

CAHO & ISA's Consensus Document on

The Imperative of Point-of-Care Ultrasound in Modern Medicine



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Preface

This Consensus Document has been developed based on the collective insights and discussions that transpired during the national webinar, co-organised by the Consortium of Accredited Healthcare Organisations (CAHO) and the Indian Society of Anaesthesiologists (ISA).

The webinar, “PCPNDT Act vis-à-vis Therapeutic Care—Roadblocks and Way Forward,” took place on 23rd May 2025.



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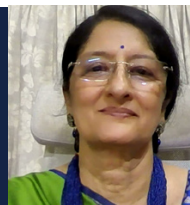
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List of Abbreviations

AI	Artificial Intelligence
ASRA	American Society of Regional Anaesthesia and Pain Medicine
CDSCO	Central Drugs Standard Control Organisation
CEHAT	Centre for Enquiry into Health and Allied Themes
CT	Computed Tomography
ED	Emergency Department
ICU	Intensive Care Unit
LMIC	Low- and Middle-Income Countries
MRI	Magnetic Resonance Imaging
NMC	National Medical Commission
PACU	Post Anaesthesia Care Unit
PCPNDT	Pre-Conception and Pre-Natal Diagnostic Techniques
POCUS	Point-of-Care Ultrasound
POUR	Postoperative Urinary Retention
RMP	Registered Medical Practitioner
ScoP	Scope of Practice
SWOT	Strengths, Weaknesses, Opportunities, and Threats
USG	Ultrasonography

1.Introduction

POCUS technology has emerged as a transformative diagnostic and therapeutic tool across various medical disciplines, revolutionising patient care in clinical settings. Its applications include, but are not limited to, critical care, anaesthesia, emergency medicine, cardiology, neonatology, trauma management, and pain management, offering rapid, radiation-free diagnostics that enhance procedural success and patient outcomes.¹⁻³

Unlike traditional radiology-based ultrasound, POCUS empowers clinicians to perform real-time imaging at the patient's bedside, facilitating rapid clinical decision-making and image-guided, timely interventions to save patients' lives.^{4,5} In resource-constrained settings, particularly in LMICs like India, POCUS holds immense potential to bridge gaps in healthcare delivery.

2. Problem Statement

In India, despite its proven utility, the adoption of POCUS has been hindered by the PCPNDT Act of 1994 and its amendment in 2003, enacted to combat female feticide by regulating ultrasound use.⁶

These regulations, while addressing a critical social issue, have inadvertently restricted the widespread integration of ultrasound technology in medical practice, limiting its potential to elevate standards of care to global benchmarks.

In resource-limited settings, such as tier II and III cities in India, where specialised medical workforce shortages are acute, POCUS offers a cost-effective, accessible solution to enhance patient care.⁷

Expanding its use across disciplines is both a clinical necessity and a strategic imperative to align India's healthcare standards with international best practices, ensuring equitable access to advanced diagnostics and improved outcomes in critical care.

To fully harness POCUS's potential as an indispensable tool in modern medicine, a holistic approach is needed—one that addresses social concerns while promoting its integration into routine clinical practice to improve patient care across diverse medical disciplines.

This 'Consensus Document' aims to analyse the nuances and practical challenges encountered by healthcare professionals and hospitals in utilising POCUS and to deliberate on the existing regulatory framework related to it.

Furthermore, it outlines potential solutions and actions to address this issue effectively.



3. POCUS and Its Uses

POCUS is an exceptionally versatile tool across multiple medical specialties, including but not limited to perioperative, vascular, anaesthesia, pain management, ophthalmology, critical care, emergency medicine, neurology, endocrinology, and urology, providing rapid, real-time imaging to improve healthcare delivery.⁸⁻²⁸

Its key applications are listed in Table 1. These applications improve diagnostic accuracy, therapeutic procedural safety, and patient outcomes across diverse clinical settings.

4. Economic Impact of POCUS

POCUS has demonstrated significant economic benefits across the ED and ICU by reducing healthcare costs and improving operational efficiency.

Studies show POCUS can save hospitals substantial amounts, ranging from \$182 (₹15,600) to \$2,826 (₹2,42,150) per patient, by avoiding expensive imaging tests like CT scans and MRIs, particularly for conditions such as pediatric appendicitis, trauma, and musculoskeletal issues like hip dysplasia and rotator cuff tears.^{29,30}

Additionally, POCUS reduces length of stay, speeds up diagnoses, and increases patient throughput, with estimated savings of over \$80,000 (₹6.85 lakhs) in some ICU settings and up to \$70 (₹5,990) per patient in ED settings.³¹⁻³³ Streamlining healthcare delivery and minimising unnecessary procedures are critical strategies for reducing referral and hospitalisation costs, particularly in India.

