# 06 - Ultrasound Beyond the Machine

## FDMSEC Insights | June -2026

## From

## FOGSI, Food Drugs & Medicosurgical Equipment Committee


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FOGSI

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## Dr. Asha Jain

### Editor & Chairperson, FOGSI FDMSE Committee

# Message From Dr. Bhaskar Pal

**Dr. Bhaskar Pal**
President FOGSI-2026

Ultrasound has become an essential part of obstetric and gynecological practice, but the quality of ultrasound service depends on much more than the machine. A clear image is important, but so are probe disinfection, safe gel use, Doppler discipline, proper reporting and reliable documentation.

This issue of FDMSE Insights on **"Ultrasound Beyond the Machine"** brings attention to the systems that make ultrasound safe, dependable and defensible. The articles on probe disinfection, USG gel safety, Doppler safety and quality assurance are especially relevant for every clinic, nursing home and hospital where ultrasound is performed daily.

I congratulate Dr Asha Jain and the FDMSE Committee for choosing a subject that is practical, timely and directly connected to patient safety. I hope this issue helps our members strengthen their ultrasound practice with simple, doable and evidence-based steps.

With best wishes,
**Dr Bhaskar Pal**
President, FOGSI

# Message from Dr Suvarna Khadilkar

**Dr. Suvarna Khadilkar**
Secretary General FOGSI

Ultrasound reporting is not merely a technical exercise. It is a clinical communication, a patient record and, when required, a medico-legal document. In busy practice, small omissions in report writing, image storage or follow-up advice may create avoidable problems later.

The June issue of FDMSE Insights addresses these important areas through articles on reporting errors, image storage, legal documentation and court-safe ultrasound practice. These are subjects that every practising obstetrician and gynecologist should revisit from time to time. Good documentation protects the patient, supports continuity of care and also protects the doctor.

I appreciate the efforts of Dr Asha Jain and the FDMSE Committee in bringing out an issue that goes beyond academic knowledge and focuses on daily clinical discipline. I am sure this issue will be useful for members working in different settings across the country.

With best wishes,
**Dr Suvarna Khadilkar**
Secretary General FOGSI

# Message From Dr.Vidya Thobbi

**Dr.Vidya Thobbi**
VP South Zone FOGSI
Incharge FDMSEC

A modern ultrasound unit is no longer judged only by resolution, Doppler quality or brand name. The real value of an ultrasound service lies in appropriate machine selection, safe use, good ergonomics, regular quality checks and sensible adoption of technology.

This issue of FDMSE Insights discusses important topics such as buying a new ultrasound machine, quality assurance, transvaginal scan ergonomics and the role of AI in ultrasound. These areas are often not discussed enough, yet they affect the safety, efficiency and long-term sustainability of our practice.

I congratulate Dr Asha Jain and the FDMSE Committee for bringing these practical issues into focus. I hope this issue encourages members to look at their ultrasound rooms, machines, reports and workflows with a fresh eye, and to make small improvements that can have a lasting impact.

Warm regards,
**Dr Vidya Thobbi**
Vice President Incharge, FOGSI

**Dr.Asha Jain**
Chairperson
FOGSI FDMSE Committee

## FOREWORD

It is my privilege to present the June issue of FDMSE Insights on the theme **"Ultrasound Beyond the Machine"**, mapped to **WHO: Essential Diagnostics**.

I am grateful to our FOGSI President **Dr Bhaskar Pal**, Vice President In charge **Dr Vidya Thobbi**, and Secretary General **Dr Suvarna Khadilkar** for their constant encouragement and guidance to the committee. Their support helps us choose subjects that are relevant not only academically, but also practically useful for doctors working in clinics, nursing homes and hospitals across India.

Ultrasound has become an inseparable part of obstetric and gynecological practice. Most of us use it every day for diagnosis, follow-up, emergency decision-making, counselling and documentation. Yet, the safety and reliability of ultrasound practice depend on many things beyond image resolution. A clean probe, safe gel handling, appropriate Doppler use, good reporting, correct image storage, ergonomic scanning, basic quality assurance and proper documentation are all part of responsible ultrasound practice.

This issue has been planned to look at these often-neglected areas. The aim is not to make ultrasound practice complicated, but to make it safer, cleaner, better documented and more defensible. A small clinic may not have a large technical team, but it can still maintain a probe cleaning log, a gel policy, a basic QA checklist, proper image backup and a clear reporting format.

I sincerely thank all the authors who have contributed their time and expertise to this issue. I hope this issue helps our members review their ultrasound rooms, reporting habits and documentation systems with a practical eye, and adopt small changes that can protect both patients and doctors.

**With warm regards,**
**Dr Asha Jain**
**Chairperson, FDMSEC, FOGSI**

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# Probe Disinfection: The Most Ignored Safety Step

**Author:- Dr. Jyothi G. S.**
**MBBS, MD (OBG), PGDMLE, FICOG, FICMCH**
**Professor and Head Department of Obstetrics & Gynaecology Ramaiah Medical College and Hospitals Bengaluru – 560054**

**Author:- Dr. Afreen Mahaboob**
**MBBS, MS (OBG), DNB (OBG)**
**Senior Resident Department of Obstetrics & Gynaecology Ramaiah Medical College and Hospitals Bengaluru – 560054**

**Introduction**

Ultrasound has transformed modern obstetric and gynecological practice. From confirming an early pregnancy to guiding complex interventions, it is one of the most frequently performed investigations in daily clinical practice. Yet, amid advances in imaging technology and increasing emphasis on diagnostic accuracy, one critical aspect of patient safety often remains neglected- probe disinfection.

An ultrasound transducer is a patient-contact medical device. During routine use, it may come into contact with intact skin, mucous membranes, blood, secretions, non-intact skin, or sterile tissues. Consequently, inadequate cleaning and disinfection can result in contamination and potential transmission of microorganisms between patients.

The American Institute of Ultrasound in Medicine (AIUM) 2025 guideline on cleaning and preparing external- and internal-use ultrasound transducers emphasizes that probe reprocessing should be determined by the type of patient contact and should include both proper cleaning and appropriate disinfection. The guideline also highlights the often-overlooked role of ultrasound coupling gel in infection prevention.

This chapter provides a practical approach to probe disinfection for busy ultrasound practices, focusing on what every sonologist, obstetrician, gynecologist, and ultrasound technician should know.

**Why Probe Disinfection Matters**

Microorganisms can survive on ultrasound transducers and associated equipment for prolonged periods. During scanning, probes may become contaminated with:

- Skin flora
- Blood
- Vaginal secretions
- Fecal contamination
- Environmental organisms
- Contaminated ultrasound gel
- Potential pathogens reported on inadequately disinfected probes include:
- Human papillomavirus (HPV)
- Hepatitis B virus

- Hepatitis C virus
- Human immunodeficiency virus (HIV)
- Herpes simplex virus
- Staphylococcus aureus
- Enterococcus species
- Candida species

Although documented transmission events are uncommon, contamination of probes is well established. Appropriate reprocessing minimizes this risk and represents an essential component of patient safety.

**The Most Important Principle: Cleaning Comes Before Disinfection**

Many healthcare workers use the terms cleaning and disinfection interchangeably. They are not the same.

**Cleaning**

Cleaning refers to the removal of:

- Ultrasound gel
- Blood
- Vaginal secretions
- Organic material
- Dirt and debris

Cleaning is performed using water, detergent, or manufacturer-approved cleaning agents. Cleaning reduces microbial burden but does not reliably destroy pathogens.

**Disinfection**

Disinfection refers to chemical or automated processes that destroy microorganisms remaining after cleaning.

Disinfection effectiveness depends upon:

- Prior cleaning
- Correct disinfectant
- Appropriate concentration
- Adequate contact time
- Manufacturer compatibility

Disinfection cannot be relied upon if cleaning has not been performed first. Organic debris may protect microorganisms from the action of disinfectants, rendering the process ineffective.

**Flowchart 1. The Correct Reprocessing Sequence**

Patient Examination Completed

↓

Remove and Discard Probe Cover

↓

Remove Gel and Visible Debris

↓

Clean Probe, Handle and Cable

↓

Inspect for Damage

↓

Apply Appropriate Disinfection (LLD or HLD)

↓

↓

Allow Required Contact Time

↓

Dry Completely

↓

Store in Clean Dry Area

↓

Document the Process

**Spaulding Classification Applied to Ultrasound Probes**

The Spaulding classification system remains the basis for determining the minimum level of reprocessing required.

**Non-Critical Devices**

Contact: Intact skin only

Examples:

- Transabdominal obstetric probes
- Routine abdominal probes

Requirement:

Cleaning + Low-Level Disinfection (LLD)

**Semi-Critical Devices**

Contact: Mucous membranes or non-intact skin

Examples:

- Transvaginal probes
- Transrectal probes
- Probes used on wounds
-

Requirement:

Cleaning + High-Level Disinfection (HLD)

**Critical Devices**

Contact: Sterile tissues

Examples:

- Intraoperative probes
- Ultrasound-guided invasive procedures

Requirement:

Sterilization whenever feasible or HLD with sterile barrier precautions according to institutional protocol

**Table 1. Probe Type, Patient Contact and Minimum Reprocessing Requirement**

| Probe Type | Patient Contact | Minimum Requirement | Documentation |
|---|---|---|---|
| External abdominal probe | Intact skin | Cleaning + LLD | Daily log |
| Obstetric transabdominal probe | Intact skin | Cleaning + LLD | Daily log |
| Transvaginal probe | Mucous membrane | Cleaning + HLD | Every cycle |
| Transrectal probe | Mucous membrane | Cleaning + HLD | Every cycle |
| Probe used over wound | Non-intact skin | Cleaning + HLD | Every cycle |
| Ultrasound-guided procedure | Potential sterile tissue exposure | HLD + sterile barrier | Procedure record |
| Intraoperative probe | Sterile tissue | Sterilization/HLD as per protocol | Procedure record |

**Practical Classification for Everyday Practice**

**Category 1: External Abdominal Scan**

Examples:

- Routine antenatal scans
- Pelvic abdominal scans

Requirement:

Cleaning + Low-Level Disinfection

**Category 2: Transvaginal Scan**

Examples:

- Early pregnancy scans
- Follicular monitoring
- Gynecologic evaluation

Requirement:

Cleaning + High-Level Disinfection after every patient

**Category 3: Scan Over Wound or Non-Intact Skin**

Examples:

- Surgical wound assessment
- Infected wound imaging

Requirement:

Cleaning + High-Level Disinfection

**Category 4: Ultrasound-Guided Invasive Procedures**

Examples:

- Oocyte retrieval
- Needle aspiration
- Drainage procedures

Requirement:

High-Level Disinfection + Sterile Barrier

**Category 5: Intraoperative Ultrasound**

Requirement:

Sterilization whenever feasible with sterile sheath and institutional infection-control measures.

**Probe Covers: Helpful but Not Sufficient**

A common misconception is that using a probe cover eliminates the need for disinfection.

This is incorrect.

Microscopic perforations have been documented in condoms and commercial probe covers used during endocavity examinations. Contamination may also occur during removal of the cover.

**Practical Rule**

New probe cover for every patient + High-Level Disinfection after every endocavity examination.

Probe covers reduce contamination but do not replace high-level disinfection.

**Coupling Gel: The Forgotten Infection-Control Link**

The AIUM guideline dedicates specific attention to ultrasound gel because contaminated gel has been implicated in healthcare-associated infection outbreaks.

**Safe Gel Practices**

✓ Use sterile gel for invasive procedures.
✓ Use sterile gel on non-intact skin.
✓ Avoid topping up partially used bottles.
✓ Discard expired products.
✓ Keep dispenser tips clean.
✓ Store products appropriately.

**Five Questions Before Using a Probe on the Next Patient**

1. Was all visible gel removed?
2. Was the handle cleaned?
3. Was the cable cleaned?
4. Was the correct disinfection method used?
5. Was the process documented?
6. If the answer to any question is “No,” the probe should not be used until reprocessing is completed correctly.

**Ten Mistakes in Probe Cleaning Seen in Busy OPDs**

1. Wiping only the probe tip.
2. Ignoring the handle.
3. Ignoring the cable.
4. Skipping cleaning before disinfection.
5. Using incompatible chemicals.
6. Not observing contact time.
7. Reusing probe covers.
8. Storing wet probes.
9. Using expired disinfectants.
10. Not maintaining a disinfection log.

**Documentation: The Forgotten Safety Tool**

A disinfection process that is not documented is difficult to verify.

A probe reprocessing log should include:

- Date and time
- Probe identification
- Operator name
- Cleaning completed
- Disinfection method
- Contact time achieved
- Equipment defects identified

Electronic systems are ideal, but a paper register remains acceptable and practical.

**Medico-Legal Implications**

Infection transmission related to ultrasound examinations may be difficult to prove conclusively because patients are exposed to multiple potential sources of infection.

However, during investigations, auditors and legal reviewers frequently assess:

- Presence of a written SOP
- Staff training records
- Disinfection logs
- Maintenance records
- Manufacturer instructions
- Audit reports

The absence of a written SOP or documented disinfection process significantly weakens the defence of a healthcare facility.

**Important Principle**

If it was not documented, it may be difficult to prove that it was done.

**Probe Disinfection Audit Checklist**

| Audit Item | Yes | No |
|---|---|---|
| Written SOP available | □ | □ |
| Staff trained in previous 12 months | □ | □ |
| Cleaning performed before disinfection | □ | □ |
| Approved disinfectant available | □ | □ |
| Contact time documented | □ | □ |
| HLD performed after every TVS | □ | □ |
| Probe covers changed between patients | □ | □ |
| Gel handling policy available | □ | □ |
| Disinfection log maintained | □ | □ |
| Probes stored dry | □ | □ |
| Damaged probes removed from use | □ | □ |
| Monthly audit completed | □ | □ |

**Key Take-Home Messages**

- Every ultrasound probe is a patient-contact medical device.
- Cleaning and disinfection are separate processes.
- Cleaning must always precede disinfection.
- External probes generally require low-level disinfection.
- Transvaginal and transrectal probes require high-level disinfection after every patient.
- Probe covers do not replace high-level disinfection.
- Safe handling of ultrasound gel is an essential infection-control measure.
- Written SOPs, logs, audits and staff training are critical for patient safety and medicolegal protection.

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# Ultrasound Gel: A Hidden Source Of Infection

**Author:- Dr. Okram Sarda Devi**
**Associate Professor, Department of Obstetrics & Gynaecology Churachandpur Medical College, Manipur**

**Introduction**

Ultrasonography has become an indispensable component of modern medical practice due to its rapid, reproducible, non-invasive, and cost-effective diagnostic capabilities. It is widely utilized for diagnosis, monitoring, and guidance during various invasive and non-invasive procedures.

Ultrasound gel plays a crucial role in ultrasonography by eliminating air between the ultrasound probe and the patient's skin, thereby facilitating efficient transmission of ultrasound waves and improving image quality. Despite its routine use and perceived safety, contaminated ultrasound gel has increasingly been recognized as a potential source of healthcare-associated infections (HAIs).

