



## Manual of Operations for Pediatric Surgeons

### Study Toward Evidence-based Pediatric Surgery

**Target Population:** All premature neonates in the neonatal care units of the participating institutions who have a birth weight less than 1500 grams and have necrotizing enterocolitis with perforation.

#### 1. Determine the intestine is perforated:

- Presence of free intraperitoneal air on abdominal radiograph.
- Stool, bile or frank pus aspirated during paracentesis.
- Clinical evidence of perforation in the joint opinion of the attending surgeon and neonatologist.

#### 2. Determine study eligibility:

##### *Inclusion criteria:*

- Birth weight less than 1500 grams.
- Gestational age 24 to 33 weeks.
- Evidence of bowel perforation based upon above criteria.
- No evidence of gastrointestinal anomaly (e.g. atresia, malrotation, etc.).
- No prior abdominal operation.

##### *Exclusion criteria:*

- Presence of grade IV intraventricular hemorrhage.
- Failure to meet all inclusion criteria.
- Refusal to enter trial by family.

#### 3. Obtain consent:

- The family of all babies meeting study criteria will be approached for entry into the trial.
- The family will be counseled by the attending pediatric surgeon regarding the goals and rationale of the study.

#### 4. Randomization to treatment arm:

- Randomize patient to PPD or LAP by selecting the randomization envelope marked with the appropriate birth weight (Less than 1000g or between 1000 and 1500g).
- Envelopes should be stored in an easily accessible location and used to randomize patients in sequential order (envelopes are numbered).
- Document use of randomization envelope on main study envelope.

## 5. Perform Intervention:

- Daily clinical care will be uniform between the two groups.
- All patients with evidence of perforated NEC will enter the clinical pathway whether or not they are consented for the study. The critical pathway is a standardized protocol approved at all participating study centers.
- Preoperative preparation is the same for both groups and will include aggressive resuscitation of intravascular volume, correction of coagulopathy, appropriate respiratory support, correction of metabolic acidosis and transfusion of PRBC's to optimize hemodynamic status.

### *Laparotomy and resection group (LAP):*

- Abdominal operation via a transverse abdominal incision.
- Resection of all frankly necrotic/non-viable intestine.
- Stomas will be created in the location selected by the attending surgeon.
- When feasible, the most proximal stoma will be proximal to the extent of disease.

### *Primary Peritoneal Drainage (PPD):*

- 1/4 inch incision placed over the right lower quadrant.
- An attempt will be made to express all stool and pus within the abdomen through this incision.
- The peritoneal cavity will be irrigated with normal saline through a 16g catheter advanced carefully into the incision. Irrigation should continue until effluent is clear.
- A 1/4 inch Penrose drain will be placed into all four quadrants through the incision. A post-procedure XRAY of the drain should ideally resemble a 'picture frame' distribution.

## 6. Failure of primary therapy:

- There will be no crossover between treatment groups.
- If patients in the LAP group clinically deteriorate following initial laparotomy, and are believed to have further intestinal necrosis or perforation, they will undergo repeat laparotomy.
- If patients in the PPD group are believed to be inadequately drained, based on reaccumulation of air or fluid within the abdomen, the original drain will be surgically explored. If drainage is not effective, a second drain will be placed.