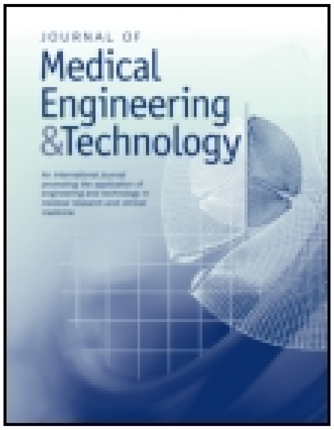

Journal of Medical Engineering & Technology
Publication details, including instructions for authors and subscription information:
http://www.tandfonline.com/loi/ijmt20

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Nehemiah T. Liu[a], John B. Holcomb[b], Charles E. Wade[b], Mark I. Darrah[c] & Jose Salinas[a]
[a] US Army Institute of Surgical Research, 3698 Chambers Pass, JBSA Fort Sam Houston, TX, USA,
[b] Center for Translational Injury Research, Department of Surgery, University of Texas Health Science Center at Houston, Houston, TX, USA, and
[c] Athena GTX, Inc., Des Moines, IA, USA
Published online: 19 Jun 2015.

JOURNAL OF Medical Engineering &Technology

http://informahealthcare.com/jmt
ISSN: 0309-1902 (print), 1464-522X (electronic)

J Med Eng Technol, 2015; 39(6): 316–321

DOI: 10.3109/03091902.2015.1054524

informa healthcare

INNOVATION

Data quality of a wearable vital signs monitor in the pre-hospital and emergency departments for enhancing prediction of needs for life-saving interventions in trauma patients

Nehemiah T. Liu*[1], John B. Holcomb[2], Charles E. Wade[2], Mark I. Darrah[3], and Jose Salinas[1]

[1]US Army Institute of Surgical Research, 3698 Chambers Pass, JBSA Fort Sam Houston, TX, USA, [2]Center for Translational Injury Research, Department of Surgery, University of Texas Health Science Center at Houston, Houston, TX, USA, and [3]Athena GTX, Inc., Des Moines, IA, USA

Abstract

This study was designed to investigate the quality of data in the pre-hospital and emergency departments when using a wearable vital signs monitor and examine the efficacy of a combined model of standard vital signs and respective data quality indices (DQIs) for predicting the need for life-saving interventions (LSIs) in trauma patients. It was hypothesised that prediction of needs for LSIs in trauma patients is associated with data quality. Also, a model utilizing vital signs and DQIs to predict the needs for LSIs would be able to outperform models using vital signs alone. Data from 104 pre-hospital trauma patients transported by helicopter were analysed, including means and standard deviations of continuous vital signs, related DQIs and Glasgow coma scale (GCS) scores for LSI and non-LSI patient groups. DQIs involved percentages of valid measurements and mean deviation ratios. Various multivariate logistic regression models for predicting LSI needs were also obtained and compared through receiver-operating characteristic (ROC) curves. Demographics of patients were not statistically different between LSI and non-LSI patient groups. In addition, ROC curves demonstrated better prediction of LSI needs in patients using heart rate and DQIs (area under the curve [AUC] of 0.86) than using heart rate alone (AUC of 0.73). Likewise, ROC curves demonstrated better prediction using heart rate, total GCS score and DQIs (AUC of 0.99) than using heart rate and total GCS score (AUC of 0.92). AUCs were statistically different ($p < 0.05$). This study showed that data quality could be used in addition to continuous vital signs for predicting the need for LSIs in trauma patients. Importantly, trauma systems should incorporate processes to regulate data quality of physiologic data in the pre-hospital and emergency departments. By doing so, data quality could be improved and lead to better prediction of needs for LSIs in trauma patients.

