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Brooke Army Medical Center
Institutional Review Board

**HUMAN SUBJECTS RESEARCH
PROTOCOL APPLICATION – Part B**

1. PROTOCOL TITLE: Heated Ultrasound Gel Satisfaction (HUGS): A Randomized Control Trial

2. ABSTRACT: Ultrasound has become one of the fastest growing diagnostic tools for Emergency Physicians, and given the increasing focus on patient satisfaction in the Emergency Department, there may be opportunities to enhance both patient satisfaction and diagnostic accuracy. The purpose of this single-blind, randomized control trial will be to investigate whether simply having warm gel, as compared to room-temperature gel, during a bedside ultrasound significantly improves patient satisfaction scores. If satisfaction scores are significantly higher, then medical directors may find it beneficial to invest in ultrasound gel warmers. We will also investigate two secondary hypotheses: 1) patient perceptions of their medical providers and 2) the overall quality of ultrasound images obtained.

3. OBJECTIVES/SPECIFIC AIMS/RESEARCH QUESTIONS.
Hypothesis: The utilization of warmed ultrasound gel significantly increases patient satisfaction with regards to their care during a visit to the Emergency Department.
Null: The utilization of warmed ultrasound gel does not change patient satisfaction with regards to their care during a visit to the Emergency Department.

Hypothesis 2: Utilization of warmed ultrasound gel significantly improves the quality of images obtained during bedside ultrasound.
Null: The utilization of warmed ultrasound gel does not change the quality of images obtained during bedside ultrasound.

Hypothesis 3: The utilization of warmed ultrasound gel significantly increases patient perceptions of their physician's professionalism.
Null: The utilization of warmed ultrasound gel does not change patient perceptions of physician professionalism.

4. MILITARY RELEVANCE. Patient satisfaction as an indicator of the quality of healthcare has evolved as an outcome measure within both the federal and civilian sectors. In fact, the DOD military health system incorporated patient satisfaction surveys to serve as a measure for how its beneficiaries perceive their care.⁶ In order to further review specific factors that may help to improve patient satisfaction scores, this study will explore the use of warmed ultrasound gel and perceived patient satisfaction. For most soldiers and dependents, warmed ultrasound gel is generally more comfortable than room temperature gel because warmed gel appears to enhance patient comfort and improve overall experience with the procedure. There is a considerable gap in the literature regarding factors that improve enhanced patient comfort in military beneficiary populations. Therefore, one of the contributions of this study will be to clarify precisely what that level of satisfaction is, if use of warmed gel is truly a satisfaction factor, and if the quality of images improve with the use of warmed gel. Generally, we aim to contribute to the generalizable knowledge of medical science, particularly in regards to patient satisfaction and the impact of warmed gel on ultrasound imaging, which would be applicable to both military and civilian settings.

5. BACKGROUND AND SIGNIFICANCE. Patient satisfaction is a growing center focus of Emergency Departments across the country. One study evaluated over 2.4 million ED visits over the course of four

52 years in eight different states. Their data showed that patients who responded with the lowest quarter of
53 satisfaction scores were twice as likely to file a complaint compared to the top quarter of patients surveyed.¹
54 In a 2005 study in *JAMA*, 93% of physicians in Pennsylvania from six of the most litigious medical services
55 reported that they practice “defensive medicine and within this group, ED physicians had the highest rates of
56 ordering more tests than medically necessary.²

57
58 In line with the concept of more tests than medically necessary, CT orders in the ED are becoming standard
59 of practice as a method of evaluating a wide variety of complaints. Levin, Parker, and Fragos (2014)
60 reported that for every 1000 Medicare ED visits between 2002-2012, CT scanner use increased remarkably
61 across the country.³ The doses of radiation that come with CT scans, however, can increase the risk to the
62 patient in the long run. For example, one abdominal CT delivers 8mSv, which is roughly equivalent to the
63 radiation from 400 chest x-rays.⁴ To counter this increase in CT scans, ultrasounds have become one of the
64 fastest growing and safer diagnostic tools for ED physicians over the past decade. Non-cardiac ultrasound
65 use increased by 121% from 2002-2012, with 21 patients per 1000 being scanned.³ With real-time
66 diagnostic capabilities at the bedside and no harmful radiation, ultrasounds provide clinicians with decision
67 tools to better care for their patients. Class I medical devices, such as the Thermasonic® Gel Warmer, heat
68 ultrasound gel to- and just-above normal body temperatures are frequently seen in Cardiology and OB-GYN
69 clinics, where echocardiograms and pelvic ultrasounds are performed routinely. Given the increase in use of
70 ultrasound and the increased focus on patient satisfaction, our aim is to identify whether warmed gel can
71 truly improve overall patient satisfaction when performing point-of-care ultrasounds in the ED.

