

# Water is a safe and effective alternative to sterile normal saline for wound irrigation prior to suturing: a prospective, double-blind, randomised, controlled clinical trial

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## ABSTRACT

**Objective:** To determine if there is a significant difference in the infection rates of wounds irrigated with sterile normal saline (SS) versus tap water (TW), before primary wound closure.

**Design:** Single centre, prospective, randomised, double-blind controlled trial. Wound irrigation solution type was computer randomised and allocation was done on a sequential basis.

**Setting:** Stanford University Medical Center Department of Emergency Medicine.

**Participants:** Patients older than 1 year of age, who presented to the emergency department with a soft tissue laceration requiring repair, were entered into the study under informed consent. Exclusion criteria included any underlying immunocompromising illness, current use of antibiotics, puncture or bite wounds, underlying tendon or bone involvement, or wounds more than 9 h old.

**Interventions:** Non-caregivers used a computer generated randomisation code to prepare irrigation basins prior to treatment. Patients had their wounds irrigated either with TW or SS prior to closure, controlling for the volume and irrigation method used. The patient, the treating physician and the physician checking the wound for infection were all blind regarding solution type. Structured follow-up was completed at 48 h and 30 days to determine the presence of infection.

**Main outcome measures:** The primary outcome measured was the difference in wound infection rates between the two randomised groups.

**Results:** During the 18-month study period, 663 consecutive patients were enrolled. After enrolment, 32 patients were later excluded; 29 patients because they were concurrently on antibiotics; two patients secondary to steroid use and one because of tendon involvement. Of the 631 remaining patients, 318 were randomised into the TW group and 313 into the SS group. Six patients were lost to follow-up (5 SS, 1 TW). A total of 625 patients were included in the statistical analysis. There were no differences in the demographic and clinical characteristics of the two groups. There were 20 infections 6.4% (95% CI 9.1%

## ARTICLE SUMMARY

### Article focus

- To determine if there is a significant difference in the infection rates of wounds irrigated with sterile normal saline (SS) versus tap water (TW), before primary wound closure.
- To validate the hypothesis that water is both a safe and effective wound irrigant.

### Key messages

- The incidence of wound infection was 6.4% in the SS group as compared with 3.5% in the TW group. This 2.9% (95% CI -0.4% to 5.7%) decrease in the infection rate with TW approached but was not statistically or clinically significant.
- This is the largest trial to validate TW as a safe and effective wound irrigant. It is the only study that was double-blinded and controlled for irrigation technique, pressures and solution volumes.
- TW has both economic and environmental advantages over SS as a wound irrigant.

to 3.7%) in the SS group compared with 11 infections 3.5% (95% CI 5.5% to 1.5%) in the TW group, a difference of 2.9% (95% CI -0.4% to 5.7%).

**Conclusions:** There is no difference in the infection rate of wounds irrigated with either TW or SS solution, with a clinical trend towards fewer wound infections in the TW group, making it a safe and cost-effective alternative to SS for wound irrigation.

## INTRODUCTION

Traumatic wounds are the second most common reason individuals seek medical care, with emergency departments (EDs) treating an estimated 11 million traumatic wounds each year in the USA.<sup>1-3</sup> The most

## ARTICLE SUMMARY

**Strengths and limitations of this study**

- The strengths of the study are its randomised design, control for technique of irrigation and volume of irrigant, successful blinding, relatively large number of subjects and the fact that very few were lost to follow-up. A limitation of the study is that the primary measured outcome of wound infection was determined by subjective indicators of infection, such as erythema or gross exudate. Given the nature of the study, more objective measures such as bacterial counts, wound cultures or wound biopsy were not practical.
- A second limitation was the six patients lost to follow-up during the study; five of these patients had wounds irrigated with SS and one had a wound irrigated with TW. This is a small number of patients lost to follow-up, and five out of six were in the SS group. Even if we assume that all these wounds became infected, it would only add further support to our conclusion that TW is a safe and effective alternative to SS as an irrigant solution.
- Although we controlled for the volume of solution and the mechanism of wound cleansing, the temperatures of the solutions were not identical. The difference in temperature of the TW (38°C), as compared with SS (room temperature), may have been a factor. TW did not reach room temperature prior to initiating irrigation.

