Evaluation of Hemorrhage Control and Tourniquet Training Effectiveness for Laypersons: TRIAGE
Study (**TouRnI**quet tr**A**inin**G E**ffectiveness)

April 3, 2018
Study Protocol and Statistical Analysis

1) *Study design:*
   a) Prospective open-label trial

2) *Consent*:
   a) Verbal consent

3) *Protocol*:
   a) All participants will receive the ACS stop the Bleed training from qualified instructors. This training is 45 to 60 minutes long, consisting of an audio-visual presentation with tourniquet application instructions followed by hands-on training under the supervision of an instructor. The training takes place in groups of 20 to 50 at a time. The audio-visual part of the training takes place in groups of 20, which are then divided in to subgroups of 4-8 for hands-on training with an instructor. There is no compensation for the study participants.
   b) The evaluation of hemorrhage control competence will take place individually. A mannequin, the Hapmed tourniquet trainer, with a traumatic amputation of the leg just above the knee will be present. A reviewer will provide instructions, including that the lights on the leg represent continued bleeding and they will have a maximum of 2 minutes to apply the tourniquet. The participant will be provided a tourniquet and told to stop the simulated bleeding. Participants will be tested in all 5 types of tourniquets sequentially using the same method but with the order of testing varying according to the randomization. The reviewer will start timing after telling the participant to begin. This will then be repeated for the other type of tourniquet the individual will need to apply. No feedback will be given to the participant throughout the testing process.
      i) Supplies for the improvised tourniquet will include a T-shirt, long stretch of gauze, a stick to act as a windlass, and a leather belt
   c) Parameters measured:
      i) The participants will be timed until they feel that they have stopped the bleeding or they tell the instructor they are done. The maximum amount of time provided to apply the tourniquet will be 2 minutes based on the results of the investigators prior studies in which the 90th percentile for time to correct application was 117 seconds.
      ii) Appropriateness of hemorrhage control will be determined by correct placements of tourniquet as defined by at least 2 inches proximal to the amputation site
      iii) Adequate pressure to stop the bleeding which will be set at 250 mmHg. For unsuccessful hemorrhage control, the reason for failure will be recorded.
      iv) Correct tourniquet application defined by:
         (1) Time to application < 120 seconds
         (2) Placement of tourniquet a minimum of 2 inches proximal to amputation
         (3) Tourniquet application pressure > 250 mmHg
   d) All the reviewers would be physicians, nurses and EMTs, trained in hemorrhage-control. The complete test for each individual will not take more than 15 mins.

4) *Randomization for the order of tourniquet application:*
   a) Permutated block randomization will be used to vary the order for application of the 5 different types of tourniquets (CAT, RAT, SWAT-T, Sof-T, and improvised tourniquet)

5) *Pre-trial questionnaire:*
   a) Study subjects will be given a pre-trial questionnaire to gather information regarding age, gender, and level of education. The questionnaire will also include questions to assess their knowledge regarding hemorrhage control and to determine their willingness and self-reported comfort level in acting as a first-responder in a mass causality scenario. Answers will be presented on a Likert-type scale or dichotomous yes-no.

6) *Post-trial questionnaire:*
   a) After the hemorrhage control training, all participants will be given a questionnaire to evaluate comfort level, self-efficacy, and other questions relating to hemorrhage control response.

7) *Sample size calculation:*
   a) Sample Size calculation was done for paired comparisons with 80% power and Bonferroni corrected for 4 pairwise comparisons for an alpha level of 0.0125 and correlation of 0.1. The largest difference was then taken as the sample size for each arm.
   b) The expected corrected proportions for the different tourniquets are:
      (1) CAT: 80-90% (Control)
      (2) RAT: 10-30%
      (3) SWAT-T: 10-30%
      (4) Sof-T: 20-40%
      (5) Improvised: < 10%
      ii) The smallest presumed difference in correct application for the CAT (control) at 80% is to the Sof-T at 40%. To attain 80% power with alpha of 0.0125 the required minimum sample size is 34.
   c) All sample size calculations performed using Stata v14.1.

8) *Statistical Analysis*:
   a) Paired statistical tests using McNemars test will be used for the univariate analysis of the primary outcome of correct tourniquet application comparing the CAT tourniquet as a control (CAT being type of tourniquet taught in the B-Con course) to each of the other tourniquet types (RAT, SWAT-T, Sof-T, Improvised) for 4 total pairwise comparisons.
   b) Descriptive statistical analysis (ANOVA, Kruskal-wallis, Mann Whitney U test, Student T-test) will be used to assess the secondary outcomes of time to tourniquet application, estimated blood loss prior to tourniquet application, and pressure applied by the tourniquet.
   c) Multiple Logistic regression will be used to assess for predictors of correct tourniquet application for each of the different tourniquet types. The model will include age, gender,

education level, any prior hemorrhage control training, and success in application for each of the other tourniquet types.

d) Descriptive statistics will also be used to assess participants responses on the questionnaires. Non-parametric statistical tests (Wilcoxon signed rank test and generalized estimating equations) will be used to assess 5-point Likert scale questions.

e) P-value for significance will be set at 0.05 after Bonferroni correction.