Keywords

Automatic data processing, data quality, life-saving interventions, pre-hospital physiologic data, vital signs

History

Received 6 April 2015
Revised 15 May 2015
Accepted 17 May 2015

1. Introduction

Pre-hospital treatment of trauma patients is a critical aspect of emergency medical practice, but, in the past, has relied on the training and experience of medical personnel using discrete physiologic data points and not on continuous data [1,2]. In addition, the ability to prioritise treatment beyond the point of injury is often faced with many difficult challenges, including erroneous measurements, loss of critical information and/or information overload [3–5]. Because appropriate and timely treatment means that life-saving interventions (LSIs) are performed when needed during all echelons of care, better data may lead to better LSI performance. Furthermore, since measurement and interpretation of electronic vital signs have become routine during pre-hospital and hospital care, improved LSI performance will require maximum utility of this data as well as improvements in data quality for rapid and accurate decision-making [6–9].

Use of data quality indices is one possible solution for assessing the quality of data during physiologic monitoring and retrospective analysis of data [9,10]. Leveraging signal quality indices to obtain signal-derived parameters has been previously described [9,10], but has not been applied to the prediction of LSIs or identification of patients requiring LSIs. Furthermore, these indices focused on waveform (electrocardiogram) signal quality rather than numeric streams (standard vital signs) such as blood pressure and heart rate. Because trends, means and standard deviations of numeric streams are potential tools for enhancing prediction of needs for LSIs, they may be suitable for assessment of numeric data quality as well [7,11,12]. We previously showed that a wearable/portable vital signs monitor can lead to improved LSI performance [11], since this technology allows for constant acquisition of multiple non-invasive physiologic vital signs across the entire critical care spectrum. However, the use of

*Corresponding author. Email: nehemiah.liu@us.army.mil

these devices is only advantageous when the quality of captured data can be maintained with minimal noise and minimal missing data. In addition, useful interfaces would identify those patients who actually required an LSI, either through some hypothesis-driven or evidenced-based model or computer algorithm that could process the captured data in real time [12].

This study was an initial effort between the US Army Institute of Surgical Research and the University of Texas Health Science Center in Houston, TX to quantitatively investigate the quality of data in the pre-hospital and emergency departments when using a wearable vital signs monitor, particularly a Wireless Vital Signs Monitor (WVSM, Athena GTX, Inc., Des Moines, IA), to provide care for the trauma patient. The goal of this study was to examine the efficacy of a combined model of standard vital signs and respective data quality indices (derived from trends, means and standard deviations) for predicting the need for LSIs in trauma patients using multivariate logistic regression models. We hypothesised that prediction of needs for LSIs in trauma patients is associated with data quality in the pre-hospital and emergency departments. Also, a model utilizing vital signs and data quality to predict the needs for LSIs would be able to outperform models using vital signs alone.

2. Patients and methods

2.1. Subjects and protocol

Approval to conduct this study was obtained from the Institutional Review Board at our Institute and from the Committee for the Protection of Human Subjects of the University of Texas Health Science Center in Houston, Texas. Because all data were analysed post-hoc, the study was considered minimal risk and informed patient consent was waived. The dataset consisted of 104 patients transported via the Life Flight helicopter service to the Memorial Hermann Hospital, a Level I trauma centre in Houston, TX, between 27 June 2011 and 6 January 2012. As previously described in the protocol [11], these patients were all available pre-hospital trauma patients who wore a WVSM system during transport to the hospital. The Life Flight Helicopter service consisted of three Eurocopter BK 117Bs and each helicopter flight crew consisted of one experienced pilot, flight medic, and nurse. Trauma patients discharged home from the emergency department (ED) were not included in this dataset. In addition, pregnant women, patients under 18 years of age and patients transported from a nursing home were excluded from the study. Patient inclusion criteria were as follows: (1) patient was over 18 years of age, (2) Code 2/3 trauma patient with blunt or penetrating trauma and (3) direct transport of the patient from the injury scene to the hospital via helicopter service [11].