common and serious complication of a traumatic wound is infection.<sup>4-7</sup> Many factors can increase the risk of wound infection, including the patient's immune status, the age of the wound prior to cleaning and closing, the presence of foreign material in the wound, bacterial inoculum, the presence of devitalised tissue and involvement of deeper structures.<sup>8</sup> Wound irrigation is the most important step in reducing the risk of infection.<sup>5</sup> The function of irrigation is to remove loose, devitalised tissue; particulate matter and bacteria from within the wound.<sup>4-9</sup>

Most EDs currently use sterile normal saline (SS) to irrigate wounds prior to closure, even though there is a paucity of scientific evidence to support its use as an irrigation fluid. Further, other studies have demonstrated that more expensive solutions such as antiseptics (1% povidone-iodine, hexachlorophen, isopropylalcohol and cefazolin) and non-ionic detergents (pluronic F-68 and polaremer 188) provide no advantage over SS.<sup>10-12</sup>

Tap water (TW) may be the ideal irrigation fluid because it is readily available and it is less expensive than SS. Several other studies have suggested that TW is a safe and effective alternative to SS in the irrigation of lacerations.<sup>13-18</sup> Fernandez completed a Cochrane Review of these studies and noted serious study limitations including: not controlling for volume and irrigation technique, poorly defined inclusion and exclusion criteria, inadequate sample size, lack of true randomisation with allocation concealment, study participants not blinded to the solution used during outcome assessment and unclear objective outcome measurements of wound infection.<sup>8</sup>

Sasson and Diner subsequently reviewed the literature regarding the appropriate irrigating solution for wound cleansing and concluded that there is insufficient evidence to either support or refute the claim that TW is comparable or superior to SS as a wound irrigant.<sup>19</sup> Thus, further prospective clinical research is needed.

**METHODS****Study design**

This was a randomised, double-blind clinical trial comparing the wound infection rate in lacerations irrigated with either SS or TW prior to closure in the ED. The study was approved by the Stanford University Institutional Review Board. Written informed consent was obtained before study participation. The trial was registered in ClinicalTrials.gov (NCT01564342).

**Study setting**

The study was conducted at the Stanford University Medical Center Emergency Department, a tertiary care facility and Level I trauma centre, with a census of 55 000 visits annually.

**Selection of participants**

The study population consisted of consecutive patients older than 1 year of age, who presented to the ED with an uncomplicated soft tissue laceration requiring repair. Patients had to provide a telephone number for follow-up in order to be enrolled in the study. Exclusion criteria included any underlying immunocompromising illness (eg, diabetes mellitus, chronic alcoholism, asplenicism, primary immune disorder, steroid use or chemotherapy), current use of antibiotics, puncture or bite wounds, underlying tendon or bone involvement, or wounds more than 9 h old.

**Interventions**

After written informed consent was obtained, enrolled patients were randomly assigned to have their wounds irrigated with SS or TW, using a sequentially numbered plastic-wrapped sterile bowl. A computer randomisation program was used to generate a code that assigned one of the study's fluids to each numbered bowl. After the identifying label was removed, the bowl was filled with the appropriate solution by an ED technician. The patient, the treating physician and the physician checking the wound for infection were all blind regarding solution type.

SS was obtained from Abbott's Laboratories. The TW was obtained from a single designated faucet in the ED. The water ran for 5 s prior to being collected.