Composition of Ultrasound Gel

Most ultrasound gels are water-based preparations contains water ,Glycerin ,Propylene glycol, Thickening agents and Preservatives. These components help provide appropriate viscosity, acoustic conductivity, and patient comfort during ultrasound examinations.

**Contamination of Ultrasound Gels**

Ultrasound gels are intended to improve acoustic coupling between the probe and the skin. However, these gels may also serve as reservoirs for pathogenic microorganisms and contribute to cross-contamination in healthcare settings.

Contamination may occur through:

**1. Extrinsic Contamination**

- Contamination of ultrasound bottle tips
- Improper handling of multi-use bottles
- Contaminated ultrasound probes/transducers
- Inadequate hand hygiene practices

**2. Intrinsic Contamination**

Contamination occurring during the manufacturing process or within the gel itself Several studies have reported microbial contamination of ultrasound coupling gels. Organisms isolated from contaminated gels include:Corynebacterium minutissimum ( associated with erythrasma, a superficial skin infection commonly seen in warm and humid climates ),Burkholderia cepacia complex ,Pseudomonas species ,Klebsiella species etc.

These pathogens have been implicated in outbreaks of healthcare-associated infections linked to contaminated ultrasound gels.

**Consequences of Ultrasound Gel Contamination**

Microorganisms present in contaminated non-sterile ultrasound gel may gain access to sterile body sites during procedures involving skin puncture or mucosal contact. This can result in serious infections, particularly in immunocompromised patients and critically ill individuals.

Potential consequences include:

- Cross-contamination between patients
- Localized skin and soft tissue infections
- Healthcare-associated outbreaks
- Increased morbidity and healthcare costs

The risk is especially significant during invasive procedures such as:

- Transvaginal ultrasonography
- Transrectal ultrasonography
- Biopsy procedures
- Vascular access procedures

**Safe Ultrasound Gel Policy**

To minimize infection risk, strict infection-control practices should be followed:

- Use single-use sterile gel packets for invasive procedures
- Avoid “topping off” partially used gel bottles
- Clean gel warmers regularly according to institutional infection-control protocols
- Store gel bottles in clean and dry environments
- Check expiry dates routinely
- Discard visibly contaminated gel immediately
- Practice proper hand hygiene before and after procedures
- Ensure appropriate cleaning and disinfection of ultrasound probes

CDC Guidelines on Ultrasound (USG) Gel

| **Aspect** | **CDC Recommendation / Guideline** |
|---|---|
| Type of Gel Preferred | Use single-use sterile ultrasound gel for invasive procedures |
| Non-invasive Procedures | Non-sterile gel may be used on intact skin |
| Invasive Procedures | Sterile gel is mandatory for procedures involving mucous membranes or sterile body sites |
| Procedures Requiring Sterile Gel | Transvaginal USG, transrectal USG, biopsies, vascular access procedures |

| | |
|---|---|
| Application Method | Avoid direct contact of bottle tip with patient or probe |
| Contamination Prevention | Use aseptic techniques during procedures |
| Probe Cleaning | Ultrasound probes should be disinfected according to Spaulding classification |
| Storage of Gel | Store according to manufacturer instructions and avoid expired products |
| Hand Hygiene | Perform hand hygiene before and after every ultrasound procedure |

**Conclusion**

Although ultrasound gel is routinely considered harmless, contaminated gel can act as a hidden source of healthcare-associated infections. Increased awareness regarding proper handling, storage, warming practices, and adherence to infection-control guidelines is essential to ensure patient safety. Strict compliance with CDC recommendations and institutional protocols can significantly reduce the risk of cross-contamination and infection transmission associated with ultrasound procedures.

**References**


1. CDC Infection Prevention and Control Guidelines
2. CDC Guideline for Disinfection and Sterilization in Healthcare Facilities
3. FDA Safety Communications on Ultrasound Gel Contamination

# 3 Quality Assurance on Ultrasound: Simple Methods

**Author:- Dr. Sugandha Goel**
**Infertility Specialist and Laparoscopic Surgeon, Director, Kamla Nagar Hospital**

**Introduction**

Ultrasound imaging is one of the most widely used diagnostic tools in modern healthcare because it is non-invasive, relatively inexpensive, portable, and free from ionizing radiation. It is utilized in numerous medical specialties, including obstetrics, gynaecology, cardiology, radiology, emergency medicine, and vascular imaging. The accuracy and reliability of ultrasound examinations depend heavily on the performance of the ultrasound equipment and the competence of the operators. Therefore, a structured Quality Assurance (QA) program is essential to ensure optimal image quality, patient safety, diagnostic accuracy, and regulatory compliance.

Quality Assurance in ultrasound refers to a systematic process of monitoring, evaluating, and maintaining equipment performance to ensure consistent production of high-quality diagnostic images. Simple QA methods can be implemented routinely in healthcare facilities without requiring extensive resources. These methods help identify equipment deterioration, prevent diagnostic errors, and reduce maintenance costs.

**Objectives of Quality Assurance in Ultrasound**

The primary objectives of ultrasound quality assurance include:

1. Ensuring consistent image quality.
2. Maintaining diagnostic accuracy.
3. Detecting equipment malfunctions early.
4. Improving patient safety.
5. Extending equipment lifespan.
6. Meeting accreditation and regulatory requirements.
7. Enhancing operator confidence and efficiency.

A well-designed QA program contributes to reliable clinical outcomes and minimizes the risk of misdiagnosis due to equipment-related issues.

Components of an Ultrasound QA Program

A comprehensive ultrasound QA program generally consists of:

- Routine equipment inspection
- Performance testing
- Preventive maintenance
- Documentation and record keeping

- Staff training and competency assessment
- Corrective actions when faults are identified

Simple QA methods focus primarily on routine inspections and basic performance evaluations that can be conducted by sonographers, radiologists, or biomedical engineers.

**Simple Methods of Quality Assurance in Ultrasound**

**1. Visual Inspection of Equipment**

Visual inspection is the simplest and most frequently performed QA procedure. It involves examining the ultrasound machine and accessories for physical damage.

Items to inspect include:

- Monitor screen for scratches or dead pixels
- Control panel functionality
- Keyboard and touch screen operation
- Power cords and connectors
- Wheels and brakes on mobile units
- Printer operation (if applicable)

Any visible defects should be documented and reported for repair.

**2. Transducer Inspection**

The transducer is the most critical component of an ultrasound system and is particularly susceptible to damage.

Routine inspection should evaluate:

- Cracks in the transducer housing
- Damage to the acoustic lens
- Cable wear and tears
- Loose connections
- Signs of fluid ingress

Damaged transducers can produce image artifacts and may present electrical safety risks. Daily visual examination is recommended before clinical use.

**3. Image Uniformity Testing**

Image uniformity refers to the consistency of brightness across the ultrasound image.

Procedure:

- Use a tissue-mimicking phantom or a uniform medium.
- Freeze the image and assess brightness distribution.
- Look for dark streaks, dropout areas, or irregular patterns.

Non-uniformity may indicate defective transducer elements or system malfunctions. This test can be performed monthly.

**4. Dead Element Detection**

Ultrasound transducers contain multiple piezoelectric elements that generate and receive sound waves. Failure of individual elements may result in image artifacts.

Simple detection methods include:

- Scanning a uniform phantom
- Observing vertical streaks or dark lines
- Using manufacturer-provided transducer testing software

Regular monitoring helps identify transducer deterioration before significant image degradation occurs.

**5. Depth of Penetration Assessment**

Depth of penetration measures the maximum depth at which useful diagnostic information can be obtained.

Procedure:

- Scan a tissue-equivalent phantom.
- Determine the deepest visible structure.
- Compare results with baseline values.

A decrease in penetration depth may indicate reduced transducer sensitivity or system performance issues.

**6. Distance Accuracy Testing**

Distance measurements are essential for clinical diagnosis and treatment planning.

Testing involves:

- Using a calibrated ultrasound phantom.
- Measuring known horizontal and vertical distances.
- Comparing measured values with actual dimensions.

Acceptable measurement errors are generally within a few millimeters depending on the application and equipment specifications.

**7. Axial and Lateral Resolution Testing**

Resolution determines the system's ability to distinguish closely spaced structures.

**Axial Resolution**

Axial resolution refers to the ability to separate structures along the ultrasound beam path.

**Lateral Resolution**

Lateral resolution refers to the ability to distinguish structures side-by-side.

Using a phantom containing closely spaced targets, operators can verify whether structures remain clearly distinguishable. Reduced resolution may indicate equipment malfunction or transducer degradation.

**8. Gray Scale Evaluation**

Gray scale performance affects tissue contrast and lesion detection.

Assessment involves:

- Scanning a phantom containing targets of varying echogenicity.
- Evaluating visibility of low-contrast structures.
- Comparing images with established baseline images.

Changes in gray scale performance may affect diagnostic confidence.

**9. Monitor Quality Assessment**

Image display quality significantly influences interpretation accuracy.

Parameters to evaluate include:

- Brightness
- Contrast
- Resolution
- Color fidelity (for Doppler systems)

Simple monitor tests may involve displaying standard test patterns and visually assessing image quality.

**10. Doppler Quality Control**

Doppler ultrasound is used to assess blood flow characteristics.

Simple QA checks include:

- Verification of color flow display
- Assessment of spectral Doppler signals
- Evaluation using Doppler flow phantoms when available

Abnormal Doppler performance can lead to inaccurate velocity measurements and diagnostic errors.

**Use of Ultrasound Phantoms in QA**

Phantoms are specially designed objects that simulate human tissue properties. They play a central role in ultrasound quality assurance.

Advantages include:

- Standardized testing conditions
- Reproducible measurements
- Objective assessment of performance

Common phantom tests evaluate:

- Depth of penetration
- Resolution
- Distance accuracy
- Uniformity
- Contrast sensitivity

Tissue-mimicking phantoms are widely recommended for routine QA programs.

**Preventive Maintenance**

Preventive maintenance complements routine QA testing.

Activities include:

- Cleaning system components
- Updating software

- Checking cooling fans
- Electrical safety inspections
- Calibration procedures
- Replacement of worn parts

Manufacturers generally recommend annual preventive maintenance by qualified service engineers.

**Documentation and Record Keeping**

Effective QA programs require accurate documentation.

Records should include:

- Equipment inventory
- Testing schedules
- QA test results
- Maintenance reports
- Repair records
- Staff training records

Trend analysis of recorded data can help identify gradual deterioration in system performance.

**Frequency of QA Testing**

Different QA activities should be performed at varying intervals:

| QA Activity | Recommended Frequency |
|---|---|
| Visual inspection | Daily |
| Transducer inspection | Daily |
| Image quality assessment | Monthly |
| Uniformity testing | Monthly |
| Distance accuracy testing | Quarterly |
| Resolution testing | Quarterly |
| Doppler testing | Quarterly |
| Preventive maintenance | Annually |

The exact schedule may vary depending on institutional policies and equipment usage.

**Role of Personnel in Ultrasound QA**

Successful QA programs require collaboration among various healthcare professionals.

Sonographers

- Perform routine inspections
- Identify image artifacts
- Report abnormalities

**Radiologists**

- Review image quality
- Establish diagnostic standards
- Supervise QA activities

**Medical Physicists**

- Conduct advanced performance evaluations
- Analyze QA data
- Recommend corrective actions

**Biomedical Engineers**

- Perform maintenance and repairs
- Ensure electrical safety
- Support equipment calibration

Each professional contributes to maintaining high-quality ultrasound services.

**Benefits of Simple QA Methods**

Implementing simple QA methods offers several advantages:

1. Early detection of equipment problems.
2. Improved diagnostic confidence.
3. Reduced downtime.
4. Lower repair costs.
5. Enhanced patient safety.
6. Compliance with accreditation standards.
7. Extended equipment lifespan.

Even basic QA procedures can significantly improve imaging performance and healthcare outcomes.

**Challenges in Ultrasound Quality Assurance**

Despite its importance, QA implementation may face challenges such as:

- Limited staff training
- Lack of dedicated QA personnel
- Time constraints
- Budget limitations
- Inadequate documentation practices

Healthcare facilities can overcome these challenges through regular staff education, standardized protocols, and management support.

**Conclusion**

Quality Assurance in ultrasound is essential for ensuring accurate diagnosis, patient safety, and reliable equipment performance. Simple QA methods such as visual inspection, transducer evaluation, image uniformity testing, depth of penetration assessment, resolution testing, and routine preventive maintenance can effectively monitor system performance. These procedures require minimal resources and can be incorporated into daily clinical practice.

A structured QA program supported by proper documentation and trained personnel helps maintain high imaging standards, reduce equipment failures, and improve overall patient care. As ultrasound technology continues to evolve, consistent quality assurance practices remain fundamental to delivering safe and effective diagnostic services.

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# 4 Doppler Safety- How much is too much ?

**Author:- Dr Vishnupriya KMN**
**Professor and Head of Unit**
**Dept of Obstetrics and Gynaecology**
**St Johns Medical College, Bangalore**

**Author:- Dr Andrea Daniella Johnson Final year PG**
**Dept of Obstetrics and Gynaecology**
**St Johns Medical College, Bangalore**

Current evidence indicates that diagnostic ultrasound and Doppler studies in pregnancy, when performed by trained professionals for medical reasons, are considered safe. However, the principle is to use them only when **clinically indicated** and for the **shortest time needed**.

Routine obstetric ultrasound scans have not been shown to harm the fetus.
Doppler ultrasound uses higher energy than standard B-mode imaging, especially spectral Doppler, so unnecessary prolonged exposure is avoided.

Medical organizations such as the American Institute of Ultrasound in Medicine and International Society of Ultrasound in Obstetrics and Gynecology recommend using Doppler only when there is a medical indication and paying attention to safety indices (thermal index and mechanical index).

There is no established number of medically indicated Doppler examinations that is considered "too much."
A high-risk pregnancy may require multiple Doppler studies over weeks or months, and these are generally considered acceptable because the benefits outweigh theoretical risks.

What is discouraged is frequent non-medical use, such as prolonged "keepsake" ultrasound sessions or repeatedly listening to the fetal heartbeat at home for reassurance without medical need.

**Obstetric Doppler Safety: Key Concepts for Practice**
ALARA Principle
ALARA = As Low As Reasonably Achievable
-Use the lowest acoustic output and shortest examination time necessary to obtain clinically relevant information.
-Doppler should only be used when there is a clear clinical indication.
-Optimize machine settings before increasing output power.

Thermal Index (TI)
The Thermal Index estimates the potential for tissue heating.

- TI = 1 → approximately 1°C potential temperature rise.
- Fetal tissues, especially in early pregnancy, may be more sensitive to heating.
- Monitor TI continuously during Doppler examinations.

Recommended practice:

- Keep TI as low as possible.
- Many professional societies recommend maintaining TI < 1.0 whenever feasible during first-trimester scanning.
- If higher TI values are necessary, exposure duration should be minimized.

Mechanical Index (MI)

The Mechanical Index reflects the potential for non-thermal bioeffects, primarily cavitation.

In obstetric imaging:

- Keep MI as low as reasonably achievable.
- Modern obstetric equipment typically operates well within accepted safety limits.