By improving turnaround times for diagnostics and decreasing the incidence of complications and readmissions, POCUS offers significant advantages to both healthcare providers and patients.³⁴

In a country where universal medical insurance coverage is lacking, government initiatives like the Ayushman Bharat Scheme are a pivotal step in India, reducing out-of-pocket expenditure by providing cashless treatment.

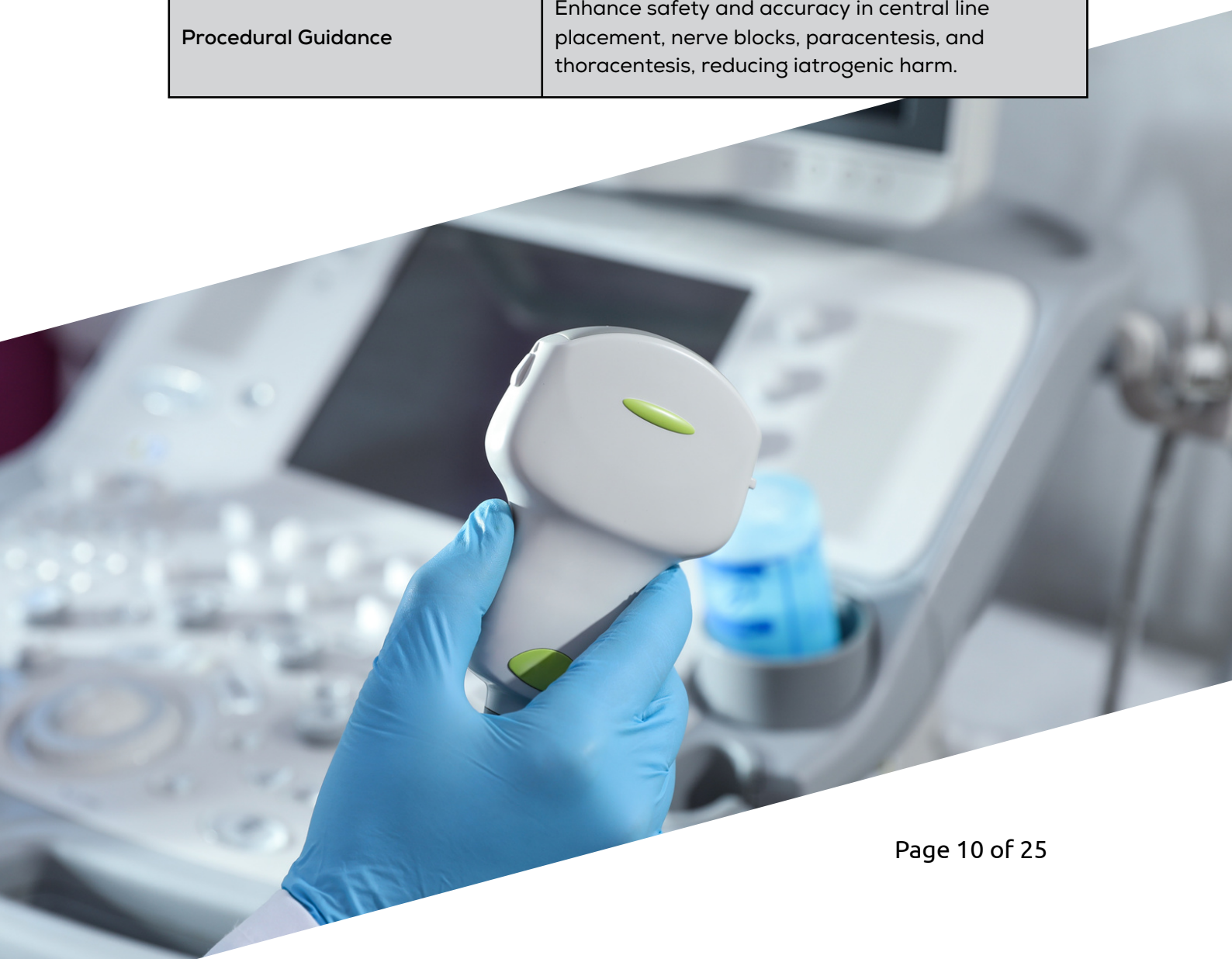
The integration of POCUS in clinical care amplifies these benefits by enabling cost-effective, accessible diagnostics at the primary care level, reducing both direct costs (through early diagnosis and cashless services) and indirect costs (by minimising travel and wage loss).