2.2. Data and quality indices

For all subjects in this study, the WVSM was used to capture numeric data (vital sign streams) at a rate of 1 Hz, electrocardiogram waveform data from a single lead at 230 Hz, oxygenation waveform data from a thumb-mounted pulse oximeter connected to the WVSM at 75 Hz and respiration waveform data at 10 Hz when available. Upon patient arrival to the ED, data were transmitted from the WVSM device through a wireless connection and stored using a computerised server system. Similarly, after the patient was moved from the ED trauma bay, data collection was stopped.

Numeric data (standard vital signs) captured by the WVSM included heart rate (HR), systolic blood pressure (SBP), diastolic blood pressure (DBP), mean arterial pressure (MAP), respiratory rate (RR), blood oxygenation (SpO_2), shock index (SI = HR/SBP) and pulse pressure (PP = SBP – DBP). All demographic information, physical exam results, Glasgow coma scale (GCS) scores (Motor, Verbal, Eye) and field and ED LSIs were manually recorded on an electronic run sheet (Tablet PCR, Zoll Medical, Chelmsford, MA) by Emergency Medical Services medics. Later, the data was entered into a study research database (https://openclinica.com, OpenClinica, LLC, Waltham, MA) for future analysis. LSIs consisted of endotracheal intubations, blood product transfusions, tube thoracostomies, cardiopulmonary resuscitations, needle decompressions, cricothyrotomies, thoracotomies and tourniquets.

Importantly, assessment of data quality of the WVSM was made by determining the percentages of valid measurements and non-zero waveform samples in each patient record and visually inspecting the entire sequences of all waveforms. Because trends, means and standard deviations are potential tools for assessing quality of vital signs [7,11,12], two separate data quality indices (DQIs) were derived from corresponding vital sign measurements: (1) percentage of valid measurements (those with numeric values, as opposed to ''not-a-number'' or ''NaN'') and (2) deviation ratio $(\mu - \sigma)/\mu$ *100, where μ denotes the mean value and σ denotes the standard deviation of values in a vital sign numeric sequence. The latter DQI was interpreted as a percentage of deviation between valid measurements in a sequence. These indices were also chosen for their practicality and ease of computation and were incorporated into the statistical analyses.

2.3. Statistical analysis

Data are expressed as means ± standard deviation. Due to the small sample size, all data were analysed using non-parametric Wilcoxon tests. Initial multivariate logistic regression analyses were also done for all subjects with independent demographic variables (age, height, race and weight) and with dependent vital sign variables (HR, SBP, DBP, MAP, RR and SI). These analyses excluded DQIs. Factors that were not significant ($p > 0.05$) were removed from the model via backward elimination. A second set of analyses were done for dependent vital sign variables (HR, SBP, DBP, MAP, RR and SI) as well as DQIs in order to compare sensitivity and specificity performance with the initial set. In addition, a third and fourth set of analyses were performed for all subjects in order to include GCS scores, with and without DQIs as dependent variables, respectively.

The accuracy of the statistical models was assessed using sensitivity and specificity scores. The power of demographics, vital sign measurements, DQIs and GCS scores to identify whether LSIs were performed was estimated using

Table 1. Demographics of patients.

Characteristics	All	LSI patients	Non-LSI patients
Age, Mean ± SD	40 ± 16	43 ± 16	38 ± 15
Gender, *n* (%)			
Male	82 (79)	26 (81)	56 (78)
Female	22 (21)	6 (19)	16 (22)
Race, *n* (%)			
White/Caucasian	62 (60)	18 (56)	44 (61)
Black	11 (10)	3 (10)	8 (11)
Hispanic	23 (22)	11 (34)	12 (17)
Asian/Pacific	1 (1)	0 (0)	1 (1)
Not Recorded	7 (7)	0 (0)	7 (10)
Mechanism of injury, *n* (%)			
Blunt	94 (90)	29 (91)	65 (90)
Penetrating	10 (10)	3 (9)	7 (10)
Eye/Motor GCS < 3	22 (21)	21 (66)	1 (1)
Eye/Motor GCS ≥ 3	82 (79)	11 (34)	71 (99)
Total GCS	12 ± 5	6 ± 5	14 ± 1
Heart Rate*	93 ± 19	100 ± 21	90 ± 16
Systolic BP*	135 ± 22	129 ± 32	138 ± 15
Respiratory Rate*	17 ± 3	16 ± 5	18 ± 3

