Author's response to reviews

Title: Development and evaluation of a novel, real time mobile Telesonography System in management of Patients with Abdominal trauma: Study Protocol

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Author's response to reviews: see over
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Dear Editor:

Re: MS #8986642437322212: Title: Development and evaluation of a novel, real time mobile Telesonography System in management of Patients with Abdominal trauma: Study Protocol

On behalf of the co-authors, I thank you for giving us the opportunity to revise and resubmit our manuscript to your journal for publication consideration. We would also like to thank the reviewers for their thoughtful comments. Our detailed responses to each of the various comments from the reviewers have been addressed in this response cover letter (see below). We strongly believe that the revision made to the manuscript has strengthened it significantly.

With best wishes and appreciation of your time.

Sincerely,

Chinwe Ogedegbe, MD, MPH, FACEP
Response to critiques from reviewer #1

ABSTRACT

R1.1. Background. Could you shorten the paragraph of the background? The paragraph can be focused on the study question and hypothesis with less than two sentences.
Response: The background has been reduced as suggested by the reviewer.

R1.2. Method. Could you add more information on the study participants’ characteristics: how many patients volunteered, how many physicians?
Response: This information is now provided in the methods section of the abstract.

R1.3. Could you add more information on study protocol: how many times running and performing the ultrasound examination?
Response: As requested, the study protocol has been expanded to include frequency of the ultrasound examination thus: “Each of the three healthy volunteers will have two sets of ultrasound e-FAST exams performed by the UTPs (one in the mobile ambulance and the other at the Emergency Department) with a total of 12 e-FAST images per volunteer. The ambulance images obtained will be transmitted to the ED, while the images obtained at the ED will be stored in the sonogram device”.

R1.4. Could you explain the method for measuring quality scale and the QUIS?
Response: Quality of the images of the e-FAST examinations obtained from the moving ambulance and at the ED will be compared to each other by 20 UTP evaluators including radiologists, ED physicians and trauma surgeons, who are blinded to the study. For this purpose, each UTP evaluator will rate each set of images along the dimensions of quality, resolution and detail using the QUIS questionnaire. These dimensions form the subsections of the validated QUIS instrument.

R1.5. Result. Please summarize expected results of the study?
Response: The expected results include the following. First, we expect that the UTPs will obtain e-FAST ultrasound images of good quality, successfully transmit them securely, and real-time, via cellular BGAN networks to the ED. Secondly, we expect that the images obtained from the moving ambulances will be comparable to those obtained at the ED along the dimensions of quality, resolution and detail. Finally, we expect the quality of the images to be similar in all cases independent of the patients’ body mass index. These expected results are already stated and implied in the study hypotheses. The abstract has been revised accordingly (see bolded section on Page 12).

R1.6. Discussion. Could you add any expected effect on the clinical practice or outcomes?
Response: We have expanded the discussion section by adding the following sentence (see bolded section on page 13): "Findings from this study, if successful, will lead to widespread adoption of utility of ultrasound diagnosis and management of trauma patients in the pre-hospital setting. This may in turn have implications for its adoption by the military in the battlefield. Although ultrasound is a well-established technology to perform e-FAST examination in the ED setting, its use in the pre-hospital setting will enable patients to be triaged to a higher acuity level with blunt trauma. Knowing that a patient has free fluid in the abdomen even with normal vital signs (as many patients do) place patients at higher risk of mortality and morbidity from their trauma. Alerting emergency departments to see these ultrasound images will allow centers to prepare and allocate resources in preparation for patient’s arrival. This would be extremely helpful in a rural setting, where decisions about air transport versus ground transport need to be made.”

R1.7. Text Background Page 6. Authors described as “The goal of this study is to develop and evaluate the effectiveness of a telesonography (TS) system in improving the efficiency, and quality of care of patients with abdominal trauma.” However, the study just will develop the TS system and measure the image quality, which, that is the feasibility, not effectiveness nor quality of care, of the TS. Could you clarify the study objectives? There is no data on effectiveness or quality of care in this study. The effectiveness means saving cost for unit care. Quality of care also means appropriate process for care.

