure patients receive **safe, respectful, and effective** care.

Keywords: premature ovarian insufficiency; mesenchymal stem cells; exosomes; ovarian rejuvenation; India; regulation

1. Introduction

Global context and definition. Premature ovarian insufficiency (POI) is a **loss of ovarian function before age 40**, diagnosed by persistent menstrual disturbance and **biochemical evidence of ovarian insufficiency**. The 2024 **ESHRE/ASRM/IMS** guideline (145 recommendations) standardizes diagnostic and management pathways and underscores broader health implications (bone, cardiovascular, cognitive) and psychosocial impacts. **Hormone therapy (HT)** is foundational for symptom control and long-term health; fertility options range from **oocyte donation** to **oncofertility techniques** such as oocyte/embryo cryopreservation and, in select settings, **ovarian tissue cryopreservation (OTC)** and transplantation. (PubMed)

Where stem cells fit. Over the past decade, regenerative strategies have sought to **restore folliculogenesis** by **protecting granulosa cells**, **improving angiogenesis**, and **modulating immune microenvironments**. Approaches include **intra-ovarian injection** of MSCs from **bone marrow**, **adipose**, **menstrual blood (MenSC)**, **amniotic membrane**, or **umbilical cord/Wharton's jelly**, as well as **cell-free extracellular vesicles (EVs/exosomes)** derived from these cells. Early human reports (cohorts and case-series) show **modest improvements** in hormonal markers (AMH/FSH), **occasional resumption of menses**, and **pregnancies**, but **randomized, adequately powered trials with live-birth endpoints** are scarce. (PMC)

India's epidemiologic signal. Analyses of national datasets report **nontrivial rates of premature/early menopause** in Indian women, with **higher prevalence in rural areas** and associations with **environmental exposures** (including indoor air pollution), **lower education**, and social determinants. For example, recent nationwide work indicates **state-level variation in menopause among women 30–49** (noting both natural and surgical causes), while LASI-based analyses report **~7% premature and ~17% early menopause** in older cohorts—figures that, while not identical to POI definitions, **contextualize the scale of early ovarian failure** and downstream risks. (PMC)

The Indian clinic and marketplace. India's fertility sector is vibrant yet **dominated by private spending**. A recent **HTAIn** analysis estimates **OOP per IVF cycle** around **₹1.1 lakh in public and ₹2.3 lakh in private hospitals**, with most expenses **outside PM-JAY** benefit packages. Public IVF services are expanding but remain **uneven**, creating structural incentives for **cash-based add-ons**—including **PRP** or "stem cell" ovarian injections—**often absent robust evidence**. (HTAIn)

Ethics and regulation in India. The **National Guidelines for Stem Cell Research (NGSCR 2017)**, co-issued by **ICMR-DBT**, state unequivocally that apart from approved **hematopoietic stem cell transplantation**, **stem cell use in patients is experimental** and **must occur only within approved clinical trials—commercial therapy outside trials is unethical**. This stance is echoed by ICMR's **Evidence-Based Status** documents and PIB communications. Concurrently, the **ART Act 2021** and **ART Rules 2022** tighten oversight over ART clinics and banks, while **NDCTR 2019** classifies cellular and regenerative products as **drugs** requiring CDSCO oversight. (Department of Biotechnology)

> **ICMR-DBT NGSCR (2017):** "**Any stem cell use in patients must only be done within the purview of an approved and monitored clinical trial… every use of stem cells in patients outside an approved clinical trial is unethical and shall be considered as malpractice.**" (Department of Biotechnology)

Problem statement. As **media narratives and clinic marketing** tout "ovarian rejuvenation," Indian patients with POI confront **three intersecting risks**: (1) **clinical uncertainty** about the efficacy and safety of stem cell/PRP approaches; (2) **regulatory ambiguity in practice** despite clear national policy; and (3) **affordability and access barriers** that push some toward **unproven, out-of-pocket interventions**.

Objectives.