Table 1: List of Speciality-wise (Few) Uses of POCUS

Speciality/Application	Use of POCUS
Airway Management	Predict difficult laryngoscopy/intubation; confirm endotracheal tube placement; and identify the cricothyroid membrane for emergency access
Cardiology	Evaluate hemodynamic instability, heart failure, and undiagnosed cardiac disease; diagnose treatable pathologies in cardiac arrest; to assess prognosis.
Anaesthesia and Pain Management	Guide regional anaesthesia techniques (e.g., peripheral nerve blocks, epidural, and spinal anaesthesia) by identifying anatomical landmarks; ensure accurate needle placement for acute and chronic pain management procedures, improving efficacy and reducing complications. Assess gastric content and volume to evaluate aspiration risk, especially in unclear fasting status or delayed gastric emptying. Postoperatively for identifying POUR and for discharge from PACU.
Pulmonology	Diagnose pneumothorax, pleural effusion, pneumonia, pulmonary oedema, and acute respiratory distress syndrome; monitor lung conditions.
Trauma Management	Identify free fluid (haemorrhage) or free air (ruptured viscus) in trauma patients; guide surgical intervention decisions and ongoing critical care assessment.
Vascular Surgery	Diagnosing deep vein thrombosis with high accuracy, providing results faster than consultative duplex scans, and screening for abdominal aortic aneurysm in emergency settings.
Ophthalmology	Evaluate ocular pathologies such as retinal detachment, vitreous haemorrhage, lens dislocation, and optic nerve sheath diameter to assess increased intracranial pressure.
Critical/Intensive Care	Monitor hemodynamic status, guide fluid resuscitation, assess cardiac function, and detect critical conditions like pneumothorax in intensive care settings.
Emergency Medicine	Rapidly assess trauma, diagnose critical conditions like cardiac tamponade, and guide emergency procedures like pericardiocentesis.

Table 1: List of Speciality-wise (Few) Uses of POCUS

Speciality/Application	Use of POCUS
Neurology	Measure optic nerve sheath diameter to detect increased intracranial pressure; assess midline shift or cerebral oedema in traumatic brain injury or stroke.
Endocrinology	Evaluate thyroid nodules, goitres, and parathyroid gland abnormalities; guide fine-needle aspiration for thyroid lesions.
Urology	Diagnosing testicular torsion, scrotal haematoma, renal stones, hydronephrosis, etc.
Procedural Guidance	Enhance safety and accuracy in central line placement, nerve blocks, paracentesis, and thoracentesis, reducing iatrogenic harm.



5. Model of the Epidemiological Triangle of Female Feticide

The application of the Epidemiological Triangle model to female feticide, as a social illness, provides a framework to dissect the complex interplay of causative factors: parents as the 'Host', doctors and ultrasound technology as the 'Agent', and society as the 'Environment' (as illustrated in Figure 1).³⁵

This model highlights that while doctors and ultrasound machines may contribute to the issue, they represent only one facet of a deeply rooted societal problem.³⁶⁻³⁸

Restricting access to POCUS through the stringent PCPNDT Act disproportionately targets the medical fraternity, potentially undermining their role while ignoring the broader dynamics at play.

Evidence suggests that female infanticide, a historical practice, declined with the rise of feticide, indicating that societal and parental attitudes (host and environment) remain significant drivers of gender-based violence.³⁶⁻³⁸

Although there have been some improvements in the sex ratio over the years (as depicted in Figure 2), these changes cannot be solely attributed to the provisions of the PCPNDT Act.

They also reflect a shift in societal mindsets, demonstrating the evolution of thinking and social values regarding the female child. Focusing solely on doctors may inadvertently shift accountability away from the broader societal and familial factors that contribute to gender bias, without addressing the root causes. Thus, it is essential to assess the situation impartially and contemplate the issue at hand to genuinely benefit society at large.