Response: We agree with the reviewer and have clarified the study objective to address the reviewer’s concerns as follows, now on page 5: “The goal of this study is to develop a novel telesonography (TS) system and evaluate the comparability of the quality of images obtained via this system among healthy volunteers who undergo eFAST abdominal examination in a moving ambulance and at the ED”. We have removed the words effectiveness and quality of care from the stated study objectives.

R1.8. Page 6-7. The next paragraph is not proper in the background section. Move it to Method section. “During phase 1, we will develop and test the TS system by interfacing a portable ultrasound and a broadcast unit. During phase 2, we will evaluate the usability of the novel TS system with two-way voice and one-way video communications capability and then compare the quality of the real time ultrasound images obtained from healthy volunteers in a moving ambulance via the developed TS system to those obtained in the ED. Specifically we will develop and test a “commercially ready” telesonography system that will provide ED physicians and Trauma surgeons ultrasound images of patients with acute trauma transmitted real time from a remote or pre-hospital setting.”

Response: As suggested by the reviewer, we have moved the noted paragraph to the methods section.

R1.9. Methods Page 7 Could you cite the following sentence you described? “In its current version, QUIS 7.0, contains a demographic questionnaire, a measure of overall system satisfaction along six domains, and hierarchically organized items of nine specific interface factors (screen factors, terminology and system feedback, learning
factors, system capabilities, multimedia, for example). Each domain evaluates the users’ overall satisfaction with that facet of the interface, as well as the factors that make up that facet, on a 9-point scale." The above sentences might be from the following web page: http://lap.umd.edu/quis/.

Response: As suggested, we have formatted the above reference, made the citation and updated the references to reflect that, now on page 6: About the QUIS, version 7.0. [http://lap.umd.edu/quis/]

R1.9. Page 9. Could you explain more characteristics of the TS you are going to invent. What’s the device for video compression? What’s the frame rate to transmit the image? What kinds of cellular system will be used among CDMA or FDMA or TDMA or WCDMA? Ultrasound image data needs a great capacity to compress and transmit it within the appropriate time interval. What’s the method to speed up the transmission of the huge burden of video clip?

Response: We have added the characteristics of the TS (see bolded section on pages 8-9). Basically, the system utilizes a patented technology (US Patent No: 7,948,933) developed for the broadcast industry by LiveU Corporation, Hackensack, New Jersey to take the video output of a standard medical ultrasound device and transmit the image in real time to a hospital or any other location. The video stream from the ultrasound device is transmitted in its entirety so the frame rate is preserved and decoded on the receiving end. The technology was developed by LiveU Corporation for high definition media/broadcast images and is being used by the major broadcast networks. The system was adapted for use with medical ultrasound in collaboration with Hackensack University Medical Center. The system utilizes proprietary implementations of video encoding /compression standard H.264, which provide adaptive bit rate, adaptive and predictive forward error correction, and error recovery mechanisms. The transmission system has a built in proprietary passive antenna to support multiple signals including 3G and 4G LTE. Multiple modular wireless communications links are employed which can include any cellular system including the latest technology such as LTE, WiMax, HSPA+, and the system is backward compatible with existing technology such as CDMA, FDMA, TDMA, WCDMA, Wi-Fi. Satellite links such as BGAN and VSAT are also supported. Cellular modems or other communications devices for the desired link plug into LiveU system to provide connectivity. The desired bandwidth is achieved by tagging the digital words representing the ultrasound video images with identifiers separating and transmitting them over the multiple communications links, and then re-assembling the digital video stream at the receiving end to re-create the images. Using multiple independent communications channels to transmit the separated digital words multiplies the available bandwidth. The multiple lines are monitored in real-time (both delay, packet loss and bandwidth) and packets are transmitted according to their priority.

R1.10. Results. Could you list the expected results?

Response: Please see response to critique 1.5 above. The expected results are now stated on page 12.
R1.11. Discussion. Could you review previous similar studies? What’s the weak point or limitation in the studies?