- **Evidence:** Appraise **biological plausibility** and **human evidence** for stem cell–based therapies in POI (including exosomes/EVs and IVA-adjacent approaches) and **clarify limits**.
- **Context:** Map **Indian regulations, financing, and service delivery** realities shaping patient choices.
- **Action:** Propose **India-appropriate solutions**—research designs, policy levers, education, and equity safeguards.

Scope/limitations. This review **does not promote** off-trial interventions. POI is distinct from general premature menopause; Indian datasets often reference **menopause timing** more broadly, so we **interpret cautiously**. Given the rarity and heterogeneity of POI etiologies, and the **early stage** of stem cell approaches in humans, **definitive clinical guidance awaits trials**. (PubMed)

Methodology

Design. A targeted, narrative synthesis integrating **(1)** basic and translational science on ovarian regeneration, **(2)** human clinical studies and meta-analyses of stem cell/PRP interventions in POI, **(3)** Indian regulatory and financing frameworks, and **(4)** professional guidelines. Emphasis was on **2020–2025** literature, with earlier landmark or contextual sources included where necessary.

Search strategy. Databases: **PubMed/Medline**, **Cochrane**, **Google Scholar**, **ClinicalTrials.gov**; websites: **ICMR-DBT**, **CDSCO**, **MoHFW/DHR** (NGSCR, NDCTR, ART Act/Rules), **ESHRE/ASRM/IMS**, **Indian Menopause Society/FOGSI/IFS**, **HTAIn**; credible **podcasts** (ASRM "Fertility & Sterility On Air", ASRM Today) and **webinars/YouTube** (IMS/BMS/academic hospitals). Representative terms: *"premature ovarian insufficiency stem cells," "menstrual blood stem cell POI*

trial," "exosomes ovarian failure," "PRP ovarian rejuvenation randomized," "ICMR stem cell guideline," "NDCTR regenerative products," "ART Act India 2021/Rules 2022," "IVF cost HTAIn." (PMC)

Inclusion/exclusion. Included **peer-reviewed** reviews, meta-analyses, clinical trials/registrations, major **guidelines**(ESHRE/ASRM/IMS; ICMR/DBT; NDCTR; ART Act/Rules), **Indian society** documents (IMS, IFS, FOGSI), reputable **press releases/industry reports** and **educational media** (society/academic channels). Excluded: promotional clinic blogs unless used **as examples of market claims**, and **low-quality** preprints without triangulating evidence.

Data extraction and synthesis. Articles were organized by **(a) biology/technical**, **(b) sociocultural**, **(c) system responses/gaps**, and **(d) solutions/best practices**. We privileged **human clinical endpoints** (resumption of menses, oocyte yield, pregnancy/live birth) over surrogate markers, and **flagged uncertainty** where data were preliminary or inconsistent. Regulatory texts were interpreted **verbatim** for compliance messaging. (Department of Biotechnology)

Timeline and scope. Searches ran through **September 14, 2025 (IST)**. Where 2025 content was newly published (e.g., meta-analyses, clinical trial postings), we used them to illustrate **direction of travel**, noting that **clinical adoption**remains **premature** without regulatory-grade evidence. (PMC)

Discussion

4.1 Biological/technical factors and evidence

Mechanistic rationale. MSCs appear to support ovarian function via **paracrine** actions—**anti-apoptotic** signaling in granulosa cells, **angiogenesis** (e.g., VEGF), **anti-inflammatory** modulation (TNF-α/IL-10 balance), **mitochondrial**support, and niche remodeling. **Cell-free EVs/exosomes** from MenSCs/amnion/Wharton's jelly replicate many benefits while **reducing tumorigenicity risk**. Animal models repeatedly show **follicular rescue** and **hormonal recovery** after chemotoxic or autoimmune injury. (PMC)

Human clinical evidence: signals, not standards.

