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Medico-Legal Challenges in Pediatric Care



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This edition explores key legal cases that impact pediatric practice in India, focusing on informed consent in minors and addressing medical negligence in pediatric care. These cases provide essential guidance for pediatricians on navigating legal challenges in their practice.

SWASTHYA ADHIKAR MANCH V. UNION OF INDIA (2013): SUPREME COURT ON INFORMED CONSENT IN MINORS

In 2012, Swasthya Adhikar Manch, an NGO from Madhya Pradesh, filed a PIL before the Supreme Court of India. It alleged that minors were enrolled in clinical drug trials at government institutions without valid informed consent from legal guardians.

Many guardians, from tribal or socio-economically disadvantaged backgrounds, were not adequately informed about the risks or the experimental nature of these trials. Consent was often verbal, poorly documented, or obtained through complex forms without translation or explanation. Some trials allegedly bypassed proper ethical oversight and administered investigational products without clear risk disclosure or benefit.

The Union of India defended the trials, claiming compliance with existing norms and approval from ethics committees. However, the Court identified systemic failures in the consent process, especially concerning vulnerable groups like children.

The Supreme Court underscored that informed consent is a legal and ethical obligation, not a formality. It emphasized that pediatric trials require guardian consent with complete understanding of the trial, and that assent from older children is ethically advisable.

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The Court directed the Union Government and the DCGI to implement reforms, including:

- Stronger ethical review and documentation
- Consent forms in local languages
- Audio-visual recording (in certain trials)
- Greater accountability for investigator.

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Following the ruling, ICMR's 2017 National Ethical Guidelines mandated parental consent and, where appropriate, child assent, with detailed guidance for pediatric research.



Key Takeaways for Pediatric Practice

- Informed consent must be voluntary, well-explained, and documented — passive or verbal consent is insufficient.
- The healthcare provider must ensure guardians fully understand the procedure in a language they comprehend.
- Assent should be obtained from cognitively mature children (usually 7+ years).
- Documentation must capture: who explained, what was explained, guardian's responses, and signatures.
- In emergencies, treatment without consent is permissible under the Doctrine of Necessity — but must be justified and recorded.