SD, standard deviation; WVSM, wireless vital signs monitor; LSI, life-saving intervention; BP, blood pressure (mm Hg); age (years); heart rate (beats per minute); respiratory rate (breaths per minute).
*Entry values taken from the run sheet.

multivariate logistic regression. JMP version 9.0.0 (SAS Institute, Cary, NC) and the R Language (http://www.r-project.org/), a well-known open-source statistical software package, were used for statistical analyses.

3. Results

The demographics of all subjects in this study are shown in Table 1 and were not statistically different between patient groups [13]. Specific injuries and interventions for LSI patients are shown in Supplemental Digital Content 1. The average flight time was 29.9 ± 44.1 min, the median flight time was 19 min, the maximum flight time was 371 min and the minimum flight time was 10 min. As such, lengths of patient records varied, with an average length of 266.7 ± 131.4 min, and generally coincided with each flight time as well as additional time spent in the pre-hospital environment and trauma bay. Of these 104 patients, 72 (69%) did not receive an LSI. The other 32 patients (31%) received a total of 75 LSIs, as detailed in Supplemental Digital Content 1. Importantly, the demographics of the chosen population [13] included HRs ranging from 53–140 beats per minute, SBPs ranging from 70–180 mm Hg and various types of injuries and LSIs (Supplemental Digital Content 1).

Moreover, 88.0% of HR, 79.8% of SpO_2, 75.8% of blood pressure (SBP, DBP, MAP) and 75.0% of RR measurements were valid, i.e. non-NaN. Mean percentages of all measurements (Figure 1) helped indicate variables for LSI model development. Final variables (after backwards elimination) are shown in Tables 2 and 3. Only these variables were used for odds ratio calculations. For the first two sets of multivariate logistic regression analyses, results showed that increasing mean HR as well as decreasing total GCS score was associated with an increased risk for LSIs. Age, height, race and weight were removed from the final models via backward elimination because they were not significantly associated with LSIs. In the model for vital signs alone (see Table 2), odds ratios were 1.05 (95% confidence interval [CI] = 1.03–1.09; $p < 0.0001$) for mean HR (per beats per minute increase). In the model for vital signs and GCS scores (see Table 3), odds ratios were 1.05 (95% CI = 1.01–1.11; $p = 0.02$) for mean HR (per beats per minute increase) and 0.68 (95% CI = 0.58–0.78; $p < 0.0001$) for total GCS score (per unit increase).

Inclusion of DQIs in the multivariate logistic regression analyses showed that decreasing the percentage of valid

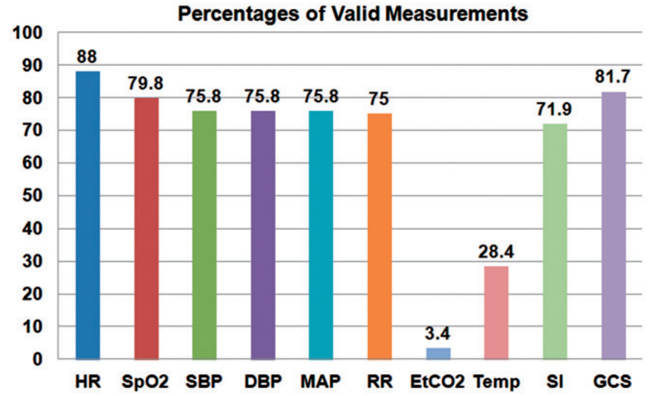

Figure 1. Mean percentages of valid measurements for WVSM subjects. Standard vital signs used for WVSM patient monitoring included heart rate (HR), blood oxygenation (SpO_2), systolic blood pressure (SBP), diastolic blood pressure (DBP), mean arterial pressure (MAP), respiratory rate (RR), end-tidal carbon dioxide ($EtCO_2$), temperature (Temp) and Glasgow Coma Scale (GCS) score. Combinations of these vital signs were also used to derive other measurements including shock index (SI = HR/SBP).