Why Doppler Requires More Caution Than B-Mode imaging:

- Color Doppler produces higher acoustic output.
- Power Doppler produces higher acoustic output.
- Spectral Doppler generally produces the highest acoustic exposure and greatest potential for tissue heating.

B-mode → Color Doppler → Spectral Doppler (increasing acoustic exposure)

**First-Trimester Caution**

The embryo is undergoing rapid organogenesis during the first trimester.

Professional organizations including the International Society of Ultrasound in Obstetrics and Gynecology, American Institute of Ultrasound in Medicine, and World Federation for Ultrasound in Medicine and Biology advise:

- Use Doppler only when clinically indicated.
- Avoid unnecessary Doppler exposure for routine reassurance.
- Exercise particular caution before 10 weeks.
- Prefer B-mode whenever diagnostic information can be obtained without Doppler.

Examples where first-trimester Doppler may be justified:

- Assessment of fetal cardiac activity when necessary.
- Evaluation of suspected pathology.

Specialized fetal medicine examinations

Spectral Doppler Exposure Time

There is no universally defined "safe number of seconds," but guidance emphasizes:

- Obtain the waveform efficiently.
- Freeze and analyze stored images rather than repeatedly reacquiring data.
- Keep the Doppler sample volume appropriately positioned before activating spectral Doppler.
- Minimize dwell time over the embryo or fetal heart.

A practical approach is:

- Activate spectral Doppler only after the anatomy has been identified in B-mode.
- Record the necessary waveforms promptly.
- Turn Doppler off once adequate information is obtained.

**Patient Counselling Points**

A balanced counselling statement might be:

"Ultrasound and Doppler examinations used for medical indications are considered safe when performed by trained professionals. We follow the ALARA principle, using the lowest possible power and shortest scanning time needed to obtain important clinical information. Doppler uses more energy than routine ultrasound, so we avoid unnecessary exposure, especially in the first trimester."

In conclusion, no proven harmful fetal effects have been demonstrated from medically indicated diagnostic obstetric ultrasound. Safety recommendations focus on minimizing theoretical risks. The benefits of clinically indicated Doppler studies generally outweigh potential concerns.

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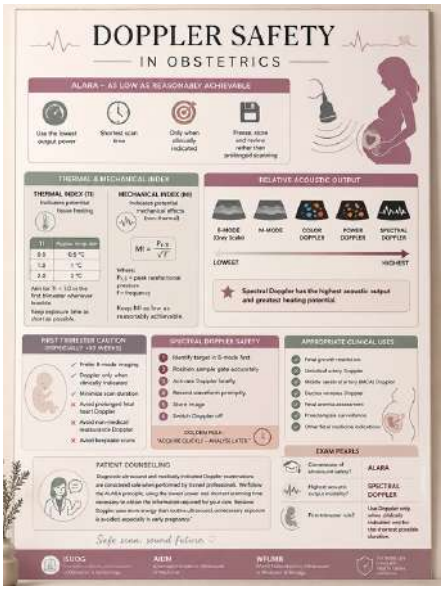


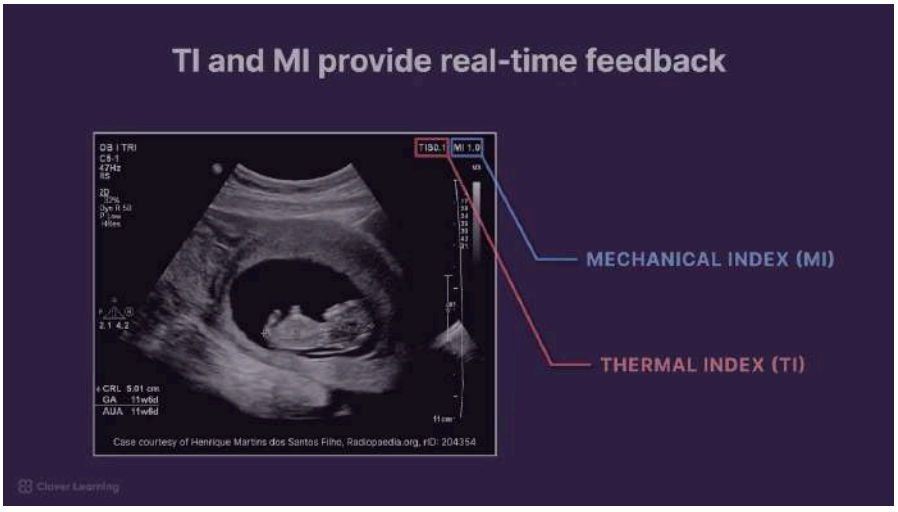

# 5 Reporting Errors that invite litigations

**Author:-Dr Geetika Sharma**
**Consultant Obstetrician, Gynaecologist & Fertility expert**
**Umang IVF & Super speciality Hospital**

## 1. Introduction

Ultrasonography has irrevocably transformed the practice of obstetrics and gynaecology. From confirming intrauterine pregnancy in the first trimester to the surveillance of fetal growth and placental function in the third, no single diagnostic modality has achieved the ubiquity, accessibility, or clinical centrality of the real-time ultrasound scan. In India alone, an estimated 50 to 60 million obstetric ultrasound examinations are performed annually, spanning the spectrum from basic government health centres to technologically sophisticated tertiary referral hospitals.

Yet this very ubiquity carries a shadow: the expectation of perfection. Patients increasingly approach the obstetric sonogram not merely as a screening tool with acknowledged limitations, but as an infallible diagnostic instrument capable of detecting every structural aberration, predicting every adverse outcome, and guaranteeing a normal child. When outcomes fall short of these expectations- as they inevitably must in some proportion of pregnancies- the search for accountability often begins at the ultrasound report.

The medicolegal consequences can be severe. Globally, missed fetal anomaly has overtaken missed ectopic pregnancy as the most frequent basis for ultrasound-related litigation.[1] In the United Kingdom, the NHS Resolution 2024/2025 report recorded obstetric litigation costs of £3.1 billion, reflecting an 11% year-on-year increase.[2] In India, the intersection of clinical negligence law, the Consumer Protection Act of 2019, and the stringent Pre-Conception and Pre-Natal Diagnostic Techniques (PCPNDT) Act, 1994 creates a uniquely complex medicolegal environment for the practising sonologist.

This article identifies the principal categories of reporting errors that render the sonologist and obstetrician vulnerable to legal action, and proposes a framework of safe reporting practices grounded in current evidence and guideline recommendations.

## 2. The Medicolegal Framework

For a claim of negligence to succeed in a court of law, the plaintiff must establish four essential elements: a duty of care recognised by law; a breach of that duty through failure to meet the accepted standard of care; a causal link between the breach and the injury sustained; and actual loss or damage to the plaintiff.[3] In the context of obstetric sonology, each of these elements finds fertile ground.

### 2.1 Consumer Protection Act, 2019

Medical services are explicitly included within the purview of the Consumer Protection Act, 2019 in India. A patient who receives a materially erroneous ultrasound report that leads to injury, adverse management decisions, or wrongful birth may approach a Consumer Disputes Redressal Commission for compensation. The Act imposes strict liability for 'deficiency in service,' and the burden of proof- once a prima facie case is established- partially shifts to the service provider.

### 2.2 The PCPNDT Act, 1994

The Pre-Conception and Pre-Natal Diagnostic Techniques Act imposes criminal liability for sex determination and selective sex-selective abortion. Sonologists are required to maintain Form F for every obstetric ultrasound, display the declaration board, maintain a proper sonography register, and ensure that the reporting physician is duly registered under the Act. Violations- including failure to complete Form F, erasures in the register, or reporting by an unregistered person- attract criminal prosecution with imprisonment up to three years and fine of up to ten thousand rupees. The medicolegal implications of PCPNDT non-compliance are routinely underestimated by practitioners.

### 2.3 Wrongful Birth and Wrongful Life Litigation

These two categories of litigation represent the most financially devastating consequences of missed prenatal diagnosis. In a wrongful birth claim, the parents allege that but for the negligent failure to detect a fetal anomaly, they would have chosen to terminate the pregnancy. In a wrongful life claim, the child alleges that they would have preferred non-existence to a life of disability. Though wrongful life suits are not yet recognised in Indian courts, wrongful birth claims have succeeded, and the trend toward greater judicial scrutiny of antenatal diagnostic errors is unmistakable. [1]

## 3. Common Reporting Errors that Invite Litigation

The literature identifies several recurring categories of ultrasound reporting errors that form the basis of medicolegal complaints. These may be broadly classified as technical errors, cognitive errors, communication errors, documentation errors, and systemic errors. [4]

### 3.1 Missed Fetal Anomaly - The Foremost Source of Litigation

"While in the 1980s, the highest volume of litigation involved missed ectopic pregnancies, nowadays the majority of lawsuits are for missed fetal anomalies. Perception and interpretation errors account for the majority of ultrasound-related litigation." - Donald School Journal of Ultrasound in OB/GYN[11]

The failure to detect a structural fetal anomaly- whether cardiac, craniofacial, skeletal, renal, or chromosomal -constitutes the single most common cause of obstetric ultrasound litigation today. [5] Several factors converge to produce this risk:

- Intrinsic limitations of the modality: Even in ideal conditions, ultrasound detects only 50–70% of major fetal anomalies. In a meta-analysis of 36 studies comprising over 900,000 fetuses, overall sensitivity for detecting fetal anomalies was approximately 40%, with a range of 15–80%. [6] Cardiac defects, orofacial clefts, skeletal dysplasia, and many chromosomal syndromes are notoriously difficult to identify sonographically.

- **Operator-dependence:** Unlike laboratory tests with standardised reagents, ultrasound quality is inextricably linked to the skill, experience, and vigilance of the operator. In India, anomaly scans are performed by radiologists, obstetricians, and general practitioners with widely varying levels of training in fetal anatomy.

- **Technical suboptimality:** Maternal obesity, unfavourable fetal lie, oligohydramnios, and advanced gestational age can significantly impair visualisation. These should be documented explicitly in the report rather than glossed over.

- **Cognitive biases:** Anchoring bias (focusing on an initial finding and missing others), satisfaction of search (ceasing examination after identifying one abnormality), and availability bias (pattern-matching based on recent memorable cases) are well-documented contributors to diagnostic error in ultrasound. [7]

**3.2 Errors in Gestational Age and Estimated Date of Delivery (EDD)**

Incorrect estimation of gestational age carries serious downstream consequences- incorrect timing of induction, erroneous classification of preterm or post-term status, and inappropriate interpretation of fetal biometric parameters. A landmark litigation case documented a patient with abdominal pain at 23 weeks by dates but only 15 weeks by ultrasound: the only report documentation was 'Uterus is normal.' Repeated discrepancies between fundal height and estimated gestational age were missed, and the case settled for $980,000.[4]

The use of the correct biometric parameter for gestational age estimation at different stages of pregnancy - crown-rump length (CRL) in the first trimester, biparietal diameter and femur length in the second and third - is essential. Reporting the dating method used and noting discordance between menstrual and sonographic dating is a mandatory element of a defensible report.

**3.3 Failure to Review Images Personally**

In busy clinical settings, there is a tendency for obstetricians to rely solely on the sonographer's verbal or preliminary report without reviewing the actual images. This constitutes a clear medicolegal risk. The reporting physician bears responsibility for the final report irrespective of who performed the scan.

**3.4 Inadequate or Ambiguous Documentation**

Vague, incomplete, or ambiguous reporting language is a significant source of litigation. Phrases such as 'appears normal,' 'within normal limits,' 'no obvious abnormality,' and 'structures seem intact' offer subjective reassurance without systematic documentation. When such reports are scrutinised in retrospect following an adverse neonatal outcome, they invariably fail to demonstrate that a complete, structured examination was performed.

Specific documentation failures that attract litigation include: absence of biometry measurements; failure to report placental location when marginal or low-lying; omission of amniotic fluid index (AFI); absence of Doppler findings in high-risk pregnancies; and failure to note technical limitations that precluded complete visualisation.

### 3.5 Misidentification of Fetal Sex - PCPNDT Violations

Under the PCPNDT Act, the disclosure of fetal sex for non-medical reasons is a criminal offence. However, litigation also arises from allegations that the sex was disclosed implicitly through wording, demeanour, or coded language. Conversely, incorrect sex reporting - identifying a female fetus as male or vice versa - while relatively uncommon, has resulted in both legal proceedings and significant patient distress.

Additionally, inadvertent or deliberate inclusion of genital images in reports, non-completion of Form F, failure to maintain the sonography register in the prescribed format, and registration lapses are all grounds for criminal prosecution under the PCPNDT Act regardless of intent.

### 3.6 Ectopic Pregnancy and Other Gynaecological Errors

Although ectopic pregnancy litigation has been overtaken in frequency by missed anomaly cases, the missed or delayed diagnosis of ectopic pregnancy remains one of the most clinically dangerous and legally actionable errors in gynaecological ultrasound. Failure to identify an adnexal mass in a patient with a positive pregnancy test and an empty uterus, or incorrectly attributing a heterotopic pregnancy to a singleton intrauterine pregnancy, have resulted in maternal death and major litigation.

Other gynaecological reporting errors with medicolegal implications include: missed ovarian malignancy in a cyst reported as 'simple'; incorrect measurement of endometrial thickness in a patient with postmenopausal bleeding; failure to characterise a fibroid or polyp in the context of abnormal uterine bleeding; and missed ovarian torsion in a patient with acute pelvic pain.

### 3.7 Delay in Communicating Critical Findings

The duty of the sonologist does not end with the written report. When a critical or unexpected finding is identified- a non-viable pregnancy, sudden fetal death, major structural anomaly, or abruptio placentae- there is a duty to communicate these findings directly and promptly to the referring clinician. Delay in communication that results in delayed treatment constitutes a separate ground of negligence independent of the report itself. [8]

### 3.8 Cognitive and Hindsight Bias in Litigation

When a missed anomaly eventually manifests postnatally, imaging performed during pregnancy is reviewed in light of the known outcome- a phenomenon known as hindsight bias. Findings that were legitimately inconclusive or within normal variation at the time of scanning may appear, in retrospect, to have been obviously abnormal. There is no clear remedy other than contemporaneous documentation of the limits of knowledge at the time of examination.

## 4. Safe Reporting Practices in Obstetric and Gynaecological Ultrasound

The following practices, grounded in ISUOG guidelines, FOGSI recommendations, and medicolegal literature, constitute the standard of defensible sonological reporting.

**4.1 Use Structured, Systematic Report Templates**

Every obstetric ultrasound report should follow a standardised template appropriate to the trimester and indication. A first-trimester report must include: number of gestational sacs and their location; embryo/fetal number and viability; CRL with gestational age; nuchal translucency (if applicable); adnexal and uterine findings; and a clear conclusion. A mid-trimester anomaly scan report must systematically document each anatomical system examined, explicitly note structures that were adequately or inadequately visualised, and provide a clear clinical recommendation.

As noted in ISUOG practice guidelines, before beginning the examination, the healthcare practitioner should counsel the woman or couple regarding the potential benefits and limitations of the routine mid-trimester fetal ultrasound scan. [9] Documentation of this pre-scan counselling in the report or patient record is advisable.

