

# WOUND IRRIGATION STUDY EXPERIMENTAL PROTOCOL

## PATIENT SELECTION CRITERIA

### Inclusion Criteria

- Age  $\geq$  1-year
- Uncomplicated laceration that requires suturing
- Patient must have a telephone number for follow-up
- Multiple wounds in one patient will be considered separate wounds and should be entered into the study individually

### Exclusion Criteria

- Any underlying immunocompromising disorder (e.g., primary immune disorder, diabetes mellitus, asplenia, chronic alcoholism, steroid use, immunosuppressive chemotherapy)
- Patient must not be on antibiotics
- Mechanical heart valve
- Wounds that are
  - Older than 9 hours
  - A result of human or animal bite
  - Puncture wound
  - Associated with bone, tendon, or neurovascular injury.

## PRE-IRRIGATION INSTRUCTIONS

1. Take out a data collection sheet and consent form from the envelope labeled "Blank Data Collection Sheets," and stamp it with the patient's medical record card. Write the patient's correct telephone numbers and the date on the data collection sheet.
2. Explain the study to the patient and have them sign the consent form.
3. ED Clerk (not the clinician doing the irrigation or laceration repair) to take an irrigation bowl that is next in line from the study cabinet, remove the I.D. sticker from the bowl and place the sticker on the data collection sheet.
4. ED Clerk will then fill the bowl **completely** with the fluid indicated on the wrapper. If saline is indicated, use saline from the bottles in the study cabinet. If tap water is indicated, obtain the water from the study faucet directly below the study cabinet. **Let the tap water run for 5 seconds before filling the bowl.**
5. Bring bowl to the bedside of the patient, without indicating which fluid was used to fill the bowl.
6. Place the data collection sheet in envelope on the wall behind the admitting desk labeled: "*Wound Irrigation Study--Patients Awaiting Wound Check.*"

## IRRIGATION INSTRUCTIONS

1. Anesthetize the wound with 1% lidocaine with or without epinephrine or 0.25% bupivacaine as you would normally.

2. All wounds must be irrigated with an 18-gauge catheter connected to a 35 ml syringe found in the study cabinet.
3. Draw up the solution into the 35cc syringe and attach the 18-gauge catheter.
4. Hold the syringe so that the catheter tip is just above the wound and perpendicular to the skin surface and push down on the plunger in a forceful manner, while prying the wound edges open. Aim the solution directly into the wound being careful to avoid getting splashed by the irrigant. Use ALL the fluid in the bowl.

### **POST-IRRIGATION INSTRUCTIONS**

1. Suture the wound in the usual manner. Do not use staples or other methods of wound closure.
2. Cover the wound in the usual manner. Do not apply antibiotic creams or lotions.
3. Give Logicare wound care instructions specifically developed for this study to patient.
4. Instruct the patient to return to the emergency department in 48 hours for a wound check (sooner for signs of infection) and to notify the admitting clerk that they are in the Wound Irrigation Study upon their arrival.

### **FOLLOW-UP VISIT**

1. The admitting clerk will recover the yellow data collection sheet from the data envelope and place it on the "Wound Irrigation Study Clipboard." A new admission chart is NOT created.
2. The Attending Physician will evaluate the wound, and complete the data collection sheet according to the following criteria (also see data collection sheet):

### **Wound Evaluation Criteria for infection: Circle all that apply**

0. No evidence of infection
  1. Simple stitch abscess
  2. Surrounding erythema less than 1 cm
  3. Surrounding erythema greater than 1 cm or lymphangitis (red streaking)
  4. Gross exudate
  5. Fever greater than or equal to 38.0°C
  6. Other (please describe): \_\_\_\_\_
3. Note the treatment rendered on the data collection sheet as follows:

### **Treatment Rendered: Circle all that apply**

0. None
1. Suture removal
2. Oral antibiotics
3. IM/IV antibiotics, discharged on oral antibiotics

4. Admitted for IV antibiotic therapy

5. Other (please describe): \_\_\_\_\_

## **DATA GATHERING**

- User computer randomization program to assign one of the study fluids to each numbered bowl.
- Check the study envelope daily for yellow data sheets and check the dates of laceration repair.
- If patient did not return at 48 hours, call the patient and ask them to return to the emergency department ASAP.
- At the thirty-day follow-up, contact the patient by telephone and complete the thirty-day wound evaluation.
- Place completed data sheets in the envelope labeled “Completed Data Collection Sheets” on the study cabinet door.
- Check data sheets against log sheets to avoid lost patients.

## **STOCKING SUPPLIES – WOUND STUDY CABINET**

- 500 ml sterile saline bottles
- 35 ml sterile syringes
- 18-gauge sterile catheters
- Bowls with computer generated labeled
- Log sheets for cabinet door
- Wound Study Packets

ANY QUESTIONS? Contact Eric A. Weiss, MD (#3152), George Oldham, MD (#2673), Tammy Edwards (342-3957)