Table 2. Logistic regression models with various risk factors (excluding GCS) for LSIs.

Variable	Odds ratio for LSIs (95% CI)*	*p* Value
Mean heart rate	1.05 (1.03–1.09)	<0.0001
With quality indices		
Mean heart rate	1.05 (1.02–1.08)	<0.0001
% valid HR values	0.97 (0.95–0.99)	0.0037
(μHR – σHR)/μHR	0.92 (0.86–0.97)	0.0039

LSIs, life-saving interventions; GCS, Glasgow coma scale; HR, heart rate; CI, confidence interval; μHR, mean value of HR sequence; σHR, standard deviation of HR values in sequence.
*Odds ratios for measurements reflect per-unit increase.

Table 3. Logistic regression models with various risk factors (including GCS) for LSIs.

Variable	Odds ratio for LSIs (95% CI)*	*p* Value
Mean heart rate	1.05 (1.01–1.11)	0.02
Total GCS score	0.68 (0.58–0.78)	<0.0001
With quality indices		
Mean heart rate	1.07 (1.02–1.15)	0.0074
% valid HR values	0.99 (0.95–1.03)	0.6601
(μHR – σHR)/μHR	0.91 (0.81–1.00)	0.0507
Total GCS score	0.66 (0.52–0.79)	<0.0001
% valid GCS scores	1.00 (0.96–1.04)	0.8988
(μGCS – σGCS)/μGCS	0.79 (0.48–0.92)	0.0003

LSIs, life-saving interventions; GCS, Glasgow coma scale; HR, heart rate; CI, confidence interval; μHR, mean value of HR sequence; σHR, standard deviation of HR values in sequence; μGCS, mean value of GCS sequence; σGCS, standard deviation of GCS scores in sequence.
*Odds ratios for measurements reflect per-unit increase.

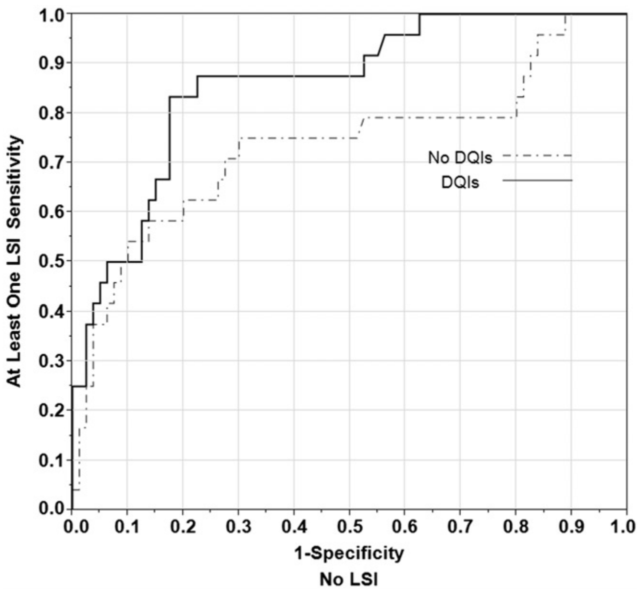

Figure 2. Receiver-operating characteristic curves for models (excluding Glasgow Coma Scale scores). Receiver-operating characteristic curves were obtained to examine the discriminating power of multivariate logistic regression models (excluding Glasgow Coma Scale scores) for the outcome of at least one life-saving intervention (LSI) in 104 subjects. The curves demonstrated better prediction for models using both vital signs and data quality indices (area under the curve [AUC] of 0.86) than for models using only vital signs (AUC of 0.73).