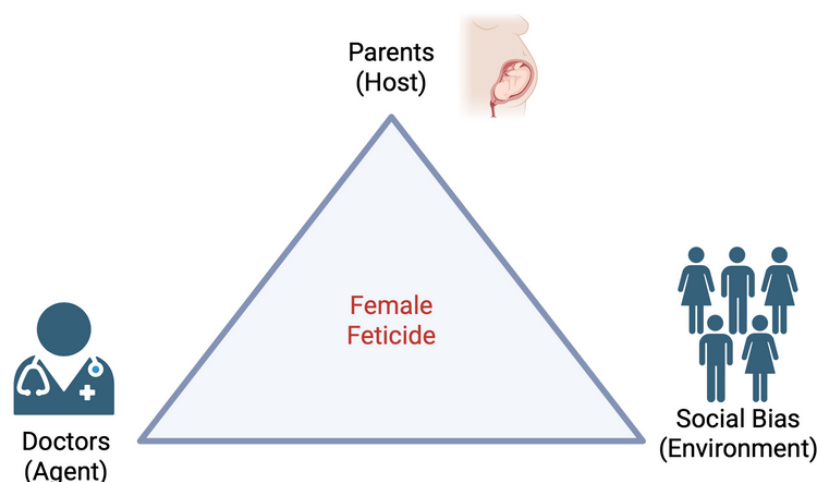


Figure 1: Epidemiological triangle model of female feticide

A balanced approach is needed—one that acknowledges the role of all three components of the triangle (Figure 1). Easing restrictions on POCUS for legitimate medical purposes, while strengthening enforcement against misuse, could restore trust in the medical community and enhance healthcare delivery, particularly in underserved areas.

Simultaneously, public awareness campaigns should be conducted, as directed by the apex court in *CEHAT vs Union of India*,³⁹ and stricter accountability for societal and familial complicity in female feticide is essential.

By holistically analysing the epidemiological triangle, policymakers can develop strategies to mitigate this social ill without imposing excessive regulatory burden on doctors and hospitals.

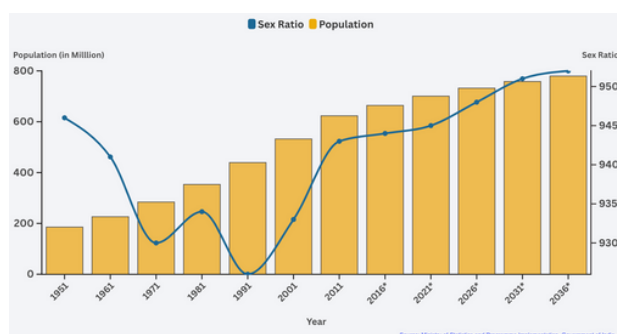


Figure. 2: Trend in population, sex ratio and average annual growth rate of population of post-independence India.

6. Barriers to Effective Utilisation of POCUS

The PCPNDT Act in India, designed to prevent female feticide by controlling the use of ultrasounds, has inadvertently posed considerable obstacles for clinicians trying to implement POCUS for non-obstetric purposes. Unfortunately, these restrictions, combined with a lack of awareness about POCUS' broader utility, have hindered the standard of care across various specialities. Below is a detailed summary of challenges and their impact.

I. Restrictive Registration Process

The PCPNDT Act imposes restrictive registration and approval requirements for all facilities using ultrasound machines, including those for non-prenatal diagnostic purposes. These bureaucratic requirements create significant delays due to a time-consuming registration process fraught with administrative hurdles and contribute to legal concerns. A pervasive lack of awareness regarding the scope of POCUS use, coupled with fears of legal repercussions under the Act, discourages hospitals and clinicians from procuring and registering these vital ultrasound machines.

This has resulted in the underutilisation of POCUS in critical areas. For hospitals and departments seeking to integrate POCUS into routine practice, these undue delays in approvals (exceeding the prescribed maximum limit of 90 days),⁴⁰ restrictions on portability of POCUS, and legal apprehensions impede timely access to essential diagnostic tools, thereby limiting their ability to provide rapid, high-quality care in perioperative and critical settings.

II. Ambiguity in Clinician Qualifications and Inconsistent Enforcement

The Act primarily focuses on geneticists and obstetricians or any RMP involved in prenatal diagnostics and/or genetic testing, leaving the role of other specialists ambiguous.

This lack of clarity regarding who is qualified to use ultrasound for non-obstetric purposes creates confusion and discourages authorities from approving POCUS use. Doctors fear operating in a legally grey area, which stifles the integration of ultrasound into other specialities.

Additionally, there are inconsistencies across states in the enforcement of the Act, regarding the requirements to comply during scrutiny, registrations, and renewals.

III. Impact of PCPNDT Act on POCUS Training and Research in India

The PCPNDT Act prohibits the sale of ultrasound equipment, which complicates the organisation of workshops and educational demonstrations. These are crucial for equipping clinicians with the skills to use POCUS effectively for procedures like guiding nerve blocks, monitoring hemodynamic status, or assessing trauma. This lack of structured training opportunities perpetuates limited awareness and expertise among clinicians; many remain uninformed about POCUS's diagnostic and procedural benefits, thus delaying its integration into clinical practice.

Concurrently, the Act's restrictive nature has led to a scarcity of ultrasound equipment in many Indian medical centres for non-obstetric purposes, directly impacting the quality and relevance of clinical research. Studies relying on outdated or conventional techniques fail to align with global standards, limiting India's contributions to advancements in fields like anaesthesia and critical care.