72 **6. RESEARCH DESIGN**

73 This is a single-blinded, randomized study will recruit a sample of 124 subjects from military and civilian
74 populations who are treated in the Emergency Department (ED) at SAMMC and require standard of care
75 bedside ultrasound for diagnosis.

76 **7. RESEARCH PLAN**

77 **7.1 Selection of Subjects**

82 **7.1.1. Subject Population.**

84 **7.1.2 Inclusion Criteria:**

- 85 • Adults 18-89 who are seen in the SAMMC Emergency Department that require standard of care
86 bedside ultrasound

88 **7.1.3 Exclusion criteria:**

- 89 • Minors under age 18
- 90 • Pregnant females
- 91 • Adults over age 90
- 92 • Vulnerable adults to include those with altered mental status, incarcerated, military basic trainees, or
93 those with a primary language other than English
- 94 • Patients with open or broken skin

96

7.1.2. Source of Research Material.

Source of Research Material	Clinical Purposes(Y/N)	Research Purposes (Y/N)
Patient Survey	N	Y
Provider Survey	N	Y
Bedside Ultrasound	Y (standard of care)	Y

97

98

99 **7.1.3. Description of the Recruitment and Prescreening Process.** Patients being treated in the ED who
100 require a standard of care bedside ultrasound for diagnosis will be approached by the AI (ultrasonographer).
101 The AI will advise patient that they are there to perform the ultrasound as ordered by his or her doctor and
102 subsequently ask if the patient would be interested in participating in a patient satisfaction survey surrounding
103 the ultrasound. If the patient says they are interested and meets inclusion/exclusion criteria, the AI will provide
104 the patient with the information sheet (see Appendix C) and explain the study to subject.

105

106 **7.1.4. Subject Screening Procedures.** N/A

107

108 **7.1.5. Consent Process.** In a private exam area in the ED, the AI will inquire whether the patient, who required
109 bedside ultrasound and who meets inclusion/exclusion criteria, would be interested in learning about a research
110 study involving how ultrasounds are performed. The AI will provide an information sheet about the study to
111 interested patients. If the patient is interested, the AI will review the information sheet (Appendix C) and answer
112 any questions the patient may have. We are requesting a waiver of documentation of consent for this project
113 as the study procedures are minimal risk and involves no procedures for which written consent is normally
114 required outside the context of research.

115

116 Because we are not using or collecting any personally identifiable information for research purposes, a HIPAA
117 authorization does not apply to this research.

118

119 **7.1.6. Compensation for participation.** None

120

121 **7.2 Drugs, Dietary Supplements, Biologics, or Devices.**

122

123 **7.2.1** N/A

124

125 **7.2.2** The Thermasonic Gel Warmer (Model 82-03 LED, 120V) is a Class I medical device that warms up to
126 three (3) gel bottles to settings of "Low" (97 Fahrenheit), "Medium" (102 Fahrenheit), or "High" (109
127 Fahrenheit) (Appendix E). For this study, we will set all gel warmers to the "Medium" setting. For a full listing
128 of the device instruction manual, please visit <http://www.parkerlabs.com/thermasonic>.

129

130 A heat-resistant glove, ULine Terry Cloth Glove (Appendix F), will be used by the AI to handle the
131 ultrasound gels. This glove is manufactured to resist temperatures up to 250 degrees Fahrenheit. In line
132 with SAMMC's infection control practices and patient safety, ultrasound operators will wear a sterile glove
133 over the terry cloth glove to prevent the spread of microbiota from subject to subject. For more information
134 about the glove, please visit their website at http://uline.com/BL_111/terry-gloves.