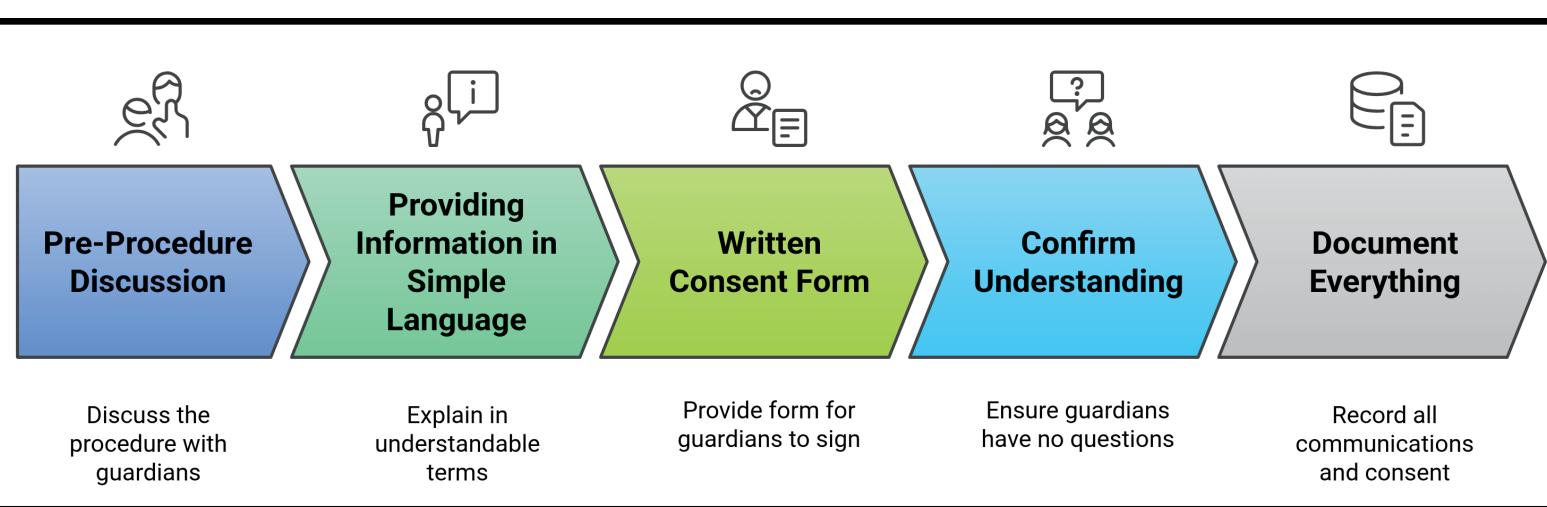


Figure 1: The Informed Consent Process in Pediatric Care



Citation

- Swasthya Adhikar Manch v. Union of India & Ors., Supreme Court of India, Writ Petition (Civil) No. 33 of 2012 <https://www.casemine.com/judgement/in/58117eca2713e179478bb3d4> Regulatory developments in the conduct of clinical trials in India <https://pmc.ncbi.nlm.nih.gov/articles/PMC5870412/> Informed consent to clinical research in India: A private law remedy <https://journals.sagepub.com/doi/10.1177/0968533220958185?icid=int.sjabstract.similar-articles.9>

SHALVI BHAT V. DR. RAMESH IYER (THANE, 2003): MEDICAL NEGLIGENCE AND MALPRACTICE IN PEDIATRIC CARE



In 2003, a pediatric case in Thane, India, raised serious concerns regarding medical negligence in the care of a child. Shalvi Bhat, a 2½-year-old child, was admitted to Dr. Ramesh Iyer's private hospital with high fever and body rashes. The family sought immediate treatment from Dr. Iyer, who began treatment for suspected pneumonia. However, after a few days, Shalvi's condition worsened, leading the family to transfer her to Nanavati Hospital, where she tragically passed away.

The family of the child, led by her mother, Uma Bhat, filed a complaint of medical negligence, alleging that Dr. Iyer failed to provide the necessary care that could have potentially saved the child's life. They pointed to inadequate medical records, failure to follow standard procedures, and the absence of essential treatment facilities at Dr. Iyer's hospital as critical factors that led to the child's deterioration.

A Committee of Doctors from the Directorate of Health Services in Maharashtra reviewed the case and concluded that Dr. Iyer had not recorded medical treatment properly. The Committee also found that the hospital lacked necessary emergency equipment, and that proper documentation of clinical findings and medication was missing. Moreover, the failure to act on the advice of a specialist, Dr. Sunita Arole, who had recommended immediate intervention, was also a key factor in the deterioration of the child's health.



The complaint was eventually taken to the State Consumer Disputes Redressal Commission (SCDRC), which ruled in favor of the complainant. The Court awarded a compensation of ₹10,00,000 to the family, recognizing medical negligence in Dr. Iyer's actions. The Court also observed that the pediatrician had failed to provide the required level of care, particularly in terms of appropriate diagnostics, emergency treatment, and proper medical record-keeping.



“ Key Takeaways for Pediatric Practice

- Adhere to the Standard of Care:** Pediatricians must ensure that the diagnosis and treatment provided align with the current medical guidelines and best practices. Failure to meet these standards can result in allegations of negligence
- Early Intervention is Crucial:** In pediatric care, early diagnosis and timely treatment are essential, especially for conditions that can rapidly deteriorate, such as respiratory infections and other critical illnesses. Delays in care can exacerbate the situation and lead to complications.
- Document Everything:** Comprehensive and accurate medical records are crucial in defending against malpractice claims. Every consultation, diagnosis, treatment decision, and patient interaction should be thoroughly documented, including discussions about treatment plans with the guardians.
- Continuous Monitoring and Re-evaluation:** Pediatric patients, especially those with serious infections or conditions, must be closely monitored. If the child's condition does not improve or worsens, the treatment plan should be re-evaluated promptly to ensure the patient receives appropriate care