- **Umbilical/amnion MSCs:** Small nonrandomized studies suggest **improved AMH/FSH** and **menses resumption**in some POI patients; **live-birth data** are sparse. New trials (e.g., **hA-MSC** safety study) are on-going. (PMC)

- **Bone marrow MSCs (BM-MSCs):** Case series (India and abroad) report **resume menses/pregnancies** after **intra-ovarian BM-MSC injections**, often **adjunctive to PRP**; **method heterogeneity** (harvest, dose, delivery) and lack of controls limit inference. (PMC)

- **Menstrual blood–derived cells (MenSCs):** Early single-arm trials suggest **symptom and cycle improvements**; mechanistic work highlights **exosome cargo** as central. (PubMed)

● **Meta-analyses (human vs preclinical):** A 2024–2025 wave of analyses highlights **promise** but stresses **low certainty** due to small, uncontrolled studies; calls for **standardized protocols** and **hard outcomes** (pregnancy/live birth, long-term safety). (PMC)

PRP: adjacent, not stem cells. PRP is **not** a stem-cell therapy but is often co-marketed as "rejuvenation." Observational cohorts show **short-term hormonal/follicular improvements**, yet **controlled data are mixed**, including studies showing **no significant gains** in pregnancy or AMH/AFC. **Safety appears acceptable**, but benefits remain **uncertain** and **non-durable** in many reports. (PMC)

IVA and IVG: horizon science. In-vitro activation (IVA)—fragmenting ovarian cortex to disrupt Hippo signaling—has generated **proof-of-concept** outputs; larger or randomized POI trials are lacking. **In-vitro gametogenesis (IVG)** is **not clinically available**; ethical/policy debate is accelerating as basic science progresses in animals and human cell systems. India needs **early policy thinking** here. (Oxford Academic)

Safety and manufacturing reality. Translational hurdles include:

● **Product variability** (source tissue, passage number, potency assays), **dose/routes** (intra-ovarian vs systemic), and **GMP** standards;

● **Risks**: ectopic tissue, **pro-tumorigenic signaling**, embolism, infection, and pregnancy/fetal safety;

● **Follow-up**: long-term oncologic and offspring monitoring is **mandatory** for any clinical program in POI. (PMDA)

Bottom line (technical): Biological plausibility is strong; human efficacy is not yet proven to guideline standards—a view aligned with **ESHRE/ASRM** guidance that **does not recommend** stem cell/PRP outside research. India's path must be **trial-first**, **GMP-secure**, and **patient-centric**. (PubMed)

4.2 Sociocultural challenges specific to India

Stigma, timelines, and expectations. For young Indian women, POI collides with **pronatalist expectations** and family pressures around marriage and childbearing, sometimes precipitating **urgent, costly care-seeking**. Qualitative work highlights how **clinic narratives** and **social media** drive interest in "rejuvenation" despite uncertainty. **Acceptance of donor oocytes** varies by religion, region, and family dynamics; **adoption** is under-utilized. (ScienceDirect)

Language and consent. India's linguistic diversity demands **multilingual counseling**; without it, discussions on **experimental vs established** therapies may be misunderstood. Patient-facing videos from **IMS/BMS** or academic channels can support **informed choice** where literacy is limited. (YouTube)

Urban–rural and regional disparities. IVF and advanced diagnostics cluster in metros; public IVF capacity is **nascent/uneven**, leaving **Tier-2/3** populations vulnerable to **unregulated offerings**. Media reports show **delays in public IVF roll-out** and **opaque pricing** in private centers. (The Times of India)

Affordability. PM-JAY excludes IVF, and typical cycles cost **₹1–3 lakh**, excluding add-ons and travel. **HTAIn**estimates provide a **public-sector cost benchmark** for potential inclusion debates. Financial toxicity fosters **distress financing** and susceptibility to **cash-based "innovations."** (Business Standard)

Environmental health and early ovarian aging. Emerging Indian analyses link **indoor air pollution** and other exposures to **earlier menopause**, underscoring the need to **address upstream risks** alongside downstream therapies. (PMC)