135

136 **7.3. Study Procedures/Research Interventions.** The principal investigator will brief ED physicians on details

137 of this study by email (Appendix D). ED physicians who identify that a patient will require an ultrasound will
138 page the ultrasound team as part of standard of care. At that time, the AI (ultrasonographer) will ask subject if
139 he/she would like to participate in a research study involving patient satisfaction and diagnostic bedside
140 ultrasound. If the patient agrees, the AI will provide an information sheet (Appendix C) and explain study
141 details/answer any questions. The patient will then be randomized and assigned a HUGS-X number that will be
142 placed in the comments section of the ultrasound image and given a 3-question patient survey (Appendix A)
143 related to patient satisfaction and perceptions about their provider which will be completed at the end of the
144 ultrasound procedure. The patient will be instructed not to provide any PII/PHI when he/she completes the
145 survey after the diagnostic bedside ultrasound and to hand it back to the AI when complete.

146
147 **Ultrasound and Warm or Room Temp Gel Procedures:**
148

149 The AIs will use either the warm or cold gel to complete their standard of care diagnostic ultrasound scans.
150 Subjects will be randomized to receive either warm or cold gel depending on the study packet number. The
151 study packet number will contain specific randomized instructions for the AI that provides the appropriate gel
152 numbered 1-6 to utilize and the 3-question patient survey and 1 question provider survey.

153 Patients and providers will be blinded to the intervention meaning both the AI and the patient will be
154 unaware of different gel temperatures being utilized until the moment it is used on the patient's ultrasound
155 area.

156 The provider (AI) will be blinded to the intervention used in two ways. The first being that six ultrasound gel
157 warmers, labeled #1-6, will be set up at a station, and the warmers will have been randomly set-up as far
158 which are actually turned on or not by the PI. The AI will not know which are turned on because the indicator
159 lights will be covered with black tape. Additionally, the AI will use heat-resistant gloves to hold the
160 ultrasound gel bottle as described in section 7.2.2. At the end of the subject's bedside ultrasound, the
161 physician completing the ultrasound will hand the patient a satisfaction survey utilizing visual analog scales.
162 As an additional measure to test our blinding measure, the AI will complete the one question survey to test
163 whether he or she was aware of the warm or room-temperature gel temperature.

164 Both surveys will be collected and stored in a locked box in C-Pod of the Emergency Department until
165 results can be entered in to the electronic spreadsheet (HUGS DataTracker Data Collection Spreadsheet,
166 Appendix G)

167
168 **The Ultrasound Image Rating:**
169

170 Ultrasound image rating is conducted weekly by the SAMMC ED/Ultrasound Quality Assurance Team on a
171 weekly basis. These meetings are already a standard practice in our department to review every ultrasound
172 obtained in the department as a way to obtain feedback from all clinicians about the quality of their
173 ultrasound studies. Their standard metric for evaluation is a 5-point Likert-type scale. During this QA review,
174 scores related to images that have a HUGS ID in the comments area will be written down and provided to
175 the PI. Their standard metric for evaluation is a 5-point Likert-type scale.

176 Table I: Summary of Study Activity/Interventions
177

Assessment:	During ED Visit:	Weekly Ultrasound QA Session:
Screening	X	
Randomization	X	
Bedside Ultrasound	X	
Anonymous Patient Survey Appendix A)	X	
Provider Survey (Appendix B)	X	
Review of Ultrasound Images for Overall Quality		X

178
179 **7.3.1 Collection of Human Biological Specimens.** N/A
180

181 **7.3.1.1 Laboratory evaluations and special precautions.** N/A
182

183 **7.3.1.2 Specimen storage.** N/A
184

185 **7.3.2 Data Collection.** Subject specific data (patient age, gender, and their satisfaction scores) will all be
186 written on the anonymous survey (Appendix A). The primary outcome will be a visual analogue scale, i.e.
187 continuous variable. By collecting a variable with greater data density than a conventional Likert scale (e.g.,
188 ordinal data), this will enable us to use more powerful statistical techniques in analyzing our data so minimizing
189 the possibility of a type II (beta) error. We will further evaluate our secondary outcomes with Likert-type scales
190 to minimize millimeter differences between patient scores. Finally, we will use binary data to evaluate whether
191 patients were overall satisfied with their visit.
192

193 Primary Outcome #1a: Overall, how satisfied are you with the experience of having a bedside ultrasound today?
194• Ranges from “Least” to “Most” on 10cm VAS (continuous data)
195

196 Primary Outcome #1b: Overall, are you satisfied with the care you received today in the Emergency
197 Department?
198• “Yes” or “No” (binary data)
199

200 Secondary Outcome #1: Overall, how professional was the physician who did your bedside ultrasound?
201• Ranges from “Least” (1) to “Most” (5) on 5-point Likert-type scale (ordinal data)
202