**4.2 Include a Limitations and Disclaimer Statement**

Ultrasound examination is a screening procedure and not a guarantee of a structurally normal fetus. Visualisation may be limited by maternal habitus, fetal position, gestational age, and amniotic fluid volume. A normal report does not exclude all congenital abnormalities."

A standardised disclaimer clause, incorporated into every obstetric report, is one of the single most effective medicolegal protective measures available to the sonologist. The disclaimer should specifically reference: the detection rate limitation of ultrasound for fetal anomalies; structures that could not be adequately visualised in the specific examination; and the recommendation for follow-up if clinical findings change.

**4.3 Document Technical Limitations Explicitly**

When visualisation is suboptimal due to identifiable technical factors- maternal body habitus, unfavourable fetal lie, posterior placenta, oligohydramnios, or advanced gestation- these must be explicitly stated in the report. A statement such as 'Complete visualisation of the fetal cardiac outflow tracts was limited due to unfavourable fetal position; repeat assessment or referral to a fetal medicine unit is recommended' is both clinically responsible and medicolegally protective.

**4.4 Obtain and Document Informed Consent**

Informed consent for obstetric ultrasound should be documented, particularly for invasive procedures (transvaginal ultrasound, amniocentesis guidance) and for anomaly scans at which unexpected findings may be disclosed. The consent process should include information about the nature and limitations of the examination, the possibility of incidental findings, and the process for communicating results.

**4.5 Maintain Meticulous PCPNDT Records**

Every sonography centre performing obstetric ultrasound must comply fully with PCPNDT Act provisions. This includes: timely completion of Form F before commencement of every examination; maintenance of the sonography registers in prescribed format without erasures, overwriting, or blank entries; display of mandatory declaration boards; registration under the Appropriate Authority; and submission of monthly reports. Non-compliance- even in the absence of any sex determination - constitutes a criminal offence and can result in closure of the facility.

**4.6 Personal Review of All Images by the Reporting Physician**

The reporting physician must personally review all stored images before issuing the final report. Reliance on a preliminary verbal summary from a sonographer, or signing a report without image review, is indefensible in court. Where multiple operators are involved in an examination, the responsible reporting physician should be clearly identified on the report.

**4.7 Adhere to ISUOG and FOGSI Standard Views**

The ISUOG Practice Guidelines mandate specific standard views for first-trimester and mid-trimester scans. Adherence to these protocols- and documentation of which views were obtained, and which were not obtainable- forms the foundation of standard-of-care compliance. The guidelines also mandate the ALARA (As Low As Reasonably Achievable) principle for fetal exposure, particularly for Doppler examinations in the first trimester. [10]

**4.8 Establish a Protocol for Communicating Critical Findings**

Every department performing obstetric ultrasound should have a documented protocol for the urgent communication of critical findings to the referring clinician. This protocol should specify the acceptable timeframe for communication, the mode of communication (telephone call followed by written report), and documentation of the communication in the patient record. The medicolegal record of communication is as important as the clinical content of the report.

**4.9 Continuous Professional Development and Audit**

Sonologists should regularly participate in structured training, particularly in fetal cardiac screening, neurosonography, and Doppler assessment. Departmental audit of missed diagnoses- conducted in a non-punitive, educational framework- is an evidence-based tool for improving detection rates and identifying systematic errors. Review of missed cases in multidisciplinary perinatal mortality meetings serves both educational and quality assurance functions.

**4.10 Avoid Absolute Reassurances in Reports**

Language such as 'normal pregnancy,' 'no abnormalities detected,' 'healthy baby,' or 'everything looks perfect' should be scrupulously avoided in obstetric ultrasound reports. Such phrases create an absolute standard of normality that ultrasound cannot guarantee, and they set the stage for a breach of expectation when an anomaly is subsequently identified. The appropriate standard is to document each structure examined, its appearance relative to established norms, and to qualify the overall conclusion with a standardised limitations statement.

**5. Summary: Error Categories and Protective Measures**

| Error Category / Litigation Risk | Protective Reporting Practice |
|---|---|
| **Missed fetal anomaly** | Document all structures examined; note limitations; include disclaimer; refer when in doubt |

| Error Category / Litigation Risk | Protective Reporting Practice |
|---|---|
| **Wrong gestational age / EDD** | State biometric parameters used; document discordance with LMP; avoid single-parameter dating in late pregnancy |
| **Failure to review images** | Reporting physician must personally review all stored images before signing the report |
| **Vague / ambiguous reporting** | Use structured system-by-system templates; avoid qualitative reassurances; be specific |
| **PCPNDT non-compliance** | Complete Form F before every scan; maintain register without erasures; ensure valid registration |
| **Missed ectopic pregnancy** | In any positive pregnancy test with empty uterus, systematically evaluate adnexae and pouch of Douglas |
| **Missed gynaecological pathology** | Characterise all ovarian cysts using IOTA criteria; measure endometrium in all postmenopausal scans |
| **Delayed critical communication** | Document verbal communication of critical findings in the patient record with time and recipient |
| **Cognitive bias / hindsight** | Document contemporaneous reasoning; note what was visible and what was not at time of examination |
| **Absolute reassurance language** | Replace 'normal pregnancy' with 'no significant abnormality detected within the limitations of this examination' |

**6. Conclusion**

The sonologist occupies a position of extraordinary clinical and medicolegal responsibility. Every obstetric ultrasound report is a medicolegal document. Its language, completeness, limitations, and conclusions will be scrutinised in courts, consumer commissions, and professional bodies in the event of an adverse outcome. The gap between what ultrasound can realistically detect and what patients expect it to detect is the fertile ground in which litigation grows.

Safe reporting is not merely a legal imperative - it is an ethical one. The mother who receives a normal anomaly scan report carries that reassurance with her through the remainder of her pregnancy and into the first days of her child's life. When that child is born with a condition that the scan could not detect, her grief is compounded by a sense of betrayal. Accurate, honest, well-qualified reporting - that acknowledges the genuine limitations of the modality -serves both truth and compassion.

The practices outlined in this article- structured reporting, explicit documentation of limitations, standardised disclaimers, PCPNDT compliance, personal image review, and clear communication protocols- do not diminish clinical confidence. They anchor it in evidence. They represent not the defensiveness of a litigious culture, but the professionalism of a discipline that takes its responsibilities to mothers and families seriously.

As the Indian medicolegal landscape continues to evolve- with expanding consumer rights, increasing awareness of reproductive choices, and a growing body of judicial precedent in prenatal diagnosis- the sonologist who practices with meticulous documentation and honest, standardised reporting will remain on the right side of both medicine and law.

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# Image Storage and Backup: Legal Requirements

**Author:- Prof. Shikha Sachan**
**Professor, Department of Obstetrics & Gynaecology, IMS, BHU City: Varanasi**

**Co-Author:- Dr Tanya Sharma**
**SeniorResident IMS, BHU**

**Beyond saving the image**

In ultrasound practice, the examination does not trulyend when the probe is removed from the patient. It endsonly when the right imagesare saved, the reportis linked to the correct patient, and the entire record can be retrieved safely when needed.[1,5] That simple idea is at the heartof this chapter. Image storageand backup maysound like technical or administrative matters, but in reality theyare part of patient safety, professional responsibility, and medico-legal protection.[1,5]

A beautifully performed scan canstill fail the patient if the images are lost, mislabeled, or impossible to retrievelater.[1,5] Many real-world problems in ultrasound practicearise not becausethe machine produced a poor image, but because the record was incomplete, stored under the wrong identity, transferred poorly, or leftwithout a reliable backup.[1,5] For that reason, image storage should be seen as an extension of clinical care. It protects continuity of treatment, supports qualityreview, and allowsthe sonologist or radiologist to stand on firm ground if the case is later questioned.[1,5]

**Why ultrasound records matter legally**

An ultrasound examination is more than a picture. It is a clinical record of what was looked at, what was found, what could not be fully assessed, and what conclusion was communicated at that point in time.[1] Once recorded, it may be revisited during follow-up care, multidisciplinary discussion, audit, insurance review, or even litigation.[1,5] This is why the stored ultrasound studymust be trustworthy.

From a legal pointof view, three questions oftenmatter: was the scan performed on the correct patient, was the recordcomplete, and can the department still produce it when required?[1,5] If the answerto any of these questions is no, even a technically sound examination may become difficult to defend. An absent image is often treated as an absent act because there is no reliableproof of whatwas seen or documented at the time.[5]

**The five pillars of safe storage**

The legal requirements around ultrasound image management can be understood through five practical pillars: identity, completeness, confidentiality, retention, and retrievability.[1,5] These are not abstract legalterms. They are everyday safety habits that determine whether an ultrasound record remains clinically useful and legallydefensible.[1,5]

**1.Correct identity**

Every image and every report must belong to the right patient.[1] The patient's name, identifier, date, and examination details should be checked before scanning and rechecked before the study is finalized.[1] A wrong-patient error is one of the most serious failures in ultrasound documentation because once the study enters the archive, the mistake can affect diagnosis, follow- up, billing, and referral.[1]

**2. Complete documentation**

Saving a few random still images is not enough.[1] A complete record should include representative images, relevant measurements, cine clips where needed, and a final report that clearly states the indication, findings, and limitations of the study.[1] The goal is to ensure that another clinician reviewing the case later can understand exactly what examination was performed and what conclusion was reached.[1]

**3. Confidentiality**

Ultrasound images are confidential patient data.[8] Access should be restricted to authorized personnel, and image transfer should happen through approved systems rather than personal phones, informal messaging, or unsecured devices.[8]Privacy breaches are not harmless shortcuts ; they are legal and ethical failures that can damage both patient trust and institutional credibility.[8]

**4. Retention**

Ultrasound records must be kept for defined periods according to policy and legal requirements.[5] Some studies may need to be stored longer because of chronic disease, obstetric follow- up, cancer care,or ongoing legal review.[5] Deletion should therefore never be casual. Records should not disappear simply because machine memory is full or because someone performed informal cleanup.[5,8]

**5. Retrievability**

A stored image is only useful if it can be found and opened when needed.[5] A study that is lost during system migration, trapped on a local machine, or saved in a format that later becomes unreadable is functionally no better than a destroyed record.[5] Retrieval is not merely a technical convenience; it is part of safe patient care.[1,5]

**What should actually be stored**

A reliable ultrasound record shouldcontain more than the final impression.[1] In most settings, the stored material should include patient identifiers, date and time of examination, operator details, representative images, relevant measurements, and the signed report.[1] Where Doppler, cine clips, or post-procedure documentation are important, those elements should also be savedas part of the record.[1]

This matters because memory fades quickly, but the record remains. When the patient returns weeks or monthslater, the stored images may be neededto compare findings, explain a management decision, or clarifywhether a lesionwas present at an earliervisit.[1,5] A good archiveprotects against confusion by preserving the evidence in a structured and reviewable form.[1,5]

**From machine memory to permanent archive**

Many ultrasound machines allow images to be stored locally, but local storage alone is not enough.[5] It may support immediate workflow, yet it is vulnerable to accidental deletion, hardware failure, theft, or failed transfer.[5] Proper record should move from the machine into an authorized archive such as PACS or another approved system.[5]

This transfer step is often underestimated. If the scan stays only on the machine because the upload failed or was never completed, the study may be effectively lost even though the examination was performed.[5] Departments should therefore monitor failed transfers, missing studies, and mismatched records as part of routine quality assurance.[1,5] The safest systems are not those that simply store data, but those that reliably prove that storage occurred.

**Backup: the silent protector**

Storage keeps records available for daily use, but backup protects them when something goes wrong. [5,8]Power failure, disk damage, accidental deletion, software corruption, ransomware, or server outage can all make a primary archive suddenly unreliable.[8] That is why backup is not a luxury. It is a core legal and clinical safeguard.[5,8]

A sensible backup system should answer a few practical questions. How often are records backed up? Are both images and reports included? Is one backup copy kept away from the primary system? Can the department actually restore records after failure?[8] The last question is especially important, because an untested backup policy may look reassuring on paper while offering very little protection in real life.[8]

In simple terms, a backup policy should ensure that records are copied regularly, stored securely, protected from unauthorized access, and tested for recovery.[8] Departments should also make it clear that personal drives, USB devices, or ad hoc exports are not acceptable substitutes for formal backup.[8]

**Privacy, cloud storage, and controlled sharing**

Modern imaging systems increasingly use networked and cloud- based storage, which can improve resilience and accessibility.[8] However, cloud storage does not reduce the department’s responsibility. Patient data still need encryption, access control,audit trails,and clear rules about where data are hosted and how they can be retrieved or deleted.[8]

The same principle applies when records are shared with referring clinicians or used for second opinion. Good referral practice means documenting what was shared, with whom, why it was shared, and when.[1,8] Images sent without the report, without clinical context, or through unapproved channels can create confusion as well as privacy risk.[1,8] In ultrasound, safe communication is part of safe storage.

**Amendments and audit trails**

Sometimes reportsneed correction. A typographical mistake, wrong side label, or clarified interpretation may be noticed after the report has been issued.[1] The safest response is not to hide the change, but to document it properly. A strongsystem should show who created the record, who accessed it, who modified it, and when the change was made.[8]

This transparency is important because silent overwriting damages trust. If a case is reviewed later, the department should be able to show the original record and any later amendment in a clear sequence.[8] Audit trails protect both patients and practitioners by making the life history of the record visible.[8]

**Common failures that lead to trouble**

Most storage-related legal problems arise from ordinary workflow gaps.[1,5,8] The most common examples are wrong-patient labeling, incomplete archiving, missing supporting images, failed backup, untracked amendments, and informal sharing through personal devices.[1,5,8] None of these failures may seem dramatic at the moment they occur, but each can become serious if the study is later questioned.

A practical lesson emerges from this: risk reduction in ultrasound is often less about buying new technology and more about using existing systems with discipline.[1,5] Clear patient identification, complete saving of images, successful transfer to archive,secure sharing,and periodic audit prevent many problems before they become medico-legal events.[1,5,8]

**A practical department approach**

The best departmental policies are simple enough to be followed every day. A workable routine may include verifying patient identity before scanning, saving the required images and measurements during the examination, checking labels before closing the study, confirming transfer to archive, issuing a clear report, and ensuring backup occurs according to policy. [1,5,8] When referral or amendment happens later, it should also pass through an approved and traceable pathway.[1,8]

Departments should periodically audit whether studies are actually reaching the archive, whether the reports match the saved images, and whether recovery from backup has been tested.[5,8] These checks may seem administrative, but they are closely linked to clinical quality. A department that cannot reliably retrieve a prior scan cannot fully support safe follow- up care.[1,5]

**Closing reflection**

Ultrasound is often judged by the quality of the live image on the screen, but safe practice extends far beyond that moment.[1,5] The real strength of an ultrasound service lies in whether the examination remains identifiable, complete, secure, retrievable, and trustworthy long after the patient has left the room.[1,5]That is the deeper meaning of image storage and backup.

