

# Medico-Legal Challenges in Pediatric Care



SOUTH  
ASIA  
PEDIATRIC  
ASSOCIATION



April 2025

Issue 1



April 2025

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I242510065269

## Topics covered:

- Swasthya Adhikar Manch v. Union of India (2013): Supreme Court on Informed Consent in Minors
- Blood Transfusion Refused by One Parent: Pediatrician Seeks CWC Intervention (Delhi, 2015)

**Editor:**

**Reviewed by:**

As pediatricians, understanding the legal implications of informed consent and handling parental disagreements are essential in minimizing medico-legal risks. This edition explores landmark judgments that shape how these issues are addressed in pediatric 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.

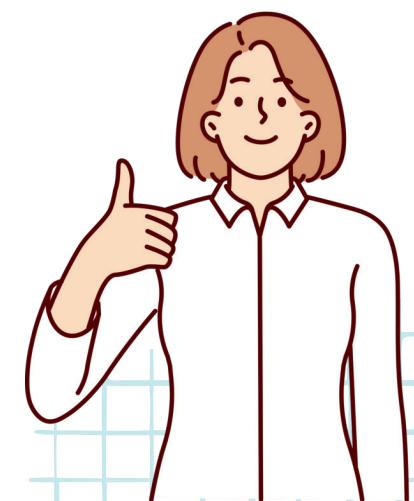
Many guardians, from tribal or socio-economically disadvantaged backgrounds, were not adequately informed about the risks or the experimental nature of these trials. Consent was often verbal, poorly documented, or obtained through complex forms without translation or explanation. Some trials allegedly 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.

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.



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.**

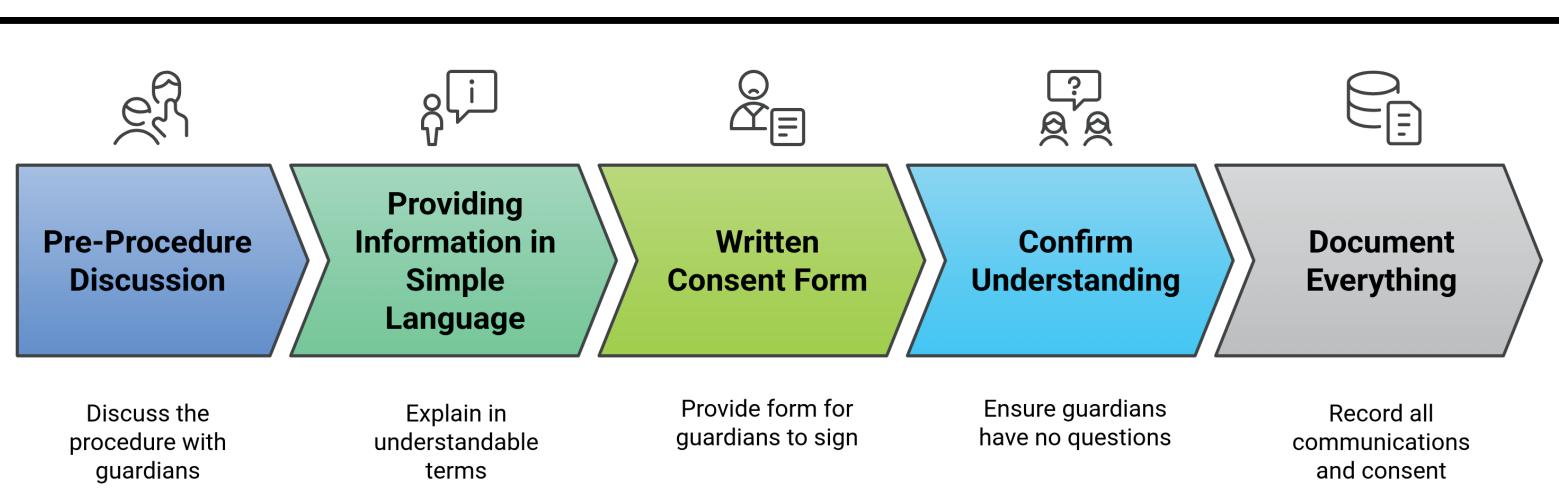


Figure 1: The Informed Consent Process in Pediatric Care

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### Citation

- Swasthya Adhikar Manch v. Union of India & Ors., Supreme Court of India, Writ Petition (Civil) No. 33 of 2012 <https://indiankanoon.org/doc/23230768/>
- Indian Council of Medical Research. National Ethical Guidelines for Biomedical and Health Research Involving Human Participants, 2017 [https://ethics.ncdirindia.org/asset/pdf/ICMR\\_National\\_Ethical\\_Guidelines.pdf](https://ethics.ncdirindia.org/asset/pdf/ICMR_National_Ethical_Guidelines.pdf)

# BLOOD TRANSFUSION REFUSED BY ONE PARENT: PEDIATRICIAN SEEKS CWC INTERVENTION (DELHI, 2015)



In 2015, a six-year-old girl was admitted to a Delhi tertiary hospital with severe anemia. A blood transfusion was advised urgently. Her father, present at admission, gave written consent after understanding the procedure. However, when the mother arrived later, she objected to the transfusion on religious grounds and explicitly denied consent.