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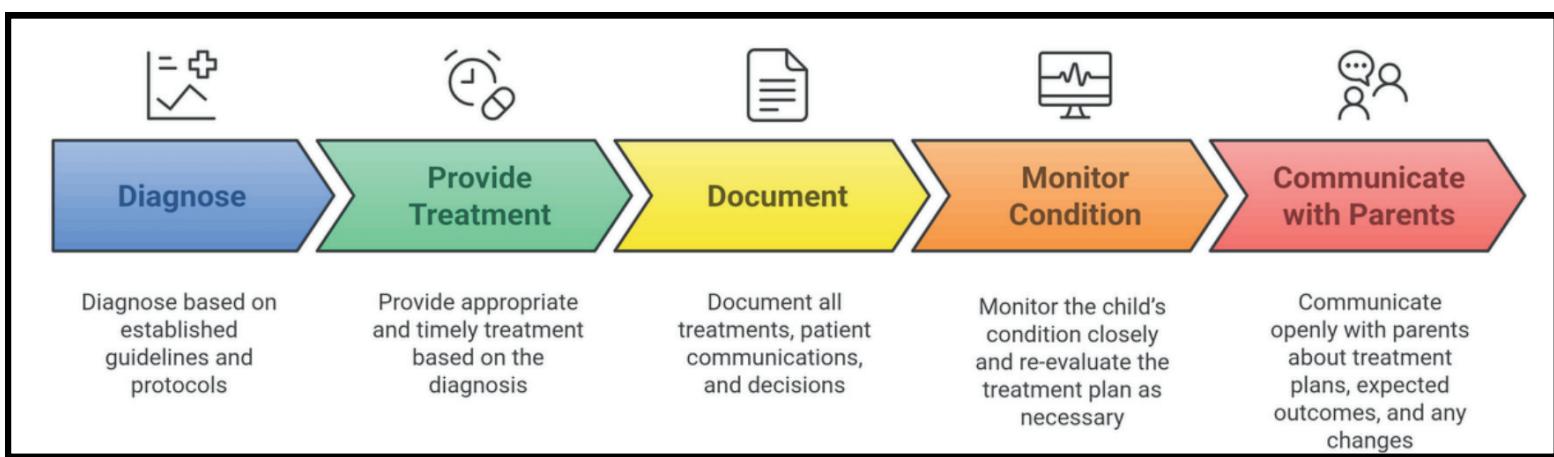


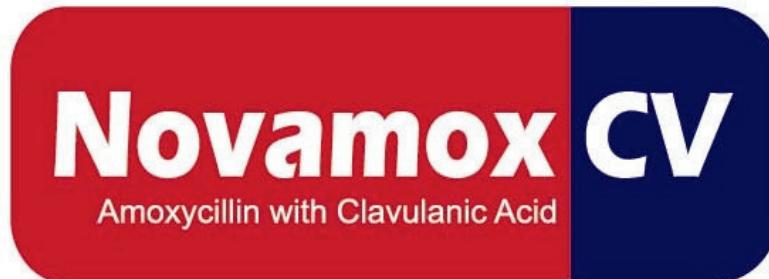
Figure 2: Key Steps to Prevent Medical Negligence in Pediatric Care

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Citation

- Shalvi Bhat v. Dr. Ramesh Iyer, Thane, 2003
<https://indiankanoon.org/doc/181414233/#:~:text=2003%20given%20by%20Civil%20Surgeon,that%20the%20child%20would%20die>
- Indian Medical Council Act, 1956 – Medical Standards for Pediatric Practice
<https://www.nmc.org.in/wp-content/uploads/2017/10/CompleteAct-1.pdf>

In Otitis Media, Sinusitis, Pharyngotonsillitis, CAP



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