All wounds were treated according to the following protocol: (1) wounds were anaesthetised with 1% lidocaine with or without epinephrine and/or 0.25% bupivacaine; (2) a 35 ml syringe equipped with an 18 gauge IV catheter was used to deliver the irrigation solution, which has been shown to produce a hydraulic pressure of approximately

8 psi;<sup>20</sup> (3) a volume of 500 ml of solution was used to irrigate each wound; (4) wound irrigation was performed by emergency medical technicians who were not involved with the wound repair or follow-up assessment and (5) after irrigation, all wounds were repaired by a physician who was not present during the irrigation using standard suturing technique. All patients received a wound care sheet at discharge from the ED and were instructed to return in 2 days for a wound check, at which time the wound was evaluated for evidence of infection.

TW from the designated sink was cultured once per month by a Microbiology Reference Laboratory for pathogens, including *Legionella* and *Pseudomonas*.

### Outcome measures

The primary outcome for this study was the difference in wound infection rates between the two randomised groups. Wound evaluation was based on the following criteria: (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, (4) gross exudate, (5) fever greater than or equal to 38°C and (6) others. A wound was classified as infected if it received a rating of 1 or higher.<sup>21</sup>

Patients who did not return to the ED within 4 days following their laceration repair were contacted by telephone to facilitate follow-up in the ED within the ensuing 24 h. If a patient could not be contacted or did not return to the ED within 24 h of contact, they were considered lost to follow-up. All patients were also contacted by telephone 1 month after injury to assess for the development of delayed infection or other complications. Patients who could not be contacted again by telephone at the 1-month follow-up were considered lost to follow-up.

### Sample size calculation and data analysis

Previous studies have used a 5% difference in wound infection rates as clinically important.<sup>18</sup> Assuming a baseline infection rate of 7%, we estimated that 300 patients in each group would have 80% power to determine a 5% difference in the infection rates between groups using a two-sided  $\alpha$  of 0.05.

Categorical variables were compared using a  $\chi^2$  test and continuous variables were compared with an independent samples *t* test, with reporting of 95% CI.

## RESULTS

During the 18-month study period, a total of 663 patients were enrolled in the study. After the assignment of a study number, 32 patients were later excluded because they did not meet the selection criteria. Twenty-nine patients were excluded because they were concurrently on antibiotics; they were evenly distributed between the TW (15) and SS (14) groups. Two patients were excluded secondary to steroid use (SS), and one because of tendon involvement (TW). Of the 631 remaining patients, 318 were randomised into the TW

group and 313 into the SS group. Six patients were lost to follow-up (5 SS, 1 TW) when they did not return for evaluation of the wound within 5 days of treatment. A total of 625 patients were included in the statistical analysis (figure 1).

There were no differences in the demographic or clinical characteristics of the two groups (table 1). Bacteria were not detected in any of the TW samples sent for analysis.

Overall, the infection rate was 4.9% (95% CI 3.4% to 7.0%). The incidence of wound infection was 6.4% in the SS group, as compared with 3.5% in the TW group. This 2.9% (95% CI -0.4% to 5.7%) decrease in the infection rate with TW approached but was not statistically or clinically significant. Wound infection severity results for TW and SS are summarised in table 2. There were no delayed infections or complications reported at the 1-month follow-up.

## DISCUSSION

Our study is the largest single-centre trial to validate TW as a safe and effective wound irrigant. It is the only study that was double-blinded and controlled for irrigation technique, pressures and solution volumes. We did not find any important differences in infection rates for wounds irrigated with either SS or TW. TW did have a trend to be superior to SS as a wound irrigant and at worst could result in a 0.4% increased infection rate compared with SS. This worst-case scenario is both statistically unlikely and clinically insignificant. As such, we feel that this adds to the existing literature, suggesting that TW is a safe and effective wound irrigant as compared with SS.<sup>8</sup>

There has been considerable debate regarding the potential advantages and disadvantages of irrigating wounds prior to closure with SS, as compared with TW. SS is most often used as a wound irrigant because it is an isotonic solution that does not interfere with the healing process or further damage tissue. It is available commercially as a sterile product.<sup>5 8</sup> TW has the advantages of being readily available and less expensive.