In the spirit of Ultrasound Beyond the Machine, this chapter reminds us that good ultrasound practice is shapednot only by probe skill and imagequality, but also by the systems that preserve the record after the scan is over.[1,5] A stored image that cannot be found,trusted, or protected is not merelya technical failure; it is a missedopportunity to safeguard patient care.[1,5,8]

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# 7 Transvaginal Ultrasonography Ergonomics And Doctors Injury

**Author:- Dr. Shalini Jain**
**MD (OBGYN), FICOG, FMAS, CIMP, ACLS**
**Secretary Raipur Menopause Society**

**Introduction**

Transvaginal ultrasound is a cornerstone of gynecological diagnosis crucial for evaluating pelvic pathology, early pregnancy and infertility. however from an ergonomic standpoint transvaginal ultrasound is one of the most high risk procedures an obstetrician/ gynecologist ( OB /GYN ) performs.

While diagnostic medical sonography has revolutionized patient care, it has extracted a significant physical toll on its practitioners. Work-Related Musculoskeletal Disorders (WRMSDs) represent an underreported occupational hazard in medicine. Epidemiological data indicates that upwards of 80% to 90% of clinical sonologists and radiologists experience symptomatic musculoskeletal pain, with a staggering 20% suffering career-ending injuries.

Performing repeated transvaginal scans (TVS) presents a hidden paradox for many clinicians. A scan can be technically flawless, yielding crystal-clear diagnostic images that significantly benefit the patient, while the doctor performing it pays a steep, cumulative price in physical health over the span of their career. Because TVS requires precise, close-quarter maneuvering, it regularly exposes the practitioner to chronic wrist, thumb, shoulder, neck, and back strain. When the ultrasound machine, examination couch, operator stool, and viewing monitor are poorly positioned, these minor daily strains quickly compound into career-threatening musculoskeletal disorders (MSDs).

Unlike transabdominal scanning, which primarily strains the shoulder through abduction and transducer pressure, TVS forces the clinician into a unique triad of biomechanical stressors: awkward pelvic-axial alignment, sustained fine-motor torque, and constrained patient-adjacent positioning. This chapter delineates the precise biomechanical pathways of injury inherent to TVS and establishes evidence-based, preventative ergonomic interventions.

**Five Posture Corrections Every Sonologist Should Make**

- **Drop the Shoulder:** Consciously lower your scanning shoulder; avoid letting it creep up toward your ear.
- **Tuck the Elbow:** Bring your scanning elbow inward, keeping it as close to your flank as possible to eliminate shoulder abduction.
- **Straighten the Wrist:** Avoid extreme flexion, extension, or ulnar/radial deviation. Keep the wrist in a neutral, straight line.

- **Loosen the Fingers:** Relax your fingers on the probe; switch from a high-pressure clamp grip to a secure but light hold.
- **Un-twist the Neck:** Align your torso and chair directly with the monitor screen so your head faces straight ahead.

Symptoms That Should Not Be Ignored by Scanning Doctors

Warning Signs of Musculoskeletal Damage

**Numbness or Tingling:** Any persistent buzzing, loss of sensation, or pins and needles in the thumb, index finger, or wrist, which are common indicators of Carpal Tunnel Syndrome.

**Dull, Aching Shoulder Pain:** Deep aches within the shoulder joint or upper back during or after a long scanning list, which may indicate rotator cuff strain.

**Localized Burning Sensations:** Burning sensations around the elbow, forearm, or wrist tendons, pointing to localized inflammation or tendonitis.

**Chronic Neck Pain or Stiffness:** A constant stiffness or restricted range of motion in the neck and upper thoracic spine.

**Loss of Grip Strength:** Finding it suddenly difficult or tiring to open jars, hold small objects, or maintain control of the transducer.

**Biomechanical Mechanics and Pathophysiology of TVS Injury**

To understand why transvaginal imaging is uniquely injurious, one must analyze the interplay between static loading and dynamic manipulation. TVS requires high-precision, low-magnitude force coupled with extreme, repetitive wrist and torque-based maneuvers to manipulate the imaging plane through a restricted anatomical pivot point, the introitus.

**1. The Transducer Pivot Fallacy and Wrist Strain**

During TVS, the patient's introitus acts as a rigid fulcrum. To sweep the ultrasound beam from the cervix to the fundus, or laterally to the adnexa, the clinician must apply substantial torque to the probe handle. Because the arm is frequently held in an unsupportable, semi-extended position, the mechanical work shifts entirely to the intrinsic muscles of the hand and the forearm flexors and extensors.

**Pathophysiology:** This sustained isometric grip, combined with repetitive ulnar/radial deviation and wrist flexion, drastically increases fluid pressure within the carpal tunnel. The result is microvascular compression of the median nerve, accelerating the onset of Carpal Tunnel Syndrome (CTS) and De Quervain’s Tenosynovitis.

**2. Contorted Spinal Torsion and Asymmetric Loading**

The spatial layout of a standard examination room frequently forces a right-handed clinician to sit to the right of the patient, face the ultrasound monitor placed across the bed, and reach across their own midline or the patient's pelvis to insert and manipulate the probe.

**Pathophysiology**: This creates a dangerous twisted trunk posture, characterized by simultaneous lumbar spine flexion and axial rotation. This asymmetric loading forces the nucleus pulposus posteriorly and laterally against the thinnest portion of the annulus fibrosus, drastically increasing the risk of lumbar disc herniation and facet joint arthropathy.

**3. Chronic Shoulder Abduction and Rotator Cuff Ischemia**

When the examination table or the clinician's chair is improperly adjusted, the scanning arm is forced into abduction away from the midline greater than 30 degrees.

**Pathophysiology:** Maintaining an abducted arm requires static contraction of the deltoid and supraspinatus muscles. When abduction exceeds 30 degrees, the intramuscular pressure within the supraspinatus exceeds the physiological capillary perfusion pressure. This induces localized tissue ischemia. Over hundreds of scanning hours, this chronic microtrauma culminates in tendinopathy of the rotator cuff, subacromial impingement, and labral tears.

**The Ergonomic Anatomy of a Transvaginal Scan**

The table below outlines the primary musculoskeletal vulnerabilities specific to the distinct phases of a transvaginal ultrasound examination.

| Anatomical Zone | Specific Mechanism in TVS | Resulting Pathology |
|---|---|---|
| **Cervical Spine** | Persistent lateral rotation and hyper-extension to visualize a poorly positioned monitor. | Cervical radiculopathy, levator scapulae spasm, thoracic outlet syndrome. |
| **Shoulder / Periscapular** | Static abduction greater than 30° combined with forward flexion to reach the pelvic introitus. | Supraspinatus tendinitis, bicipital tenosynovitis, myofascial pain syndrome. |
| **Forearm / Wrist** | Pinch-grip pinch forces on narrow probe handles; repetitive rotational torque to sweep the adnexa. | Lateral epicondylitis ("tennis elbow"), carpal tunnel syndrome, flexor tendonitis. |
| **Lumbar Spine** | Forward slouching and axial twisting due to fixed, non-adjustable exam tables. | Disc protrusion, paraspinal muscle strain, sacroiliac joint dysfunction. |

**Evidence-Based Ergonomic Interventions**

Mitigating the risk of WRMSDs requires a deliberate, systemic restructuring of the scanning environment. Ergonomics is not a passive state but an active clinical discipline.

Figure 2: Geometric Optimization of Patient and Operator Positioni…

**1. Geometric Optimization of the Examination Space**

The 30-Degree Rule: Adjust the clinician's chair height and the examination bed so that the scanning arm can operate with the arm adducted closely to the torso. Shoulder abduction must strictly be maintained below 30 degrees.

Pelvic Elevation and Articulation: Utilize a dedicated endovaginal scanning wedge or an articulating examination table to elevate the patient's pelvis. Elevating the pelvis drops the introitus into a straight horizontal plane relative to the clinician's hand, entirely eliminating the need for the clinician to stoop forward or hunch their shoulders to gain an adequate angle of entry.

Monitor Co-Axial Alignment: Position the ultrasound monitor directly in the clinician's central line of sight. The top of the monitor screen should sit at or slightly below eye level, allowing a 15-degree downward gaze. This prevents sustained cervical rotation and hyperextension.

**2. Transducer Grip and Force Dynamics**

Palmar Modification: Avoid a high-force pencil grip or closed pinch-grip on the shaft of the transvaginal probe. Instead, utilize a relaxed, palmar grip where the handle rests within the palm, allowing larger muscle groups like the brachioradial is and biceps to share the rotational load.

**Cable Management**: The weight of a hanging, unsupported transducer cable adds significant drag, exponentially increasing wrist strain. Loop the cable loosely around your neck, anchor it to the ultrasound console cable management arm, or use a forearm cuff to negate the downward gravitational pull.

In simple language, just do a few small changes in the TVS room:

**Step 1: Bring the Patient to the Bed Edge**

Ensure the patient's buttocks are positioned slightly over or completely flush with the very edge of the examination table. If the patient is too far up the bed, you will be forced to overextend your arm, straining your lower back and shoulder.

**Step 2: Table Height Optimization**

Lower the examination bed so that when your hand is positioned on the probe inside the pelvic space, your forearm is completely horizontal or angling slightly downward, at a 90-degree to 100-degree elbow flexion. Never scan with your forearm angled upward.

**Step 3: Console Co-Location**

Pull the ultrasound console directly alongside the bed. Angle the control panel and keyboard so you do not have to reach backward or awkwardly sideways to reach the freeze, measurement, or gain buttons.

**Step 4: Primary Screen Realignment**

Swivel the ultrasound monitor so it sits directly in your straight line of sight as you look past the patient's knees. Your neck must remain perfectly neutral, completely eliminating lateral rotation or tilting.

**3. Administrative Controls and Scheduling Interventions**

Avoid scheduling consecutive back-to-back transvaginal or high-difficulty pelvic scans, such as complex endometriosis mapping or oocyte retrievals. Interleave transvaginal procedures with transabdominal scans or administrative reporting blocks to allow ischemic muscular tissues to reperfuse.

To combat the unique physical strains of transvaginal scanning, specifically the repetitive pinch grip and sustained arm elevation, gynecologists need a targeted physical therapy regimen. This routine focuses on two main goals: stretching structures that become tight and ischemic, or starved of blood flow, during a scan, and strengthening the postural muscles required to stabilize the shoulder and forearm.

**Targeted Physical Therapy Regimen**

**1. Carpal Tunnel and Forearm Care**

The goal here is to relieve fluid pressure within the carpal tunnel and prevent inflammation of the flexor tendons caused by holding the endocavity probe. The Reverse Wrist Flexor Stretch (The "Stop" Stretch)
Target: Forearm flexor muscles and the median nerve.

**How-to: Extend your scanning arm straight out in front of you with your palm facing away, as if** signaling stop. Use your opposite hand to gently pull your fingertips back toward your body until you feel a deep stretch in your forearm.
Dosage: Hold for 20 to 30 seconds. Repeat 3 times per side. Perform this directly between patient consultations.

**Tendon Gliding Exercises**

These exercises ensure that the tendons inside the carpal tunnel slide smoothly against one another, preventing the adhesions and swelling that lead to carpal tunnel syndrome. Move through these positions sequentially:

The Straight Hand (Position 1): Start with your hand completely open, fingers pointing straight up, and your thumb resting naturally against the side of your hand.

The Hook Fist (Position 2): Bend only the top two joints of your fingers down, keeping your main knuckles perfectly straight, creating a claw or hook shape.

The Flat Fist or Tabletop (Position 3): Straighten your fingers out flat, but bend at the main knuckle so your hand forms a 90-degree angle, resembling a tabletop.

The Full Fist (Position 4): Clench your fingers down into a standard, tight fist.

**2. Shoulder and Rotator Cuff Stability**

Because transvaginal scanning requires sustained, low-level activation of the shoulder muscles to steady the probe, gynecologists frequently experience fatigue in the upper trapezius and weakness in the lower scapular stabilizers.

"W" and "Y" Scapular Retractions

Target: Lower trapezius, rhomboids, and infraspinatus, counteracting the forward-slouched posture of scanning.

How-to: Stand with your back flat against a wall.

The W: Bring your elbows down and back, tucking them toward your ribs to form a W shape with your arms. Squeeze your shoulder blades tightly together.

The Y: Slide your arms up the wall into a wide Y position, reaching high while keeping your shoulders pulled down away from your ears.

Dosage: Hold each position for 5 seconds. Repeat for 2 sets of 10 repetitions daily.

Sleeper Stretch

Target: Posterior shoulder capsule, which tightens drastically when the arm is continuously held forward or abducted.

How-to: Lie on your side on a flat surface, directly on your scanning shoulder. Bring that arm straight out in front of you at a 90-degree angle to your body, then bend the elbow up to 90 degrees so your fingers point toward the ceiling. Use your opposite hand to gently push your wrist down toward the floor for internal rotation.

Dosage: Hold for 30 seconds. Repeat 3 times. Do not force this stretch; stop at the first sign of resistance or pinch.

**3. Micro-Breaks: The "Quick Cleanse" Routine**

If you are running behind on a heavy clinic day and cannot do a full exercise routine, implement this 30-second micro-break immediately after cleaning your ultrasound probe between patients: The 10-10-10 Recovery: Roll your shoulders backward 10 times, perform 10 rapid finger extensions by flaring your fingers wide out of the fist position, and take 10 seconds to let your

scanning arm hang completely dead and relaxed at your side to allow fresh, oxygenated blood to rush back into the tissues.

**Conclusion**

Musculoskeletal wellness is a foundational prerequisite for diagnostic excellence. The precise manipulation required by transvaginal ultrasonography exposes the clinician to a high density of biomechanical hazards. By recognizing early prodromal symptoms, such as burning neck pain, nocturnal hand numbness, or focal shoulder weakness, and aggressively implementing structural ergonomic changes, physicians can safeguard their health, protect their longevity in medicine, and maintain the highest standards of patient care.

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# 8 AI Features in Ultrasonography: What is Useful, What is Hype?

**Author:- Dr R.J. Mahajan,**

**Assistant Professor (OBG), IGMC, SHIMLA, HP.**

Artificial Intelligence (AI) has rapidly entered the field of ultrasonography (USG), especially in obstetrics and gynecology (OBG), radiology, fetal medicine, and reproductive medicine. Ultrasound has always been operator-dependent, with image quality and interpretation varying according to training, experience, machine quality, and patient factors. AI promises to reduce this variability by assisting image acquisition, automating measurements, improving workflow, and supporting clinical decision-making.

Manufacturers now market AI-enabled ultrasound systems with features such as automated fetal biometry, automatic follicle counting, lesion characterization, AI-guided image acquisition, triage alerts, and workflow automation. Terms such as “smart imaging,” “deep learning,” “auto OB,” “AI assist,” and “intelligent ultrasound” are increasingly used in advertisements and conferences.

However, despite impressive demonstrations, many AI applications remain highly dependent on image quality, machine training datasets, and user oversight. Some functions genuinely improve efficiency and reproducibility, whereas others are over-marketed and insufficiently validated for routine independent use.

This chapter critically evaluates AI features in ultrasonography with emphasis on:

- Auto measurements
- Follicle counting
- Fetal biometry
- AI triage systems
- Limitations and biases
- Validation requirements
- Medicolegal and ethical concerns
- Clinician responsibility and caution notes

The focus is not whether AI will enter ultrasound practice- it already has- but whether clinicians understand where it helps and where caution is essential.