203 The subject survey form will not contain any PHI/PII. Completed packets will be taken to the locked bin in C-Pod
204 of the Emergency Department. We will also store the completed provider surveys in the same container to allow
205 for further evaluation of provider answers regarding which type of gel they believe they used and if the blinding
206 method imposed by the PI prevented the provider from knowing which gel they utilized.
207

208 New study packets will be kept in a separate designated bin within the Emergency Department, next to the
209 ultrasound gel warmers, so that associate investigators may access all required materials while working in the
210 department. The PI or available AI will pick up completed packets weekly and will either log the data
211 immediately or store them in the designated locked bin in the ultrasound team room until they can be entered
212 into the HUGS DataTracker spreadsheet.
213

214 Subject bedside ultrasounds, like any clinical ultrasound done in our hospital, are uploaded automatically to the
215 IMPAX system. Each week, the SAMMC ED/Ultrasound Quality Assurance Team reviews all bedside
216 ultrasounds for quality assurance purposes. Their standard metric for evaluation is a 5-point Likert-type scale.
217 This type of data is ordinal (and is the basis for secondary outcome #2). These scores will be logged by the PI or
218 available AI into an Excel Spreadsheet found on a password-protected computer behind a locked door in the
219 ultrasound team room. As all investigators are blinded to which ultrasounds were conducted with warm or cold
220 gel, there is no concern for a bias regarding the rating of quality for each ultrasound or during entering survey
221 data to the HUGS DataTracker. Upon transfer of all data to the spreadsheet, the paper surveys and hand-
222 written scores for each ultrasound will be shredded.
223

224 **7.4 Statistical Consideration**

225 **7.4.1 Sample Size Estimation.** This study will be developed to assess our primary outcome with a two-tailed
226 alpha of 0.05 and a beta of 0.2 (power of 0.8), with equal numbers in the warm and cold gel groups. Based on
227 previous studies on visual analog scales and patient satisfaction in the Emergency Department, we will be using
228 an effect size of 0.11 (indicating 11mm on the VAS) with a standard deviation of 0.21 (indicating 21mm on the
229 VAS).⁵

Estimate Required Sample Size	114
Estimate Subject Drop Out / Withdrawal	10
Total Enrollment Requirement	124

Enrollment at Each Site	
BAMC	124

233 **7.4.2 Primary (i.e., primary outcome variables) and secondary endpoints.** As discussed in 7.4.1, this study
234 has been powered to detect an effect size of 11mm on the VAS for a statistically significant difference when
235 investigating our primary outcome (1a).

236 #1a: Overall, how satisfied are you with the experience of having a bedside ultrasound today?

237 Ranges from “Least” to “Most” on 10cm on VAS

238 #1b: Overall, are you satisfied with the care you received today in the Emergency Department?

239• “Yes” or “no”

240 #2: Overall quality of images

241• Ranges from lowest quality (1) to highest quality (5) on a Likert-type scale

242 #3: Overall, how professional was the physician who did your bedside ultrasound?

243• Ranges from “Least” (1) to “Most” (5) on Likert-type scale

244 **7.4.3 Data analysis.** The patient satisfaction scores will be compared (warm vs. cold groups) using
245 independent sample t-tests. If the data are ordinal or not normally distributed with equal variances, the
246 equivalent non-parametric test will be used. Independent sample t-tests will also be used to compare the quality
247 ratings of the ultrasound images.

248 **7.5 Confidentiality.** The PI or available AI will pick up completed packets weekly and will either log the data
249 immediately or store them in the designated locked bin in the ultrasound team room until they can be entered
250 into the HUGS DataTracker spreadsheet. It will not be possible to associate survey forms with patient charts.
251 Data from the anonymous surveys will be entered into an Excel Spreadsheet (HUGS DataTracker, Appendix G)
252 which will be stored on a password protected computer behind a locked door. The completed paper surveys will
253 be immediately shredded once entered electronically. Once the data has been analyzed, the anonymous data
254 will be destroyed.

258 file will be deleted.

259
260 The bedside ultrasounds, which are part of routine clinical care in our department, are stored within the
261 electronic IMPAX database. All completed ultrasounds for the past week within our emergency department are
262 automatically queued for review by our ultrasonography team. This process is inherent in our system and is not
263 specially designed for this research. They will know that an ultrasound study is part of the research study as the
264 "HUGS" identifier will be seen in the comments box of the ultrasound images. Only medical providers within the
265 military healthcare system have access to these scans.