Several other smaller trials have compared infection rates in acute soft tissue wounds that were sutured. Pooled results demonstrated a significant reduction in infection rates in wounds cleaned with TW, as compared with normal saline.<sup>8 13 17 18</sup> A significantly higher infection rate in the saline group was reported by Angeras, but the irrigation technique and solution volumes were not standardised.<sup>13</sup> Two trials measured infection rates in children and demonstrated no statistically significant difference in the infection rates when wounds were cleansed with either SS or TW.<sup>14 15</sup> Dire and Welsh compared infection rates in wounds cleaned with different solutions (including SS) and found no statistical difference.<sup>11</sup>

Our study was not designed to identify why TW might be superior to SS as a wound irrigant. The hypotonicity of TW could disturb the osmotic potential of a bacterial cell, leading to cell death. It is also unknown what role chlorination of TW plays in its efficacy and safety as a wound

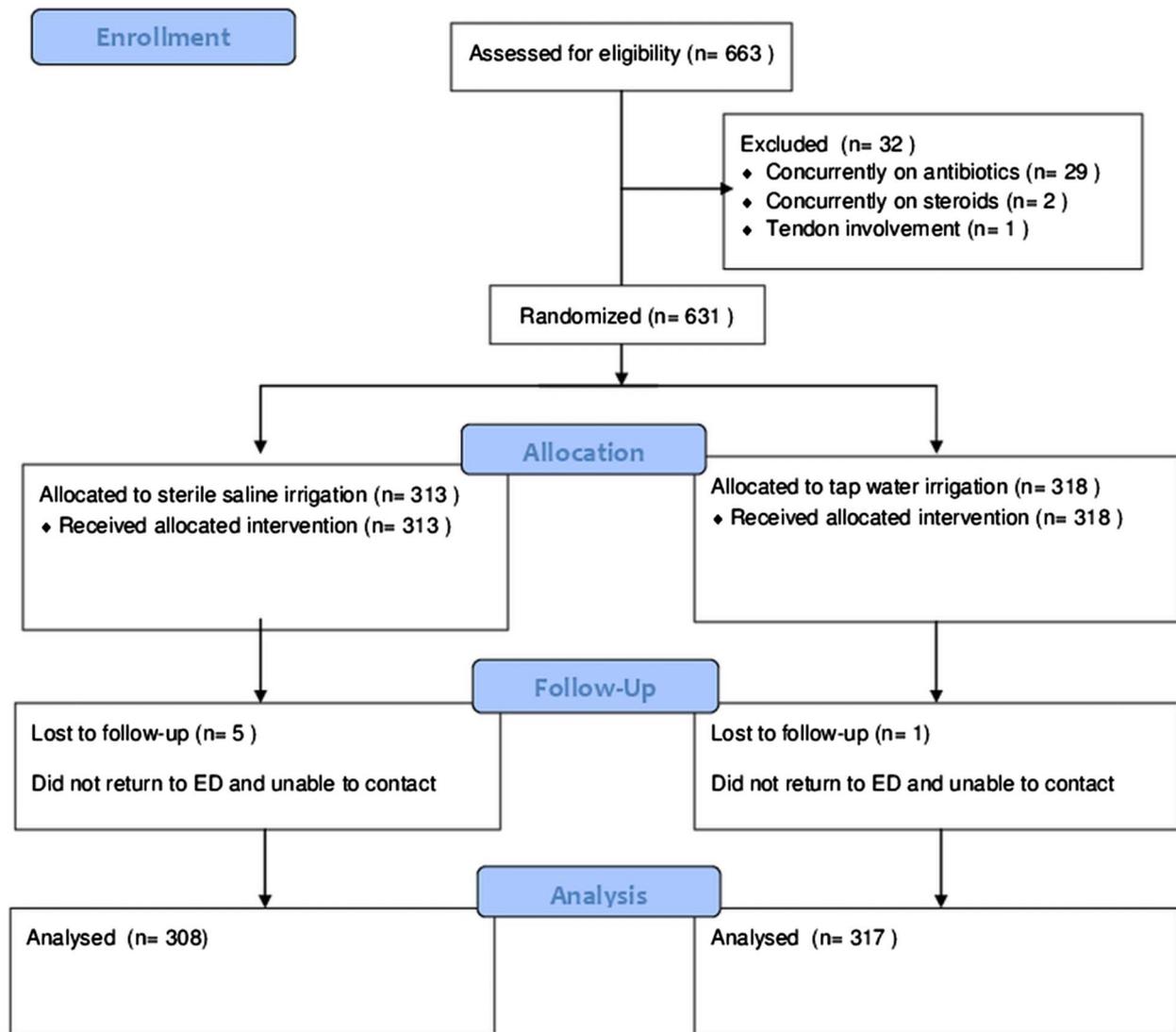


Figure 1 CONSORT flow diagram.

irrigant. Future studies are needed to determine if there is an optimal range of chlorination content, or whether chlorine is required at all in TW used for wound irrigation.

It may be that the mechanism of cleansing (ie, mechanical irrigation) and the volume of solution used are the most important variables in preventing wound infection, rather than the irrigant solution. Wounds become infected when they contain more than  $10^5$  bacteria/gram of tissue.<sup>10 22</sup> The threshold infective inoculum is reduced to  $10^2$  in the presence of dirt.<sup>23</sup> High-pressure irrigation (>8 psi) with copious amounts of solution has been shown to be the single most effective method of reducing bacterial counts in wounds.