**Understanding AI in Ultrasound**

AI in ultrasonography mainly uses:

- Machine learning (ML)
- Deep learning (DL)
- Convolutional neural networks (CNNs)

These systems are trained on large datasets of ultrasound images. The software learns to identify patterns, anatomical landmarks, borders, and measurements.

AI functions in ultrasound can broadly be divided into:

| Function | Examples |
|---|---|
| Image acquisition assistance | Probe guidance, angle correction |
| Automated measurements | BPD, HC, AC, FL |
| Counting and segmentation | Follicle count, ovarian volume |
| Pattern recognition | Placenta localization, lesion classification |
| Workflow optimization | Auto-reporting, triage |
| Decision support | Risk flagging, anomaly alerts |

AI does not "understand" anatomy like a clinician. It recognizes statistical image patterns learned from training datasets.

**Why AI Became Attractive in Ultrasonography**

Ultrasound has several characteristics that make it suitable for AI integration:

- Highly operator-dependent
- Large image volumes
- Repetitive measurements
- Need for rapid workflow
- Inter-observer variability
- Shortage of trained sonologists in many regions

In busy OBG settings, especially infertility clinics and antenatal units, AI appears attractive because it can:

- Reduce scanning time
- Improve standardization
- Reduce fatigue-related errors
- Assist junior operators
- Increase patient throughput
- However, increased speed does not always mean increased accuracy.

**AI in Automated Measurements**

**What Are Auto Measurements?**

AI-based auto measurement tools automatically identify anatomical landmarks and calculate dimensions.

Common examples include:

- Biparietal diameter (BPD)
- Head circumference (HC)
- Abdominal circumference (AC)
- Femur length (FL)
- Nuchal translucency
- Endometrial thickness
- Ovarian volume

Many modern ultrasound systems offer "one-click biometry."

**What is Truly Useful?**

**1. Improved Speed**

AI can significantly reduce the time required for routine fetal biometry.

Studies show:

- Faster acquisition
- Reduced manual tracing
- Quicker report generation

This is especially useful in:

- Busy antenatal clinics
- High-volume fetal medicine units
- Screening programs

**2. Better Reproducibility**

Manual measurements vary among operators. AI can reduce:

- Inter-observer variability
- Intra-observer variability

Standardized landmark recognition helps improve consistency.

This is valuable in:

- Serial fetal growth monitoring
- IVF follicular tracking
- Research settings
- Telemedicine workflows

**3. Assistance to Beginners**

Junior sonographers may struggle with:

- Correct planes
- Accurate caliper placement
- Image orientation

AI guidance systems can:

- Suggest optimal planes
- Highlight landmarks
- Warn against poor alignment

This may shorten the learning curve but does not replace training.

**What Is Hype?**

**1. "Fully Automated" Claims**

No current ultrasound AI system can independently perform comprehensive diagnostic scans safely without clinician oversight.

Most AI systems still require:

- Good image acquisition
- Correct probe positioning
- Human confirmation

Poor-quality images produce poor AI output.

The phrase "AI performs the scan automatically" is often misleading.

**2. Overconfidence in Border Detection**

AI frequently struggles with:

- Maternal obesity
- Oligohydramnios
- Fetal movement
- Multiple pregnancy
- Abnormal anatomy

Automated calipers may appear precise while being fundamentally incorrect.

False confidence is dangerous because clinicians may accept values without careful verification.

**3. AI as a Replacement for Expertise**

AI assists measurements but does not replace:

- Clinical reasoning
- Pattern recognition
- Differential diagnosis
- Contextual interpretation

A perfectly measured fetal abdomen does not guarantee that fetal growth restriction has been recognized correctly.

**AI in Follicle Counting**

Follicular monitoring is central to infertility management and assisted reproductive technology (ART).

Traditional follicle counting is:

- Time-consuming
- Operator-dependent
- Variable

AI-assisted follicle assessment aims to:

- Automatically identify follicles
- Measure diameters
- Calculate ovarian volume
- Estimate follicular cohorts

**Useful Applications**

**1. Faster IVF Monitoring**

Automated follicle counting significantly reduces scan duration in busy IVF clinics.

Benefits include:

- Rapid assessment
- Standardized measurements
- Reduced operator fatigue

**2. Better Documentation**

AI-generated follicular maps improve:

- Record keeping
- Serial comparison
- Treatment planning

Some systems generate 3D ovarian reconstruction with automated counts.

**3. Reduced Observer Variation**

Different clinicians often count follicles differently, especially small follicles.

AI improves reproducibility in:

- Antral follicle count (AFC)
- Controlled ovarian stimulation monitoring

**Limitations of AI Follicle Counting**

**1. Difficulty with Complex Ovaries**

AI performs poorly in:

- Endometriomas
- Hemorrhagic cysts
- PCOS with crowding
- Poor image quality

Follicles may be:

- Missed
- Double counted
- Incorrectly segmented

**2. Small Follicles Remain Problematic**

Very small follicles (<5 mm) are inconsistently identified.

This affects:

- Ovarian reserve estimation
- PCOS evaluation

**3. AI Cannot Interpret Clinical Context**

A follicle count alone does not determine:

- Ovarian response quality
- Ovulation timing
- Clinical prognosis

Clinical correlation remains essential.

**AI in Fetal Biometry**

Fetal biometry is one of the most widely adopted AI applications in obstetric ultrasound.

**Current AI Capabilities**

Modern AI systems can:

- Detect standard planes
- Freeze optimal images
- Place calipers automatically
- Generate gestational age estimates

Some systems even provide:

- Automated growth charts
- Growth trend alerts
- Estimated fetal weight calculations

**Genuine Benefits**

**1. Standard Plane Recognition**

Obtaining the correct plane is critical.

AI helps identify:

- Trans thalamic plane
- Trans ventricular plane
- Abdominal circumference plane

This improves consistency.

**2. Reduced Scan Time**

Automated fetal biometry may reduce routine anomaly scan duration.

This helps:

- High-volume centers
- Rural outreach screening
- Resource-limited settings

**3. Better Workflow Integration**

AI-linked reporting systems can:

- Transfer measurements automatically
- Reduce transcription errors
- Generate structured reports

**Major Concerns**

**1. Abnormal Fetuses Challenge AI**

AI training datasets often contain predominantly normal fetuses.

Performance may decline in:

- Skeletal dysplasia
- Hydrocephalus
- Congenital anomalies
- Severe growth restriction

AI may either:

- Fail to recognize abnormality
- Generate misleading measurements

**2. False Reassurance**

This is perhaps the biggest danger.

A scan with:

- Correctly generated numbers
- Beautiful automated graphics
- Structured AI report

may still miss critical pathology.

Clinicians must not confuse automation with diagnostic completeness.

**3. Hidden Errors**

Auto-generated measurements may not be reviewed carefully due to:

- Time pressure
- Trust in technology
- Automation bias

This can lead to:

- Wrong gestational age
- Incorrect growth interpretation
- Missed fetal compromise

**AI Triage Systems in Ultrasound**

**What Is AI Triage?**

AI triage systems prioritize or flag scans requiring urgent attention.

Examples:

- Suspected fetal anomaly alerts
- Abnormal placental localization

- High-risk cardiac images
- Ectopic pregnancy suspicion
- Ovarian torsion alerts

These systems aim to:

- Improve workflow
- Reduce missed emergencies
- Assist non-specialist settings

**Potentially Useful Areas**

**1. Rural and Low-Resource Settings**

AI triage may help identify:

- High-risk pregnancies
- Gross anomalies
- Urgent referrals

This may be valuable where expert sonologists are unavailable

**2. Emergency Departments**

AI may assist rapid triage for:

- Free fluid
- Ectopic pregnancy suspicion
- Fetal viability
- Cardiac activity

**3. Quality Assurance**

AI can flag:

- Missing standard images
- Incomplete examinations
- Poor image quality

This may improve audit performance.

**What Is Overhyped?**

**1. AI "Diagnosis"**

Most current systems are not validated for independent diagnosis.

An alert saying "Possible anomaly detected" does not establish a diagnosis.

**2. Unrealistic Expectations**

AI triage systems often work well in:

- Controlled environments
- High-quality images
- Selected patient populations

Real-world performance may be far lower.

**3. Liability Confusion**

If AI fails to flag a critical anomaly:

- Responsibility still rests with the clinician.

This is frequently misunderstood.

**Limitations of AI in Ultrasound**

**1. Dependence on Image Quality**

AI cannot compensate for severely poor images.

Factors affecting performance:

- Obesity
- Scarring
- Oligohydramnios
- Fetal position
- Machine quality

“Garbage in, garbage out” remains true.

**2. Dataset Bias**

AI learns from training data.

If datasets are limited:

- Ethnically narrow
- Device-specific
- Demographically restricted

performance may not generalize.

For example:

- Fetal biometric norms may differ across populations.
- AI trained mainly on Western populations may underperform elsewhere.

**3. Limited Rare Disease Recognition**

Rare anomalies are underrepresented in datasets.

Therefore AI may:

- Miss uncommon conditions
- Misclassify atypical findings

Human expertise remains critical in fetal medicine

**4. Black Box Problem**

Many AI systems provide outputs without transparent reasoning.

Clinicians may not know:

- Why a measurement was chosen
- Why an alert was generated
- Why a case was classified as normal

This reduces interpretability.

**5. Overfitting**

Some AI systems perform excellently in development datasets but poorly in real-world practice.

This occurs when algorithms:

- Memorize training patterns
- Fail to generalize

External validation is therefore essential.

**Bias in AI Ultrasound Systems**

Bias in AI is a major concern.

Sources of Bias

**1. Population Bias**

Training datasets may inadequately represent:

- Asian populations
- African populations
- Rural populations
- High-risk pregnancies

**2. Equipment Bias**

Algorithms trained on one manufacturer's machine may underperform on another system.

**3. Operator Bias**

AI may inherit patterns from:

- Expert operators only
- Selected academic centers

Performance may drop in community settings.

**Consequences of Bias**

Bias may lead to:

- Incorrect measurements
- Missed anomalies
- Unequal diagnostic performance
- Worsening healthcare disparities

AI systems should therefore undergo:

- Multicenter validation
- Diverse population testing
- Real-world assessment

**Validation of AI Systems**

**Why Validation Matters**

Commercial AI tools are often marketed aggressively before adequate clinical validation.

Validation must answer:

- Does the AI improve outcomes?
- Is it accurate across populations?
- Is it reproducible?
- Is it safe?

**Important Validation Parameters**

**1. External Validation**

Testing should occur outside the original development center.

**2. Prospective Studies**

Real-time clinical use is more meaningful than retrospective image analysis.

**3. Comparison with Experts**

AI should be benchmarked against experienced fetal medicine specialists and sonologists.

**4. Clinical Outcome Relevance**

Improved speed alone is insufficient.

The key question is:…….Does AI improve patient care?

**Doctor Responsibility in the AI Era**

**AI Is an Assistive Tool**

The clinician remains responsible for:

- Scan quality
- Interpretation
- Clinical correlation
- Final diagnosis
- Documentation

AI does not transfer medicolegal liability away from the doctor.

**Key Responsibilities of Clinicians**

**1. Verify All Automated Measurements**

Never blindly accept AI-generated values.

Always review:

- Plane quality
- Caliper placement
- Anatomical landmarks

**2. Maintain Ultrasound Skills**

Overdependence on automation may erode clinician competence.

Operators must remain capable of:

- Manual measurements
- Independent scanning
- Diagnostic reasoning

**3. Recognize AI Failure Situations**

Clinicians should be especially cautious in:

- Congenital anomalies
- Multiple pregnancy
- Severe obesity
- Poor acoustic windows
- Complex adnexal pathology

**4. Explain AI Use to Patients When Relevant**

If AI significantly contributes to workflow or reporting, transparency may be ethically appropriate in some settings.

**Medicolegal Concerns**

**Who Is Liable?**

Current legal frameworks generally hold:

- The clinician
- The reporting doctor
- The healthcare institution

responsible for errors.

AI companies are rarely directly liable in clinical practice.

**Documentation Matters**

Clinicians should document:

- Difficult scans
- Poor visualization
- AI-assisted measurements when relevant
- Need for repeat imaging

**Risk of Automation Bias**

Automation bias occurs when clinicians trust AI output excessively despite contradictory evidence.

Example:

- AI labels anatomy “normal”
- Clinician ignores suspicious finding

This is a recognized patient safety risk.

**Ethical Issues**

**1. Informed Use**

Patients should not assume AI equals superior diagnosis automatically.

**2. Data Privacy**

AI systems often require:

- Cloud storage
- Large datasets
- Image sharing

This raises concerns regarding:

- Confidentiality
- Data ownership
- Cybersecurity

**3. Equity Concerns**

AI benefits should not remain limited to expensive tertiary centers.

**AI Caution Note for Clinicians**

**Practical Clinical Caution Points**

Always remember:

- AI assists; it does not diagnose independently.
- Automated measurements require human verification.
- Abnormal anatomy reduces AI reliability.
- Poor image quality severely affects performance.
- AI may miss rare or atypical pathology.
- Beautiful graphics do not guarantee diagnostic accuracy.
- Clinical correlation remains essential.
- Responsibility remains with the clinician.

**Sensible Use of AI in Ultrasound**

**Where AI Is Truly Helpful**

AI is genuinely useful for:

- Workflow efficiency
- Routine measurements
- Standardization
- IVF follicle monitoring
- Structured reporting
- Quality checks

**Where Human Expertise Remains Essential**

Human judgment remains irreplaceable in:

- Fetal anomaly detection
- Complex gynecologic pathology
- Clinical integration
- Counseling
- Ethical decision-making
- Emergency interpretation

**Future Directions**

The future of AI in ultrasonography may include:

- Real-time anomaly detection
- AI-guided remote scanning

- Portable smart ultrasound
- Predictive analytics
- Integration with electronic medical records
- Personalized risk assessment

However, future success depends on:

- Robust validation
- Ethical regulation
- Transparent algorithms
- Continuous clinician oversight

**Conclusion**

AI in ultrasonography is neither a miracle nor a meaningless gimmick. Some applications- particularly automated measurements, fetal biometry assistance, workflow optimization, and follicle counting- already provide practical clinical value. They can improve speed, standardization, and reproducibility in busy ultrasound practice.

At the same time, many claims surrounding AI remain exaggerated. Current systems still depend heavily on image quality, operator skill, and human oversight. AI performs best in structured, repetitive tasks and worst in atypical, complex, or abnormal cases where clinical judgment is most important.

The greatest risk is not that AI will replace clinicians, but that clinicians may overtrust AI-generated outputs without adequate verification. Automation bias, poor validation, hidden algorithmic bias, and false reassurance are genuine concerns.

Ultrasound remains a dynamic clinical examination—not merely a measurement exercise. The clinician must continue to integrate anatomy, pathology, patient history, and real-time interpretation. AI should therefore be viewed as an intelligent assistant rather than an autonomous diagnostician.