Response: To our knowledge, and after a careful review of the literature, we are not aware of any studies that has developed a novel TS system and evaluated its utility in a pre-hospital setting. While still images are readily transmitted in real time, the secure transmission of suitable quality video images for evaluation and diagnosis from a remotely located medical expert, in real time remains to be demonstrated. This transmission technology is unique in that it will provide for secure cellular communication across several carriers (instead of one carrier), allowing for broader bandwidth, which reduces the risk of dropped or weak signals, as well as permits the sending of more detailed, higher quality pictures. In addition to cellular, this system enables ready connection to BGAN satellite or to any available Internet modalities such as LAN/WAN, cable/optical fibers, and Wi-Fi.

R1.12. Could you describe the expected effect of this study result in clinical practice or outcomes?

Response: Please see response R1.6 above.

Response to critiques from reviewer #2

R2.1a. The intended use of this system is not entirely clear to me. I was wondering if the author could expand on their view of the utility of this system. How long are their transport times? Are these transports between rural facilities to definitive care or transports from the scene to hospital?

Response: Please see response to critique 1.6 (reviewer #1) above. Findings from this study, if successful, will lead to widespread adoption of utility of ultrasound diagnosis and management of trauma patients in the pre-hospital setting. This may in turn have implications for its adoption by the military in the battlefield. Although ultrasound is a well-established technology to perform e-FAST examination in the ED setting, its use in the pre-hospital setting will enable patients to be triaged to a higher acuity level with blunt trauma. Knowing that a patient has free fluid in the abdomen even with normal vital signs (as many patients do) place patients at higher risk of mortality and morbidity from their trauma. Alerting emergency departments to see these ultrasound images will allow centers to prepare and allocate resources in preparation for patient’s arrival. This would be extremely helpful in a rural setting, where decisions about air transport versus ground transport need to be made.

R2.1b. I understand the utility of looking for pneumothoracies in the unstable patient but how does a FAST exam change management en route in an ambulance? Would the ambulance be redirected to a different centre? The unstable patient directed to the
OR? It should only take 5 minutes to perform on arrival in the ED. Really not a substantial time saving... If experts are not available to perform it in the ED why not have telemonitoring to the ED rather than to a moving ambulance?

Response: With regard to the effect of FAST on change in management, according to the study by F. Walcher and colleagues (British Journal of Surgeons, 2006; 93; pp238-242), the use of pre-hospital FAST has led to a change in either prehospital treatment or management in 30% of abdominal trauma patients as well as a change in triage decisions regarding transportation to admitting hospital in 22% of abdominal trauma patients. Thus FAST does change the decision made by ambulances with regards to their redirection to an admitting hospital. With regards to the issue of having telemonitoring to the ED from the ambulance, the utility of this telemonitoring will substantially reduce the ED time especially in rural areas with long distance travel. This advantage of prehospital FAST was confirmed by the study of L Melniker and colleagues (Randomized Controlled Clinical Trial of point-of-care limited ultrasonography for trauma in the ED – The sonography outcomes assessment program trial Ann Emerg Med, 2006; 48: 227-235), which demonstrated that prehospital ultrasonography reduced the time from ED presentation to operative care (57 vs. 166 mins).

R2.2. If the authors could explain/elaborate on the power calculations. Having 20 raters/observers seems excessive to me. The article cited as the rationale for the power calculation (Sibert et al) used 7 raters but suffered from poor inter-rater reliability. It is unclear how introducing more raters will improve this reliability. Generally reliability is inherent in the rating tool used but can be improved with pre-study training of the raters. I have never used a power calculation to justify number of raters.

Response: The reviewer is correct that this is not a statistical power issue, it is a reliability issue. By aggregating the ratings of 20 UTP’s, each pair of whose ratings may only correlate .10 or .20 across targets we can magnify the small level of agreement between pairs of raters into a highly reliable (e.g. coefficient alpha = say .80 or .90) composite (average) rating. Aggregation is powerful because the agreement is generally systematic and the disagreement is more random, thus an average of 20 raters will have averaged out the random disagreement and thus boosted the small amount of agreement into a strong signal. We also agree with the reviewer that if we were studying diagnostic accuracy based on images we would want to train raters to a diagnostic criterion, as we would never use 20 diagnosticians in practice. However, our ratings are of image quality and there was no criterion to which to train raters, image quality is an inherently subjective impression. Thus we opted to use aggregation rather than training to overcome the reliability issue.