<sup>4-8 24</sup> Potable TW in developed countries contains an insufficient number of bacteria to cause wound infections, and the few bacteria isolated from TW are not generally skin pathogens.<sup>18 25</sup> Antimicrobial irrigating solutions have not shown any benefit over SS in reducing the incidence of wound infections.<sup>10</sup>

TW has both economic and environmental advantages over SS as a wound irrigant. TW is much less expensive than SS and is more readily available. At our institution,

the cost of a 500 ml bottle of SS is \$0.75; the patient charge is in excess of \$10. With the number of lacerations treated each year, the use of TW could generate annual savings of \$7.5 million for the hospitals and \$100 million for patients. Irrigating accessible wounds directly under a faucet could result in additional cost savings by eliminating the need for sterile bowls, syringes and catheters. Others have investigated this technique and found equivalent rates of wound infections using TW as compared with SS for irrigation.<sup>14 18</sup>

From an environmental perspective, the use of TW would yield fewer plastic bottles to discard and has beneficial ramifications in situations where SS is not readily available. When water can be adequately disinfected, this would include disaster and humanitarian relief settings, field operations for the military and medical clinics, and hospitals in developing countries.

#### Strength and limitations of the study

The strengths of the study are its randomised design, control for technique of irrigation and volume of

**Table 1** Enrolment and infection rates by patient age, gender, mechanism of injury, laceration length and wound location subdivided into sterile saline and tap water groups