This dual barrier—restricted training and limited research capacity—places India at a significant disadvantage in maintaining cutting-edge healthcare practices, compromising clinician proficiency and the nation’s ability to innovate in medical science.

IV. Lack of National Practice Guidelines

The absence of clear national guidelines or a defined scope of practice for non-obstetric POCUS use creates ambiguity, leaving doctors without standardised credentialing or privileging processes to ensure competency and legal compliance.

Resistance from authorities, compounded by a lack of awareness among stakeholders, further exacerbates these challenges, undervaluing POCUS’s potential and delaying its integration into clinical practice, ultimately compromising the standard of care.

Collectively, these challenges, restrictive regulations, legal ambiguities, fear of repercussions, equipment limitations, and inadequate training have significantly impeded the evolution of POCUS as a widespread tool in Indian healthcare. This situation places India at a disadvantage compared to global standards, where POCUS is increasingly integral to high-quality, patient-centred care.



7. SWOT Analysis

A SWOT or situational analysis assesses a project’s strengths, weaknesses, opportunities, and threats. This evaluation aids in identifying factors that can either support or hinder the project’s objectives. By understanding these elements, organisations can develop strategies that leverage their strengths, address weaknesses, capitalise on opportunities, and mitigate threats.⁴¹

The SWOT analysis on POCUS for the Indian setting is depicted in Figure 3.

8. Recommendations

To utilise POCUS within a legal framework, we advocate for the following potential solutions to promote the clinical use of POCUS and foster a fair healthcare ecosystem in India.

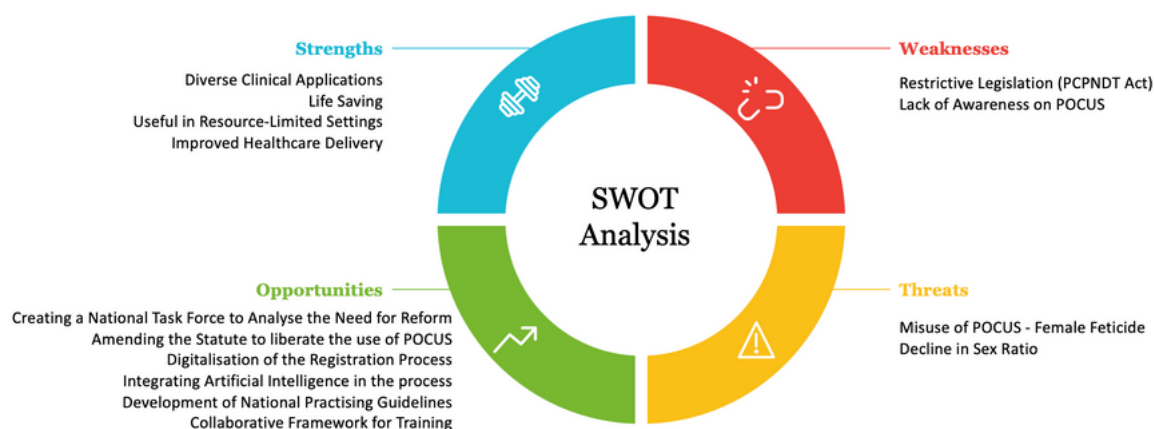


Figure 3: Situational Analysis of POCUS – Indian Scenario

I. To Combat the Lack of Awareness of POCUS in Clinical Practice

A targeted advocacy campaign is essential to address the lack of awareness about POCUS in clinical practice.

Engaging legislative and bureaucratic stakeholders through data-driven presentations at the national and regional levels can highlight POCUS's diagnostic precision, cost-effectiveness, and improved patient outcomes, supported by real-world case studies.

To drive informed policy reforms and ensure equitable access to this transformative technology, raising awareness through professional networks and sharing evidence-based success stories is critical.

II. Registration of Doctors to Utilise POCUS

Professional societies at the national level, in collaboration with their respective state chapters, should come together to create unified guidelines for doctors and hospitals to register under the PCPNDT Act within their districts.

These guidelines should clearly outline the scope of practice and require doctors to sign an undertaking to adhere to the provisions of the Act.

Additionally, it would be beneficial to streamline the process to address bottlenecks, with assistance from the appropriate authorities at the district or state level.

III. Geo-Tagging & Integrating Artificial Intelligence in POCUS

Geo-tagging of POCUS devices should be mandated to enable real-time tracking and monitoring, and POCUS images and reports should be integrated into electronic patient records to enhance transparency and accountability.

Additionally, AI-driven real-time image vetting must be implemented. The "Silent Observer" or "Ghost Observer" method in ultrasound machines can assist in preventing illegal sex determination tests by recording and storing ultrasound images linked to an online portal, which allows health authorities to monitor and verify the data and to flag any misuse of diagnostic techniques.

