

Suggested guidelines for management of \geq Stage II NEC during the trial period

- Clinical judgement and surgical consultations are critical
- Bowel rest (Stage II: 7-10 days, Stage III: 10-14 days), gastric decompression, systemic antibiotics after investigations to rule out sepsis, parenteral nutritional support
- Initial broad-spectrum antibiotic support should be guided by local resistance pattern. Usually involves treatment with vancomycin/ampicillin, gentamycin, and metronidazole for 7-10 days.
- Prompt correction of electrolyte abnormalities, persistent metabolic acidosis, and coagulopathy.
- Operative intervention may be required in presence of persistent clinical deterioration or signs of impending intestinal perforation/gangrene.
- Intestinal perforation is the only absolute indication for laparotomy.
- In absence of pneumoperitoneum, abdominal paracentesis may be helpful in confirming presence of intestinal gangrene in conjunction with other available data.
- Primary peritoneal drain may be an adjunctive therapy prior to preplanned laparotomy or an alternative to surgery, in unstable, especially extremely low birth weight neonates with birth weight <1000 grams. [*No clear evidence of benefits yet, trials in progress*]
- Contrast enemas prior to re-initiation of enteral feeds in neonates with perforated NEC or when feed intolerance develops in neonates with medical NEC. Enteral feeds (fresh breast milk preferred) usually started at and increased by 20-25 ml/kg/day.

*Definitions

*Severe thrombocytopenia: Platelet count <50,000 mm³

*DIC (Disseminated intravascular coagulation): A systemic thrombo-hemorrhagic disorder seen in association with well-defined clinical conditions and laboratory evidence of procoagulant activation, fibrinolytic activation, inhibitor consumption, and biochemical evidence of end organ damage or failure. Usually involves prolongation of PT, aPTT, TT, hypofibrinogenemia, elevated FDPs, and peripheral smear showing schistocytes and thrombocytopenia with large platelets (Bakshi L, Arya LS, Indian Pediatr 2003, 40:721-30]

*For the study purpose systemic hypotension is defined as any systemic hypotension that needs inotrope/s support.