266
267 **7.5.1 Certificate of Confidentiality.** N/A

268
269 **8.0 RISKS/BENEFITS ASSESSMENT**

270
271 **8.1 Risks.** There are minimal risks for this study. Although this survey is anonymous and cannot be tracked
272 to specific individuals, there is a small risk of inadvertent breach of confidentiality. Participants will not be
273 identified and will be reminded not to add identifiers to their survey documents. For the ultrasound images
274 on IMPAX, only military providers within the military healthcare system have access. Risk of a confidentiality
275 risk is similar to the normal, daily risk of breach in our healthcare system.

276
277 • There is also the risk of brief discomfort to subjects related to the gel temperature. Medical devices heat the
278 gel to a maximum temperature of 104 degrees. Injuries from gel at this temperature or at room temperature
279 are very unlikely to occur.
280 • Although there is a minimal risk of gel being contaminated with microbiota, we will further mitigate the risk by
281 excluding patients with broken skin in the area of where an ultrasound probe would be placed onto the skin.

282
283 **8.2 Potential Benefits.** There may be direct benefits to participants. Subjects enrolled in the warm gel
284 group may benefit from a more comfortable ultrasound.

285
286 **9.0 ADVERSE EVENTS, UNANTICIPATED PROBLEMS, AND DEVIATIONS**

287
288 **9.1** An adverse event in this study would be either a burn to the patient, infection, or a breach of confidentiality.
289 These are considered rare but serious, as described above. Adverse events during the study would be
290 documented by the ultrasonographer or another member of the research team and reported by the PI to the IRB
291 as required.

292
293 **9.2 Reporting Unanticipated Problems Involving Risks to Subjects or Others, Serious Adverse Events and**
294 **Deaths to the Office of the IRB, BAMC.**

295
296 All unanticipated problems involving risk to subjects or others, serious adverse events, and all
297 subject deaths related to the study will be reported within 48 hours of the research team's
298 knowledge of the event by phone (210-916-0606), by e-mail (BAMC_IRB_AE@amedd.army.mil),
299 by facsimile (210-916-1650) or via letter addressed to Human Protections Administrator, Office of
300 the Institutional Review Board, Brooke Army Medical Center, Attn: MCHE-CI, 3698 Chambers
301 Pass, Fort Sam Houston, TX 78234-6315. A complete written report will follow the initial
302 notification within 10 working days.

303
304 **9.3 Research Monitor.** N/A

305
306 **10.0 WITHDRAWAL FROM STUDY PARTICIPATION.** Subjects may withdraw from the study at any time
307 prior to turning in his/her survey. Their survey packet, if they began to write on it, would be shredded if they
308 withdraw from the study prior to turning it in. Regardless of participating in the study, the patient would still

309 receive the bedside ultrasound as it is part of their clinical care. Because this is an anonymous survey, once
310 the survey is turned in, data will be used and transferred to the Excel Spreadsheet (HUGS DATA
311 TRACKER). There would be no adverse effects for the patient if he or she decided to withdraw from the
312 study.

313

314 **11.0 USAMRMC Volunteer Registry Database.** N/A

315

316 **12.0 REFERENCES.**

317

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329 and Assessment of Department of Defense Effects

330

331 **13.0 TIME REQUIRED TO COMPLETE THE RESEARCH (including data analysis).** Up to 18 months: 12
332 months for recruitment and up to 6 months for analysis and manuscript preparation.

333

334 **14.0 STUDY CLOSURE PROCEDURES:** All paper surveys will be shredded and any computer data with
335 subject numbers will be deleted upon entry into the data collection spreadsheet. After study completion, a final
336 closure report will be submitted to the IRB. Ultimately, a manuscript will be generated with the intent of
337 submitting to a peer-reviewed medical journal for publication.

338

339 **Appendices:**

340 Appendix A: *Anonymous Subject Survey*

341 Appendix B: *Provider Survey*

342 Appendix C: *Subject Information Sheet*

343 Appendix D: *Email to Emergency Medicine Staff*

344 Appendix E: *Thermasonic Product Information Sheet*

345 Appendix F: *ULine Terry Cloth Information Webpage*

346 Appendix G: *HUGS DataTracker Data Collection Spreadsheet*