This system aids in tracking ultrasound usage and identifying suspicious cases, ultimately helping to prevent illegal practices. It is crucial that the silent observer method be designed to be tamperproof to ensure the integrity of the recorded data.

Alternatively, AI-powered fetal gender masking models at the software level to permanently block fetal sex information display in devices intended for non-obstetric use can be explored.

Implementing a personal login system for using POCUS is also advisable to protect individuals from unauthorised access and liability.

IV. Amendments to the PCPNDT Act

The time has come to objectively re-examine the 31-year-old PCPNDT Act and associated rules to adapt to medical advancements that aid in patient care.

Hence, we recommend amending the legislation to incorporate digitalisation of the registration process, explicitly adding and expanding the exemptions within the purview of the Act to liberalise the use of POCUS by a spectrum of doctors, incorporate advanced technological integrations, and implement stricter enforcement mechanisms.

a. Tiered Classification & Registration of USG

It would be preferable to introduce a tiered classification system for ultrasound machines based on their primary intended use, technical capabilities, and potential for misuse in fetal sex determination. For the purposes of the PCPNDT Act, ultrasound machines shall be classified into the following categories:

- **Category A (High Risk):** Machines primarily designed and marketed for obstetric imaging, fetal biometry, or general abdominal and pelvic imaging, where fetal visualisation is a common application. These machines shall be subject to the most stringent registration, reporting, and monitoring requirements under this Act.

- **Category B (Medium Risk):**
Machines with limited or specialised capabilities, primarily used for non-obstetric purposes (e.g., advanced cardiac, vascular, musculoskeletal, or superficial organ imaging), but which could potentially be adapted for limited fetal visualisation with specific probes or software. These machines shall require a simplified registration process and adherence to specific guidelines to prevent misuse.
- **Category C (Very Low Risk):**
Machines designed exclusively for highly specialized non-obstetric applications, such as ophthalmic A-scan/B-scan (for eye structure measurement), specific intraoperative or ICU bedside units (for vascular access, guided procedures, or basic trauma assessment), where fetal imaging is technically unfeasible or irrelevant. These machines, if certified by an approved regulatory body (e.g., CDSCO) as technically incapable of fetal sex determination, may be exempt from full registration and reporting requirements under this Act, subject to a strict declaration of their limited use.

This tiered system minimises undue regulatory hurdles for equipment that cannot feasibly be used for sex determination (e.g., ophthalmic or ICU bedside ultrasound machines), reducing hurdles faced by doctors and hospitals.

b.Exemption for Specific Probes and Non-Obstetric Machines

Exempt specific ultrasound probes and machines that are technically unsuitable for accurate fetal imaging or sex determination from stringent registration requirements.

Very high-frequency linear probes (used for superficial structures) or low-frequency phased array probes (used for cardiac imaging) that are physically incapable of producing clear fetal images can be exempted.

Additionally, manufacturers can be made to obtain CDSCO certification mandatorily, confirming that Category C machines or specific probes are unsuitable for fetal imaging. Healthcare facilities using these machines/probes must submit a declaration of non-obstetric use during registration.

Exempting probes and machines with no practical application in fetal imaging reduces the administrative burden on specialised medical fields while maintaining oversight.



c. Mandatory Technical Safeguards for Category B USG

Mandate manufacturers of Category B ultrasound machines to incorporate software and hardware safeguards to minimize their potential for misuse in sex determination.

Implement restrictions on fetal biometry calculations, Doppler settings, or imaging modes that could facilitate sex determination.

Furthermore, the Union Government, in consultation with CDSCO and medical professional bodies, shall prescribe technical standards for Category B ultrasound machines.

Manufacturers shall incorporate software and hardware safeguards, including restricted fetal biometry calculations, specific probe compatibility, and mandatory audit trails for imaging parameters, to prevent misuse for sex determination.

d. Digitalisation of the Registration Process

The registration process for all ultrasound machines, including POCUS devices, could be conducted via a unified registration portal while leveraging AI to verify the pre-requirements, streamline approvals, and ensure clear timelines to prevent unnecessary delays.

Additionally, as indicated by the Kerala High Court in *Qualified Private Medical Practitioners and Hospitals Association vs State of Kerala*,⁴² registration could be made compulsory only for those operating a Genetic Counselling Centre, Genetic Clinic, Genetic Laboratory, etc., which are used for conducting any prenatal diagnostic procedures or tests.