The safest and most effective future lies in balanced collaboration:
skilled clinicians using validated AI carefully, critically, and responsibly.

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# Buying a New Machine: Beyond Price & Brand

**Author:- Dr. Prerna Saigal**
**MBBS, MD consultant Ob n Gyn Kalayani Hospital Pathankot**

Introduction - We often get calls from different company executives 'mam/sir want to change your ultrasound machine. Ours is the best and very reasonably priced'.. While price and brand are definitely the major determinats, they do not guarantee long term clinical or financial success.. An economically priced machine may have high operational cost, and a good brand might offer features which may not be of use to you.

To be a smart investor we must look beyond the price tag. Here are nine vertical pillars of a comprehensive ultrasound procurment strategy.

**1. Clinical need assessment**

We have to be clear in our mind about the facility's actual requirements beforenegotiating. Buying a machine with too many feature is a waste of capital and buying one with too less a feature is a compromise.

- **Speciality fours** : we should be clear in our minds before buying that what do we need [eg cardiology, obs/gyn, musculoskeletal], or a machine with combined features

- **Form factor** : decide whether you need a machine with traditional console (best for high pt load), portable laptop style (ideal for point of care or er) or a hand held device( for quick rounds ).

- **Patient demographics** :- units dealing with bariatrics require machines with advanced penetration capabilities.

**2. The probe portfolio (transducers)**

Transducers are the brain of an ultrasound machine and often are responsible for upto 30-40% of the cost and are fragile too.

- **Selection** : make sure that the machinw has the exact frequencies and array types that you nedd 'linear , convex, transabdominal, transvaginal, or 4d volume probes,

- **Pinless vs tradional** : pinless versions are better as there is less mechanical wear and tear and the lifespan of machine is increased.

- **Single - crystal technology** : look for probes using single crystal technology as it gives better bandwidthand image resolution.

**3. Service contracts and total cost of ownership (tco)**

Here comes a very important determinant the after sale service. A comprehensive service contract protects you from expensive component failures.

- **Contract tiers** :- analyse clearly what all is included in your service contract .whether it is full- service contract (parts, labor and probes), biomed support contract or preventive maintenance only.

- **Probe coverage** : a machine is as good as it's protes. So make sure that the contract covers probe replacement or offers a good probes exchange discount as probes are most prone to accidental damage.

**4. Uptime guarantees and response times**

Every lost hour of an ultrasound machine extails revenue loss and delayed patient care.

- **The 95% rule** : you should have a written uptime guarantee (typically 95% to 98%) within your agreement. If the service provider fails, he should extend or refund the fee.

- **Response windows** : the key performance indiators should be clearly defined for tech response times (eg 4- hours phone response, 24 hours on - site arrival).

- **Loaner availability** : the service provider should be able to give a 'stand by' machine within 24-48 hours for complex repairs

**5. Software upgrades and future -proofing**

Software is the heart of an ultrasound machine if we do not upgrade the software, the machine become obsolete .

- **Software updates vs upgrades** : ensure that updates ( bug fixes and minor patches) are free where as upgrades (new clinical features or advanced ai automation, are chargeable.

- **Subscription models** : ask the vendor whether he offers software as- a-service (saas) styling which lets you unlock advanced packages like automated follicle counting when your volume justifies it.

**6. Connectivity : Dicom and Pacs integration**

An ultrasound machine cannot work as an isolated system. It must have connections with your digital health system

- **Dicom and pacs integration** : ensure that the machine is dicom friendly [ digital imaging and communications in medicine ) including store, print, worklist, query/ retrivre and structured reporting

- **Pacs compatibility** : the company representative should make sure that the machine is compatible with picture archiving and communication system (pacs) and electronics health record (ehr)

- **Cyber security :** the machine should run on a secure operating system with active encryption, antimaliware protection and user authentication to protect patient data.

7 **Clinical and technical training :** it is the man behind the machine that matters. Staff should be acquianted with the advanced features.

- **Applications Training :** the vender should ensure on-site "apps training" daysafter installation followed by a revital session 1-3 months later.

- **Turnover Support :** the vender should provide accers to online learning modules or remote video support to train new staff.

**8 Warranty clarity :** one must look at the fine print to know exactly what is protected.

- **Inclusions :** make sure that the warranty covers the console, software and all purchased probes and not just the hardware.

- **Travel costs :** verify that the service engineer's travel cost is covered for 'on site' repairs duringthe warranty period.

**9 Component lifecycle and replacement costs**

Every machine undergoes wear and tear. Knowing the costs of parts prevents shocks later when these parts breakdown after expiry of warranty.

- **Perishable parts** : you must know the cost of high wear items like trackballs, control panels & monitors.
- **End of life [eol] supports :-** ensure about the availability of spare parts and service support after discontinuation of particular model.

Table of questions to ask the vendor before singing while buying an ultra sound machine.

| **Category** | **Question to ask the vendor** | **What to look for red/flags** |
|---|---|---|
| **Clinical Needs** | Does this specific model configuration support all the clinical software packages (e.g.. Elastography,4d) we ordered without needing hardware retrofits ? | Red flag : if they say a feature requires a future hardware board upgrade, it will cost significantly more later. |
| **Probes & tech** | Are the included probes traditional pin-type or modern pinless connectors, and what is the exact cost to replace each probe model out- of warranty ? | Pinless is more durable. Get exact probe replacement costs written down so they cannot inflate prices later. |

| Category | Question to ask the vendor | What to look for red/flags |
|---|---|---|
| **Service Contracts** | Does the post warranty service contract price lock in for the next 3-5 years, and does it explicitly include or exclude probe accidental damage ? | Look for : a multi-year price cap (e.g.. Maximum 3% increase per year) and at least a discount on accidental probe drops. |
| **Uptime & response** | What is the exact guaranteed uptime percentage in writing, and what is the penalty or remedy if you fail to meet it ? | Look for : a 95%-98% uptime guarntee. The remedy should be an automatic extension of the warranty/service contract. |
| **Uptime & response** | Within how many hours will a field engineer be on -site after a ticket is logged, and do you guarntee a loaner machine if parts take over 48 hours ? | Look for : a maximum 24- hour on-site response for critical down-time.ensure loaner machine delivery is freeof charge |
| **Software upgrades** | Are software updates( bug patches) and software upgrades ( new clinical features ) free during the warranty period, and what 'os'does the machine run on ? | Red flag: if the machine runs on an outdated operating system (like windows 10 ), it will pose security and it compliance risks. |
| **Dicom/pacs** | Is there a written guarantee that your engineers will fully intergrate this machine with our specific 'pacs' and 'ehr' systems before final sign- off | Do not make the final payment until data flows seamlessly both ways (worklist and image store). |
| **Training** | How many days of on-site applications training are included, and do we have access to remote or online training for new staff later? | Look for : at least 2-3 days of initial training , plus 1 follow-up day a month later after the staff has used the machine. |
| **Warranty details** | Does the warranty cover 100% of parts, travel,and labor, or are there hidden fees for trave,l distances or after-hours emergency calls? | Red flag: 'parts-only warranties. Travel and labor costs can easily cost thousands of rupees per visit. |
| **Replacement & eol** | For how many years after this specific model is discontinued do you guarntee the availibility of factory-certified spareparts ? | Look for : a minimum guarntee of 7 to 10 years of pos-discontinuation parts and service support. |

**Conclusion**

While finalising the deal for an ultrasound machine one should focus not only on brand prestige or price tag, but should keep in mind our clinical needs. Secure future proof software, ensure good service terms and workout the long term cost of ownership. By selecting a system that is compatiable with existing hospital' it' infrastructure and future digital expansion, we can ensure a machine that delivers clinical excellence and financial returns for years to come.

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# 10 USG Documentation That Saves You in Court

**Author:- Dr Sonal Gupta**
**MBBS, MD, FICOG, CIMP**
**Director, NIMS Hospital, Faridabad, Haryana**

**Introduction**

Ultrasound is arguably the most frequently used diagnostic tool in modern obstetrics and gynecology. From confirming an early pregnancy to evaluating fetal growth, infertility, adnexal pathology, postmenopausal bleeding, and gynecological emergencies, ultrasound findings influence countless clinical decisions every day.

Yet, when ultrasound-related disputes reach consumer courts, medical councils, insurance reviews, or PCPNDT authorities, the central question is often not whether the diagnosis was perfect. The question is whether the medical record demonstrates that the doctor acted reasonably, followed accepted practice, communicated findings appropriately, and advised suitable follow-up.

In India, ultrasound practice operates within a unique medico-legal environment. Obstetricians and radiologists must simultaneously satisfy clinical standards, patient expectations, consumer protection laws, and the requirements of the Pre-Conception and Pre-Natal Diagnostic Techniques (PCPNDT) Act. In states such as Haryana, where PCPNDT implementation is closely monitored, documentation deficiencies themselves may attract regulatory scrutiny, even in the absence of any allegation of sex determination.

Good documentation is therefore not paperwork. It is an extension of patient care. It demonstrates that the doctor performed an appropriate examination, recognised limitations, communicated significant findings, advised the next step, and maintained regulatory compliance.

The report that protects a doctor years later is usually the report written carefully on the day of the scan.

**Why Documentation Matters More Than Ever**

Most ultrasound-related medico-legal disputes arise from one of three situations:

1. A significant abnormality was missed.
2. An abnormality was detected but not communicated effectively.
3. Appropriate care was provided, but the documentation does not prove it.

A missed diagnosis may be defensible if the examination was performed appropriately and recognised limitations were documented. Poor documentation is much harder to defend.

Common allegations encountered in obstetric and gynecological practice include:

- Missed ectopic pregnancy
- Missed fetal anomaly
- Incorrect gestational dating
- Wrong fetal number in multiple pregnancy
- Missed placenta previa
- Failure to identify placenta accreta spectrum risk
- Delayed diagnosis of ovarian torsion
- Failure to recognise a significant adnexal mass
- Missed retained products of conception
- Incorrect IUCD localisation
- Follicular monitoring disputes
- Failure to communicate emergency findings

Years later, neither the doctor nor the patient may accurately remember what happened during the consultation. The ultrasound report, stored images, referral records, and clinic documentation become the most reliable witnesses.

A complete record demonstrates that the doctor exercised reasonable skill, followed accepted protocols, recognised limitations, communicated findings, and advised appropriate follow-up.

**The Indian Reality: PCPNDT Compliance Is Also Documentation**

For Indian practitioners, medico-legal protection begins before the probe touches the patient.

The PCPNDT Act was introduced to prevent sex selection and female feticide. While its objectives are widely supported, many inspections and proceedings involve documentation deficiencies rather than allegations of sex determination itself.

Consequently, ultrasound documentation in India has a dual purpose:

- Ensuring quality patient care
- Demonstrating regulatory compliance

Every ultrasound unit should ensure:

- Valid PCPNDT registration
- Display of mandatory notices
- Proper maintenance of Form F
- Preservation of records for the legally required period
- Maintenance of referral documentation where applicable
- Availability of stored images and reports
- Proper machine registration and documentation
- Regular internal audits of compliance records

A recurring lesson from PCPNDT inspections across India is simple:

**What is not documented is often presumed not to have been done.**

For this reason, documentation should never be viewed as an administrative burden. It is both a clinical responsibility and a legal safeguard.

**Common Documentation Mistakes Seen in Daily Practice**

Most documentation deficiencies are not due to negligence. They occur because clinics become busy and shortcuts gradually become routine.

**1. Inadequate Clinical Indication**

One of the most common deficiencies is failure to document why the scan was performed.

Examples of inadequate indications include:

- "Pregnancy scan"
- "Routine ultrasound"
- "USG advised"

A better approach is to document the actual clinical question:

- 7 weeks amenorrhoea with spotting
- Lower abdominal pain with positive pregnancy test
- Assessment of fetal growth in gestational hypertension
- Evaluation of postmenopausal bleeding
- Reduced fetal movements
- Suspected ectopic pregnancy

A clear indication demonstrates the purpose of the examination and supports the clinical relevance of the findings.

**2. Failure to Document Limitations**

Not every structure can be visualised optimally in every patient.

Limitations may arise from:

- Maternal obesity
- Abdominal scarring
- Retroverted uterus
- Reduced amniotic fluid
- Advanced gestation
- Unfavourable fetal position
- Patient discomfort

When limitations are recognised but not documented, future reviewers may incorrectly assume that a complete assessment was possible.

Documenting limitations is not an admission of inadequacy. It is evidence of clinical honesty.

**3. Insufficient Image Storage**

A report without supporting images is vulnerable.

Representative images should support important conclusions, including:

- Gestational sac
- Crown-rump length
- Cardiac activity
- Placental location
- Cervical length where relevant
- Fetal biometric measurements
- Ovarian pathology
- Adnexal masses
- IUCD position

Stored images frequently become the most important evidence available years after the examination.

**4. Failure to Document Communication**

Many doctors verbally explain findings but never record that the discussion occurred.

A single sentence may later become invaluable:

"Findings explained to patient and accompanying relative. Follow-up advised."

For urgent findings, documentation should specify:

- What was communicated
- To whom it was communicated
- When it was communicated
- How it was communicated

**5. Vague or Overconfident Report Wording**

Statements such as:

- "Normal fetus"
- "All anomalies excluded"
- "No abnormality"

may create unrealistic expectations and increase medico-legal risk.

Ultrasound findings should be described accurately, acknowledging recognised limitations when appropriate.

**Court-Sensitive Situations and Practical Documentation Pearls**

Certain clinical situations repeatedly appear in litigation, complaint reviews, and expert opinions. These deserve particularly careful documentation.

**Suspected Ectopic Pregnancy**

Avoid documenting only:

"No intrauterine pregnancy seen."

A safer and more clinically useful statement is:

"No intrauterine gestational sac visualised. Ectopic pregnancy cannot be excluded. Correlation with serum beta-hCG and repeat ultrasound examination recommended."

The report should also document:

- Adnexal findings
- Free fluid if present
- Clinical symptoms
- Follow-up advice

**Fetal Anomaly Screening**

One of the commonest sources of obstetric litigation is the assumption that a normal anomaly scan guarantees a normal baby.

Ultrasound can reduce risk but cannot eliminate it.
Safer wording includes:
"No major structural abnormality identified on this examination. Ultrasound has inherent limitations and cannot exclude all fetal anomalies."

The report should clearly describe:

- Structures assessed
- Structures not adequately visualised
- Any recommendation for repeat assessment

**Placenta Previa and Placenta Accreta Spectrum Risk**

Placental abnormalities remain an important cause of maternal morbidity.
Documentation should include:

- Placental location
- Distance from the internal os where relevant
- Previous cesarean section history
- Suspicion of placenta accreta spectrum if present
- Follow-up recommendation

Failure to document these factors can become significant when complications occur later in pregnancy.

**Ovarian Torsion**

Ovarian torsion remains a classic medico-legal challenge because Doppler findings can occasionally appear reassuring despite the presence of torsion.

Reports should avoid over-reliance on Doppler findings alone.
A useful statement is:
"Clinical correlation advised. Ovarian torsion cannot be excluded solely on Doppler findings."