As both parents had legal guardianship, the hospital faced a deadlock — one parent's consent versus the other's objection — while the child's condition remained critical. Despite multiple counselling attempts by senior clinicians and a hospital social worker, no resolution was reached.

Given the delay and risk to the child's life, the hospital escalated the case to its legal desk, which referred the matter to the Child Welfare Committee (CWC) under the Juvenile Justice Act, 2015. The CWC reviewed medical records, consent history, and urgency of the situation, and authorized the transfusion in the child's best interest. The procedure was performed the same day, and the child recovered without complications.

This case highlights a recurring challenge in pediatric care — parental disagreement in urgent medical decisions, especially when influenced by beliefs or unclear custody dynamics. While Indian law allows parents to make healthcare decisions for minors, this right is not absolute. When such decisions jeopardize the child's health, authorities like the CWC may intervene.

Under Article 21 of the Constitution, a child's right to life and health prevails over parental objections. The JJ Act empowers CWCs to act in cases of medical neglect, conflict, or denial of care. Indian courts have consistently ruled in favor of the child's best interest in such cases, even when religious or personal beliefs are involved.



The case also underscores the importance of documentation and escalation. The hospital was not found negligent, having followed due process: recording the dispute, initiating counselling, consulting legal authorities, and protecting the child within a lawful framework.

## Key Takeaways for Pediatric Practice

- Consent from one parent may be inadequate if the other, with equal guardianship, objects. Disputes should first be addressed through counselling.
- If treatment is urgent and consensus isn't possible, escalate to the CWC or local authorities without delay.
- Article 21 ensures the child's right to life and health, overriding unresolved parental conflicts.
- Detailed documentation is critical — include timelines, nature of objections, mediation attempts, legal steps, and clinical decisions.
- Hospitals must have clear protocols for escalating such cases to legal or child protection bodies promptly.

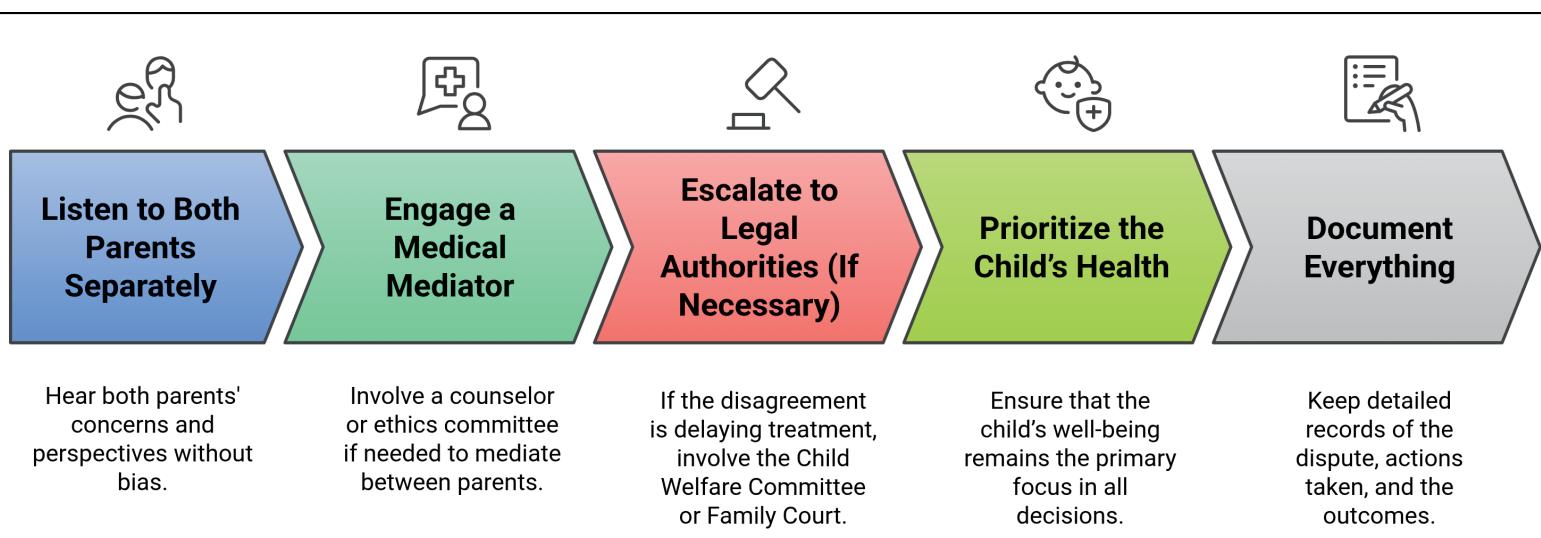


Figure 2: Decision-Making in Parental Disagreements



### Citation

- Juvenile Justice (Care and Protection of Children) Act, 2015 <https://cara.wcd.gov.in/pdf/jj%20act%202015.pdf>
- Article 21, Constitution of India – Right to Life <https://indiankanoon.org/doc/1199182/>
- Case Notes: Internal documentation and reports, tertiary care hospital, Delhi, 2015 (name anonymized for confidentiality)

## ADVERTISEMENT SECTION