Classification	Enrolment (%)				p	Infection (%)			
	Saline		Water			Saline		Water	
Age (years)					0.37				
0–10	46	(14.7)	48	(15.1)		2	(4.3±5.9)	1	(2.1±4.0)
11–20	45	(14.4)	50	(15.7)		3	(6.7±7.3)	3	(6.0±6.6)
21–30	87	(27.8)	100	(31.4)		4	(4.6±4.4)	2	(2.0±2.7)
31–40	59	(18.8)	66	(20.8)		2	(3.4±4.6)	2	(3.0±4.1)
41–50	41	(13.1)	28	(8.8)		6	(14.6±10.8)	0	(0.0)
Over 50	35	(11.2)	26	(8.2)		3	(8.6±9.3)	3	(11.5±12.3)
Gender					0.89				
Male	213	(68.1)	218	(68.6)		10	(4.7±2.8)	7	(3.2±2.3)
Female	100	(31.9)	100	(31.4)		10	(10.0±5.9)	4	(4.0±3.8)
Mechanism					0.86				
Blunt	174	(55.6)	179	(56.3)		12	(6.9±3.8)	7	(3.9±2.8)
Sharp	139	(44.4)	139	(43.7)		8	(5.8±3.9)	4	(2.9±2.8)
Laceration length					0.40				
<3 cm	213	(68.1)	218	(68.6)		11	(5.2±3.0)	6	(2.8±2.2)
3.1–6 cm	69	(22.0)	68	(21.4)		7	(10.1±7.1)	4	(5.9±5.6)
>6 cm	9	(2.9)	16	(5.0)		1	(11.1±20.5)	1	(8.3±1.6)
Not recorded	22	(7.0)	16	(5.0)		1	(4.5±8.7)	0	(0.0)
Wound site					0.99				
Head or neck	134	(42.8)	136	(42.8)		3	(2.2±2.5)	2	(1.5±2.0)
Trunk	1	(0.3)	0	(0.0)		0	(0.0)	0	(0.0)
Prox extremity	52	(16.6)	54	(17.0)		8	(15.4±9.8)	6	(11.1±8.4)
Distal extremity	126	(40.3)	128	(40.3)		9	(7.1±4.5)	3	(2.3±2.6)
Overall data	313	(100.0)	318	(100.0)		20	(6.4±2.7)	11	(3.5±2.0)

p Values for statistical enrolment difference were calculated by  $\chi^2$  or the Fischer's exact test (\*a 95% CI included for infection rates).

irrigant, successful blinding, relatively large number of subjects, and the fact that very few were lost to follow-up. A limitation of the study is that the primary measured outcome of wound infection was determined by subjective indicators of infection, such as erythema or gross exudate. Given the nature of the study, more objective measures such as bacterial counts, wound cultures or wound biopsy were not practical.

A second limitation was the six patients lost to follow-up during the study; five of these patients had wounds irrigated with SS and one had a wound irrigated with TW. This is a small number of patients lost to follow-up, and five out of six were in the SS group. Even if we assume that all these wounds became infected, it would only add

further support to our conclusion that TW is a safe and effective alternative to SS as an irrigant solution.

Although we controlled for the volume of solution and the mechanism of wound cleansing, the temperatures of the solutions were not identical. The difference in temperature of the TW (38°C), as compared with SS (room temperature), may have been a factor. TW did not reach room temperature prior to initiating irrigation.

Telephone follow-up and self-reporting at the 1-month interval could have led to some misclassification by the patients conveying wound status, but the risk of misclassification should have been similar in both groups, and late complications subsequent to laceration repair are not common.

## CONCLUSION

There is no difference in the infection rate of wounds irrigated with either TW or SS solution, with a clinical trend towards fewer wound infections in the TW group, making it a safe and cost-effective alternative to SS for wound irrigation.

**Contributors** EW, GO and TF conceived and designed the study protocol. EW, GO, TF and ML acquired, analysed and interpreted the data. JQ performed the statistical analyses. EW drafted the manuscript and all authors contributed to the manuscript. EW and JQ made revisions to the manuscript.

**Table 2** Infection Criteria (A wound was classified as infected if it exhibited any of the following infection criteria)

Infection criteria	Tap water (n=11)	Saline (n=20)
Stitch abscess	0	1 (5)
Erythema (<1 cm)	6 (55)	10 (50)
Erythema (>1 cm)	3 (27)	7 (35)
Gross exudate	2 (18)	2 (10)
Fever $\geq 38^\circ\text{C}$	0	0

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**Competing interests** None.

**Ethics approval** The study was reviewed and approved by the Stanford University Institutional Review Board.

**Provenance and peer review** Not commissioned; externally peer reviewed.

**Data sharing statement** No additional data are available.

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# 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)