4.3 Current system response and gaps

Regulatory clarity, enforcement gaps. On paper, India's **NGSCR 2017** is explicit: clinical stem cell use (outside HSCT) is **experimental** and limited to **approved trials**; **NDCTR 2019** treats regenerative products as **new drugs**, requiring **CDSCO** oversight; **ART Act/Rules** regulate clinics/banks. In practice, **promotional claims** and **cash-based offerings**persist. Policymakers and councils have issued **cautionary advisories** and **evidence digests** to curb misuse. (Department of Biotechnology)

Clinical guidance. The **2024 ESHRE/ASRM/IMS** guideline is the global reference for POI; Indian professional guidance (IMS, IFS) aligns on **HT for POI**, screening for **comorbidities**, and **counseling**. However, **India-specific POI guidance** on **regenerative interventions** is limited; **ISAR/FOGSI** documents discuss "add-ons" cautiously, reflecting **evidence gaps**. (PubMed)

Public financing and service delivery. IVF is **largely OOP**; **HTAIn** has modeled **per-cycle costs** and recommended consideration for **public packages** (with OPD coverage adjustments), but **PM-JAY** currently **excludes infertility**. Public facilities offering IVF are **few**, and **state schemes** vary. (HTAIn)

Information ecology. Podcasts/webinars (ASRM/IMS) and **society toolkits** offer **evidence-based patient-friendly content**, but **misinformation** remains rife. Coordinated **patient education in Indian languages** is under-built. (ASRM)

Research infrastructure. India has **GMP/GLP** capacity in academic centers and industry, cord-blood banking guidelines, and increasing experience with **cellular products** regulation. Yet **disease-specific** POI stem-cell trials remain **few**, with many "rejuvenation" efforts **outside trial norms**. (Indian Council of Medical Research)

4.4 Innovative solutions and best practices (India-adapted)

1) Trial-first, registry-enabled roadmap.

- **Multicenter Phase 1/2 trials** for **intra-ovarian MenSC/amnion/umbilical MSCs** or **exosomes**—**GMP-grade**, dose-finding, **DSMB-oversighted**, with **biorepository** and **≥24-month** maternal/offspring follow-up.
- **National POI-RegMed Registry** (ICMR stewarded) capturing **eligibility, procedures, safety events, cycles, pregnancy/live birth**, and **patient-reported outcomes** (quality of life, decisional regret). (ClinicalTrials)

2) Consent that works in India.

- Standardize **multilingual consent** (Hindi, Bengali, Marathi, Tamil, Telugu, Kannada, Malayalam, Odia, Punjabi, Assamese, Gujarati, etc.) explaining **experimental status**, **alternatives** (HT, donor oocytes, adoption), **uncertain benefits**, and **out-of-pocket risks**. Use **teach-back** and video aids (IMS/BMS). (YouTube)

3) Transparent clinic communications.

- Under **ART Act/Rules**, require ART clinics that advertise "rejuvenation" to **disclose trial registration**, **ethics approvals**, **GMP source**, and **outcomes**. Enforce **misleading-ads** penalties for off-trial claims (align with ICMR/PIB advisories). (Press Information Bureau)

4) Financing pilots, not hype.

- Following **HTAIn** costing, pilot **limited public financing** for **trial-enrolled** women with POI (travel/lodging, monitoring, HT), not the experimental product itself—**reducing inequity** while maintaining scientific rigor. Consider **OPD coverage adjustments** in PM-JAY as HTAIn suggests for IVF packages. (HTAIn)

5) Technical standardization.

- Develop **ICMR/CDSCO** technical standards for **POI cell products**: source (menstrual/amnion/umbilical), **release testing** (identity, purity, potency), **viability**, **sterility**, **EV characterization** (size, cargo markers), **dose/volume**, and **ultrasound-guided delivery** SOPs. Link with **NDCTR** guidance for **investigational new drugs**. (CDSCO)

6) Evidence-aligned counseling.

- Embed 2024 **ESHRE/ASRM** recommendations into **IMS/FOGSI/IFS** Indian practice notes: **HT for bone/heart/brain health**, **donor oocyte** as established fertility option, OTC in **oncofertility** pathways where feasible, and **stem-cell/PRP** only **in trials**. (PubMed)

7) Environmental and preventive lens.