**Adnexal Masses**

When an adnexal mass is identified, the report should document:

- Size
- Morphology

- Solid components
- Papillary projections
- Doppler characteristics
- Recommended follow-up

The goal is not necessarily to provide a definitive diagnosis but to document a structured assessment and appropriate advice.

**Postmenopausal Bleeding**

Postmenopausal bleeding remains one of the most important gynecological indications for ultrasound.

Documentation should include:

- Endometrial thickness
- Uterine pathology
- Ovarian findings
- Any technical limitations
- Recommendation for gynecological evaluation where appropriate

Failure to document endometrial assessment adequately may become problematic if malignancy is diagnosed subsequently.

**Retained Products of Conception**

Documentation should include:

- Endometrial thickness
- Presence or absence of retained tissue
- Vascularity
- Clinical correlation
- Follow-up advice

Careful documentation assists both clinical management and medico-legal review.

**IUCD Localization**

When evaluating an IUCD, documentation should clearly state:

- Presence
- Position
- Orientation
- Evidence of displacement if present
- Need for further evaluation if localisation remains uncertain

Incomplete descriptions frequently contribute to later disputes.

**Follicular Monitoring**

Follicular monitoring may appear straightforward but generates a surprising number of disagreements regarding timing and treatment planning.

Documentation should include:

- Number of follicles
- Follicular measurements
- Endometrial thickness

- Follow-up schedule
- Advice provided to the patient

Clear documentation reduces misunderstandings and supports continuity of care.

**Emergency Findings Require Immediate Communication**

A report generated hours later may not be sufficient when urgent intervention is required.

Certain findings require immediate communication to the treating clinician, emergency team, or patient.

**Table 1. Emergency Findings That Should Be Communicated and Documented Immediately**

| Finding | Recommended Action |
|---|---|
| Suspected ectopic pregnancy | Immediate treating doctor notification |
| Ruptured ectopic pregnancy | Emergency referral |
| Ovarian torsion | Urgent gynecological review |
| Placenta previa with active bleeding | Immediate obstetric consultation |
| Severe fetal compromise | Urgent obstetric communication |
| Massive retained products with bleeding | Emergency management advice |

Whenever critical findings are communicated, documentation should include a statement such as:

"Critical finding communicated telephonically to Dr _____ at _____ PM."

This single sentence may become crucial evidence during future review.

**Safe Wording for Limitations and Referral Advice**

The wording of an ultrasound report is often scrutinized more closely than the diagnosis itself. The objective is not to create uncertainty but to accurately communicate both the findings and the limitations of the examination.

Overconfident language creates unrealistic expectations and increases medico-legal vulnerability. Conversely, vague wording may fail to guide appropriate clinical action.

**Table 2. Unsafe vs Safe Report Wording**

| Avoid | Prefer |
|---|---|
| Normal fetus | No abnormality identified within the limits of this examination |
| All anomalies excluded | No major structural abnormality identified on this examination |

| Avoid | Prefer |
|---|---|
| Definitely not ectopic pregnancy | Ectopic pregnancy cannot be excluded; clinical and biochemical correlation advised |
| No abnormality | Clinical correlation recommended |
| Complete evaluation achieved | Assessment limited by fetal position, maternal body habitus, or technical factors |
| No placenta accreta | No sonographic features suggestive of placenta accreta spectrum identified on this examination |
| No ovarian torsion | Clinical correlation advised. Ovarian torsion cannot be excluded solely on Doppler findings |

Such wording reflects the realities of ultrasound practice while demonstrating appropriate clinical judgment.

**Record Retention, Image Storage and Audit Trail**

Modern medico-legal practice increasingly relies on digital evidence. The ultrasound report alone is often insufficient if supporting records are unavailable years later.

Every ultrasound unit should maintain:

- Original reports
- Stored ultrasound images
- Digital backup systems
- Referral records
- Consent documentation
- PCPNDT records
- Audit logs where available

An effective audit trail should ideally demonstrate:

- Who performed the scan
- Date and time of examination
- Date and time of report generation
- Any subsequent modifications
- Record of image storage and retrieval

In the event of litigation, a complete audit trail demonstrates transparency and professionalism. Clinics should periodically verify backup systems and ensure that archived records remain accessible.

**Box 1. Top 5 PCPNDT Documentation Mistakes Seen During Inspections in Haryana**

While most practitioners are aware of the prohibition on sex determination, many inspections reveal documentation deficiencies rather than intentional violations. The following issues repeatedly attract regulatory scrutiny.

**1. Incomplete Form F**

Missing clinical indications, absent signatures, incomplete patient information, or blank fields remain among the most common observations.

**Risk Reduction Tip:** Never leave applicable sections incomplete. Ensure every required field is reviewed before submission.

**2. Mismatch Between Registers, Reports and Images**

Authorities frequently cross-check patient registers, Form F records, stored images and issued reports.
Differences in dates, patient identifiers or scan details may trigger further investigation.
**Risk Reduction Tip:** Ensure all records contain identical patient identifiers and dates.

**3. Inadequate Record Preservation**

Failure to produce records years later may be interpreted as failure to maintain records.
This includes:

- Form F records
- Referral documentation
- Ultrasound reports
- Ultrasound images
- Consent forms

**Risk Reduction Tip:** Maintain both physical and digital backup systems.

**4. Missing Referral Documentation**

Where referral documentation is required, inability to produce it during inspection may create avoidable compliance concerns.
**Risk Reduction Tip:** Digitally archive referral documents whenever possible.

**5. Poor Documentation of Clinical Indication**

Generic entries such as:

- Pregnancy scan
- Routine ultrasound
- USG advised

may be viewed as inadequate.

**Risk Reduction Tip:** Record the actual clinical indication such as viability assessment, dating scan, growth assessment, bleeding per vaginum, decreased fetal movements, infertility monitoring or suspected ectopic pregnancy.

**Practical Rule**

**A PCPNDT inspection should be able to reconstruct the entire patient encounter from the records alone.**

If an inspector can understand why the patient attended, what scan was performed, what findings were documented, what images were stored and what advice was given, the documentation is usually on much stronger footing.

**Court-Safe Ultrasound Documentation Template**

The following checklist can be implemented immediately in any obstetric or gynecological ultrasound practice.

**Table 3. Court-Safe Ultrasound Documentation Checklist**

**Before the Scan**

□ Correct patient identification
□ Date and time recorded
□ Clinical indication documented
□ LMP and gestational age recorded
□ Relevant clinical history documented
□ PCPNDT documentation completed
□ Consent obtained where required
□ Chaperone documented for TVS
□ Referral details documented where applicable

**During the Scan**

□ Appropriate protocol followed
□ Scan route documented
□ Relevant measurements recorded
□ Key images saved
□ Significant pathology documented
□ Limitations documented
□ Emergency findings identified

**After the Scan**

□ Clear impression provided
□ Follow-up advice documented
□ Referral urgency specified
□ Emergency communication documented
□ Findings explained to patient
□ Findings explained to relative where appropriate
□ Report signed
□ Images archived
□ Records backed up

**The 10-Second Court Test**

Before signing any ultrasound report, ask yourself:

□ Can another doctor understand why I performed this scan?
□ Have I documented the indication?
□ Have I recorded the relevant history?
□ Have I saved images supporting my conclusions?
□ Have I documented important limitations?
□ Have I clearly stated my impression?

□ Have I documented the advice given?
□ Have I documented any emergency communication?
□ Are my PCPNDT records complete?
□ If this report is reviewed five years later, will it accurately reflect what happened today?

If the answer to all ten questions is yes, the report is likely to be clinically useful, PCPNDT compliant, and significantly more defensible during future scrutiny.

**Key Take-Home Messages**

1. Documentation is patient safety, not bureaucracy.
2. In Haryana and other states with active PCPNDT enforcement, compliance documentation is as important as clinical documentation.
3. Never document only findings; document communication and advice as well.
4. Always record the limitations of the examination.
5. Save representative images supporting major conclusions.
6. Emergency findings should be communicated and documented immediately.
7. Maintain complete Form F and PCPNDT records.
8. Regular audits of documentation systems reduce risk and improve quality.
9. A defensible report clearly records why the scan was done, what was seen, what could not be seen, what was concluded and what advice was given.
10. The report that protects a doctor in court is usually the report written carefully on the day of the scan.

**Conclusion**

Ultrasound is far more than an imaging modality. It is a clinical decision-making tool that influences some of the most important moments in obstetric and gynecological care. While no examination can eliminate diagnostic uncertainty, meticulous documentation can demonstrate that the doctor acted with reasonable skill, followed accepted protocols, recognised limitations, communicated significant findings and advised appropriate follow-up.

In India, and particularly in states such as Haryana where PCPNDT compliance is closely monitored, documentation serves an additional regulatory purpose. A well-maintained record protects not only the patient but also the practitioner and the institution.

Ultimately, the safest ultrasound report is not the longest report. It is the report that accurately captures the clinical encounter, supports patient safety, satisfies regulatory requirements and demonstrates professional judgment. Such documentation forms the foundation of defensible practice and remains one of the most effective safeguards available to ultrasound practitioners.

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# APPENDIX

## Toolkit

# Ultrasound Practice Red Flags

**Twenty errors that can create infection risk, diagnostic error or medico-legal difficulty**

1. A transvaginal probe is unsafe if it is only wiped after use and not processed with appropriate high-level disinfection.

2. A probe cover should never be treated as a substitute for cleaning and disinfection.

3. A probe with cracks, peeling, exposed surface damage or cable injury should not be ignored.

4. A gel bottle that is repeatedly refilled can become a source of contamination in the clinic.

5. A gel nozzle touching the patient, couch or probe cover is a simple but important infection-control failure.

6. Sterile gel should not be replaced with routine gel during invasive ultrasound-guided procedures.

7. Doppler should not be used in early pregnancy merely to show fetal heart activity when B-mode or M-mode can answer the clinical question.

8. A scan report without patient identity, date and indication is weak documentation even if the scan was done correctly.

9. A report that does not mention limitations may later appear overconfident and incomplete.

10. Wrong laterality in an adnexal lesion, ovarian cyst or ectopic suspicion can create serious clinical and legal problems.

11. A suspicious finding should not be hidden behind vague terms such as “? lesion” without advice for referral or follow-up.

12. Emergency findings such as ectopic pregnancy, severe oligohydramnios, placenta previa with bleeding, fetal demise or torsion suspicion should be communicated and documented promptly.

13. A machine hard drive should not be the only place where important images are stored.

14. Thermal printouts should not be considered permanent documentation because they may fade over time.

15. Image sharing on casual messaging groups can breach patient confidentiality if identity is visible and consent is not considered.

16. A doctor who performs repeated transvaginal scans in a poor posture may develop chronic wrist, shoulder, neck or back injury.

17. A clinic should not buy a machine only by price or brand without checking probe cost, service support, warranty and upgrade policy.

18. AI-generated measurements should not be accepted blindly without checking image quality and clinical consistency.

19. A service visit or probe repair that is not recorded may leave gaps in machine maintenance documentation.

20. An ultrasound unit without SOPs, logs and checklists may look disorganised even when the doctor's clinical skill is good.

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# Minimum Ultrasound Documentation Template
# For clinic use and medico-legal protection

| Section | What must be documented |
|---|---|
| Patient details | Name, age, registration number, date and time of scan. |
| Clinical indication | Reason for scan, relevant symptoms, LMP or gestational age where applicable. |
| Scan type | Abdominal, transvaginal, transrectal, Doppler, procedure-guided or bedside emergency scan. |
| Consent/chaperone | Consent for transvaginal scan or invasive procedure, and chaperone details as per clinic policy. |
| Findings | Systematic findings relevant to the clinical question. |
| Measurements | Clearly labelled measurements with units and correct laterality. |
| Image record | Important images saved with patient identity and measurement labels. |
| Limitations | Obesity, bowel gas, fetal position, pain, empty bladder, late gestation or poor acoustic window. |
| Impression | Clear clinical impression without overclaiming certainty. |
| Advice | Follow-up, referral, repeat scan, urgent review or additional imaging where indicated. |
| Communication | Urgent or significant findings explained to patient and/or referring doctor where required. |
| Operator details | Name, signature, qualification or clinic stamp as per local practice. |

# Ultrasound Machine Purchase Checklist

| Area | Questions to Ask Before Buying |
|---|---|
| Clinical need | Will the machine be used mainly for obstetrics, gynecology, infertility, fetal medicine, oncology, procedures or general OPD work? |
| Probes | Which probes are included, and what is the replacement cost of each probe? |
| Image quality | Has the machine been tested on real patients with different body types and clinical indications? |
| Doppler | Is colour, power and spectral Doppler quality adequate for the intended clinical work? |
| Storage | Does the machine support image storage, export, USB backup, DICOM or PACS if needed? |
| Reporting | Is there an inbuilt reporting system, and can it be customised for ObGyn practice? |
| AI features | Are AI measurements validated, editable and clinically useful, or are they only sales additions? |
| Service support | What is the local service response time, and who will attend breakdowns? |
| Warranty | What is covered under warranty, and are probes covered separately or fully? |
| AMC/CMC | What will be the annual maintenance cost after warranty ends? |
| Software | Are updates included, paid, or unavailable after purchase? |
| Training | Will the company provide training for doctor and staff after installation? |
| Loan/finance | Will the expected clinical use justify the monthly payment and long-term cost? |

# FDMSEC COMMITTEE RECOMMENDATIONS

## Ten practical actions for safer ultrasound practice

1. Every clinic performing ultrasound should maintain a written probe cleaning and disinfection SOP according to the type of probe and patient contact.

2. Transvaginal probes should undergo cleaning followed by high-level disinfection after every use, irrespective of probe cover use.

3. Clinics should stop the practice of refilling ultrasound gel bottles and should use sterile gel whenever the scan or procedure requires asepsis.

4. Every ultrasound room should display a small Doppler safety reminder, especially for obstetric and first-trimester scanning.

5. Each clinic should maintain a daily ultrasound machine checklist covering probe condition, cables, image saving, date/time settings, cleanliness and obvious machine defects.

6. Ultrasound reports should be structured enough to include indication, findings, measurements, limitations, impression and follow-up advice.

7. Important images should be stored with patient identity and measurement labels, and a backup system should be maintained outside the machine hard drive.

8. Ultrasound rooms should be arranged ergonomically so that repeated transvaginal scanning does not cause avoidable injury to the doctor.

9. AI features and automated measurements should be used as assistance, not as a replacement for the doctor's judgement and responsibility.

10. Before purchasing a new ultrasound machine, clinics should assess clinical need, probe requirements, service response, warranty, software support, storage options and long-term maintenance cost.

# 06 - Ultrasound Beyond the Machine

## FDMSEC Insights | June -2026

## From

## FOGSI, Food Drugs & Medicosurgical Equipment Committee

**Dr.Bhaskar Pal**
President
FOGSI

**Dr.Suvarna Khadilkar**
Secretary General
FOGSI

**Dr. Vidya Thobbi**
Vice President Incharge
FOGSI

**Dr. Asha Jain**
Chairperson
FOGSI FDMSEC

## Dr. Asha Jain

### Editor & Chairperson, FOGSI FDMSE Committee