However, both registered and unregistered institutions must comply with the restrictions laid down by the PCPNDT Act regarding sex detection activities, and appropriate authorities should be empowered to conduct inspections and inquiries at any facility using such devices, ensuring compliance regardless of registration status.⁴²

e. Portable Ultrasound Machines

Rule 3B (1) (a) of the PCPNDT Rules states that portable USG machines are to be used only within the premises where they are registered and solely for providing services to indoor patients.⁴³

Restricting the use of portable ultrasound machines to indoor patients limits their effectiveness as valuable diagnostic tools. It would be beneficial to allow portable POCUS devices, equipped with built-in AI safeguards, to be used beyond indoor settings, particularly in the continuum of care for those patients discharged from hospitals, emergency care and outreach scenarios.

Expanding their use to all patients within registered healthcare centres, as well as in remote or non-traditional settings, is essential for diagnostic and life-saving purposes.

f. Sale & Procurement

Rule 3A of the PCPNDT Rules enforces strict restrictions on the sale, distribution, and authorisation of ultrasound machines capable of determining the sex of a fetus.⁴³

It is essential to establish a separate, transparent, and streamlined process for the procurement and distribution of POCUS devices that are intended specifically for non-obstetric or general diagnostic applications, ensuring robust accountability.

Perhaps, it would be beneficial if CDSCO consider implementing a fast-track evaluation and regulatory approval process for AI-integrated POCUS devices specifically designed to prevent the detection of fetal gender.

The current lack of a clear pathway complicates the procurement and distribution of POCUS devices for legitimate clinical, training, and research purposes, even for applications that do not fall under the PCPNDT regulations.

g. Graded Penalty System

A graded penalty system can be introduced to deter violations, imposing significantly higher punishments for entities registering USG devices for non-prenatal diagnostic purposes but engaging in prohibited activities.

For example, POCUS usage in the operating theatre, although there is a lower risk of sex detection in this scenario if done contrary to the provisions of the act, indicates a highly intentional and often clandestine operation.

Therefore, a higher penalty should be imposed compared to that of an obstetric ultrasound, where the presence of the ultrasound machine and the opportunity for its use are much greater.

We believe these measures will enhance oversight, prevent misuse of diagnostic technologies, and align with the legislative intent to prohibit unauthorised prenatal diagnostic techniques while supporting legitimate medical applications.

V. Training and Certification

We recommend the following comprehensive framework to strengthen and streamline the process of training, credentialing, and privileging for POCUS use in India.

First, establish a standardised credentialing and privileging process overseen by a multidisciplinary task force comprising representatives from professional societies across relevant medical disciplines (e.g., radiology, emergency medicine, anaesthesia, cardiology, etc.). This task force should define eligibility criteria and mandate comprehensive training through accredited programs, including hands-on practice, simulation-based learning, and didactic modules.

Second, a clear ScoP for POCUS must be defined, specifying permissible applications (e.g., diagnostic assessments in emergency care, critical care, etc.).¹² The ScoP should be tailored to different specialities, ensuring clarity on clinical contexts and limitations.

Third, education and competency standards should align with the defined ScoP, drawing on recommendations from the ASRA expert panel, emphasising structured curricula, supervised practice, and ongoing assessment to ensure proficiency.^{2,44,45} Training programs should incorporate tiered competency levels (basic, intermediate, advanced) to cater to varying clinical needs and expertise.

Finally, a national body, such as a POCUS Accreditation Council under the aegis of the NMC or any appropriate authority, should be established to accredit training courses, ensuring uniformity in quality, adherence to evidence-based standards,

and compliance with regulatory requirements. This body would also maintain a registry of credentialed practitioners and conduct periodic audits to uphold standards.

These measures will foster safe, effective, and regulated POCUS use, enhancing clinical outcomes while ensuring compliance with legal and ethical standards. Furthermore, such capacity building will help realise the recent Lancet Commission publication on transforming access to diagnostics.⁴⁶

VI. National Consensus/Practice Guidelines to Regulate the Use of POCUS

To regulate and promote the effective use of POCUS in India, we recommend the establishment of a multidisciplinary task force at the national level to develop comprehensive national consensus and practice guidelines. This task force should collaborate with policymakers, professional associations, and regulatory bodies such as the NMC to ensure alignment with existing healthcare regulations, including the proposed amendments to the PCPNDT Act.

The guidelines should outline standardized protocols for POCUS applications, defining appropriate clinical indications, training requirements, and quality assurance measures to ensure safe and effective use across specialities.

The task force can encourage widespread, ethical, and evidence-based POCUS integration by fostering collaboration. These guidelines will provide clarity, enhance clinical decision-making, and promote stakeholder confidence, ultimately streamlining the registration process and avoiding administrative delays, thereby improving patient outcomes while ensuring regulatory and legal compliance. The proposed action plan for the implementation of POCUS in India is illustrated in Figure 4.