- Integrate **air-quality and household energy** counseling (clean cookstoves) and **tobacco cessation** into POI care, aligning women's health with **clean-fuel policies** (PMUY). These public-health steps are **low-cost, high-reach** in rural India. (PMC)

8) Education and media partnerships.

- Co-produce **short, subtitled videos** with **IMS/IMSociety** explaining POI, **why trials matter**, and **how to spot misinformation**; amplify via **Doordarshan/All India Radio** and **state health** channels.

9) Bench-to-policy alignment for horizon tech.

● Establish an **ethics/policy foresight group** (ICMR-DBT + bioethicists + community reps) to monitor **IVA/IVG**science and propose **anticipatory regulations** for any future Indian translation. (Nuffield Council on Bioethics)

Conclusion

What we know. POI is a **life-course condition** with impacts far beyond fertility. **HT** remains the **evidence-based mainstay** for symptom control and long-term health; fertility solutions include **oocyte donation** and **oncofertility techniques**. **Stem cell–based interventions** (MSCs, MenSCs, amnion/umbilical sources) and **exosomes** show **biological promise** with **early human signals**, but **robust, regulatory-grade evidence** for **live births and long-term safety** is **not yet established**. PRP is **adjacent** and **not stem cells**; findings are **mixed** and largely **nonrandomized**. (PubMed)

What India needs. India's **regulatory position is clear**: **no clinical stem cell therapy outside approved trials**. Yet **market pressure, information asymmetries, and OOP financing** create a risk of **premature adoption**. The policy opportunity is to **leverage India's scientific capacity**—GMP manufacturing, clinical research networks, and digital health—to run **high-quality, multilingual, patient-centered trials** while **protecting families from exploitation**. (Department of Biotechnology)

Stakeholder implications.

● **Clinicians/ART centers:** Counsel using **2024 ESHRE/ASRM** guidance; **do not offer** stem cell/PRP for POI outside trials. Build **registry participation**, use **standardized consent** and **transparent outcome reporting**. (PubMed)

● **Researchers/industry:** Co-design **Phase 1/2 trials** with **potency assays**, **DSMBs**, and **long-term surveillance**; prioritize **cell-free exosome** approaches where risk–benefit may be favorable; publish **negative** as well as **positive**results. (PMC)

● **Regulators (ICMR/DBT/CDSCO) and MoHFW:** Enforce **advertising and practice** norms; issue **advisories** in regional languages; publish **clinic compliance dashboards**; develop **product standards** and **inspection checklists**for POI trials. (Press Information Bureau)

● **Payers/HTAIn:** Test **coverage pilots** for **trial-enrolled** women (travel/monitoring/HT), explore **OPD adjustments**if IVF packages are evaluated, and **guard against** public funding of **unproven therapies**. (HTAIn)

● **Communities/advocacy:** Use **IMS/IMSociety/BMS** resources and **credible podcasts** to navigate claims; **report**misleading ads to regulators.

Future research. Priorities include **randomized or well-matched cohort trials** with **live-birth** primary endpoints, **comparative** evaluations of **MSC sources** vs **exosomes**, **dose/route** optimization, and **fertility + general health outcomes** (bone/heart/mental health). India should build a **POI biobank** and **harmonize data models** across centers to accelerate learning.

Policy recommendations (India):

1. **Issue a joint IMS–FOGSI–IFS advisory** reaffirming **trial-only** status of stem cell/PRP for POI, linked to **ART Act** compliance.

2. **Stand up an ICMR POI-RegMed Registry** and require trial enrollment for any ovarian "rejuvenation."

3. **Fund multicenter trials** via DBT/ICMR with **GMP** manufacturing and **independent DSMBs**.

4. **HTAIn to evaluate** the **budget impact** of coverage for **supportive POI care** (HT, counseling, bone health) and travel for **trial participation**, not the experimental product.

5. **Launch a multilingual education campaign** to counter misinformation and support **informed choices**.

India can **lead globally** by proving that **innovation and ethics** need not be trade-offs.

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