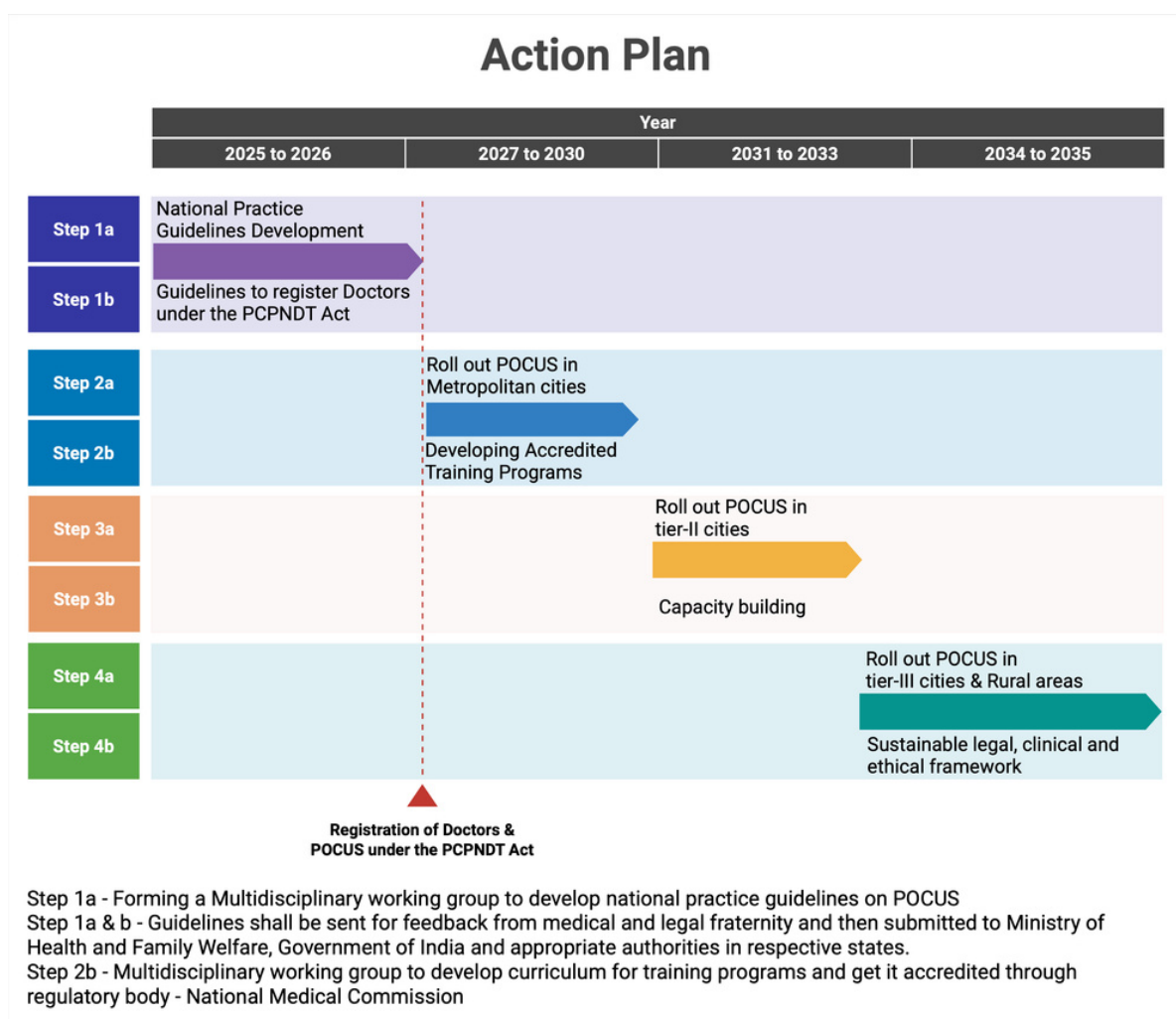


Figure 4: The action plan for POCUS implementation in India

10. Conclusion

POCUS holds transformative potential to revolutionise healthcare delivery in India, particularly in resource-constrained settings, by enabling rapid, accurate diagnostics and enhancing patient outcomes across diverse medical specialities.

However, the PCPNDT Act's restrictive framework, inadequate training, ambiguous regulations, and a lack of national guidelines hinder its widespread adoption.

To unlock POCUS's full potential, a balanced approach is essential—one that addresses the social issue of female feticide while promoting ethical POCUS integration in clinical practice, which will empower clinicians and bridge gaps in healthcare delivery.

11. Acknowledgment

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