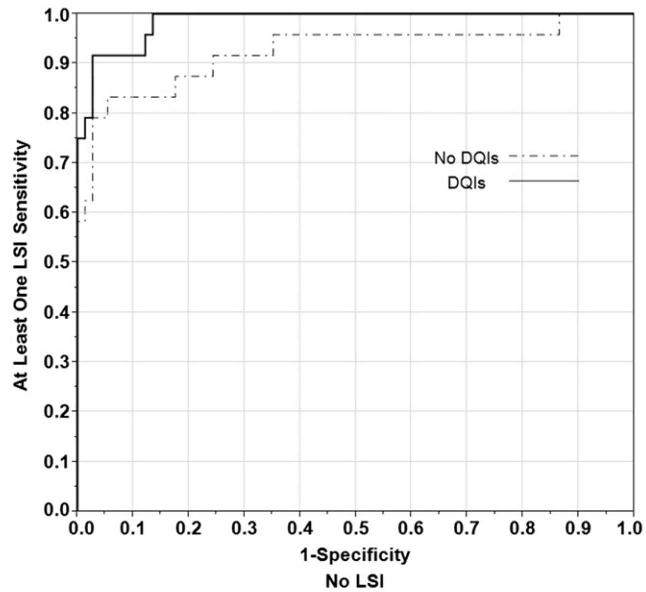

Figure 3. Receiver-operating characteristic curves for models (including Glasgow Coma Scale scores). Receiver-operating characteristic curves were obtained to examine the discriminating power of multivariate logistic regression models (including Glasgow Coma Scale [GCS] scores) for the outcome of at least one life-saving intervention (LSI) in 104 subjects. The curves demonstrated better prediction for models using vital signs, GCS scores and data quality indices (area under the curve [AUC] of 0.99) than for models using only vital signs and GCS scores (AUC of 0.92).

measurements and deviation ratio ($(\mu - \sigma)/\mu *100$) were also associated with an increased risk for LSIs. Although patient records varied in length, as noted above, this did not affect DQI calculations because DQIs were calculated based upon means, percentages and standard deviations (see Data and quality indices) and the WVSM itself was consistent over time. In other words, the WVSM usually yielded either good data or bad data for durations rather than for sporadic time points (seconds). Thus, datasets could exhibit high or low data quality indices, regardless of their size. In the model for vital signs and data quality indices (see Table 2), odds ratios were 1.05 (95% CI = 1.02–1.08; $p < 0.0001$) for mean HR (per beats per minute increase), 0.97 (95% CI = 0.95–0.99; $p = 0.0037$) for percentage of valid HR values (per unit increase) and 0.92 (95% CI = 0.86–0.97; $p = 0.0039$) for HR deviation ratio (per unit increase). In the model for vital signs, GCS scores and DQIs (see Table 3), odds ratios were 1.07 (95% CI = 1.02–1.15; $p = 0.0074$) for mean HR (per beats per minute increase), 0.66 (95% CI = 0.52–0.79; $p < 0.0001$) for total GCS score (per unit increase), 0.91 (95% CI = 0.81–1.00; $p = 0.0507$) for HR deviation ratio (per unit increase) and 0.79 (95% CI = 0.48–0.92; $p = 0.0003$) for GCS deviation ratio (per unit increase).

Importantly, ROC curves (see Figure 2) demonstrated better prediction of LSI needs in patients using HR and DQIs (area under the curve [AUC] of 0.86) than using HR alone (AUC of 0.73). Likewise, ROC curves (see Figure 3) demonstrated better prediction using HR, total GCS score and DQIs (AUC of 0.99) than using total GCS score and HR (AUC of 0.92). All AUCs were statistically significant ($p < 0.05$).

4. Discussion

This study was designed to investigate the importance of data quality, especially when using a wearable vital signs monitor, and how data quality may influence decision-making and trauma systems. Unlike previous work [13], it was the first to show that data quality could be used in addition to vital signs for identifying trauma patients that required LSIs. Furthermore, the utility of standard vital signs and DQIs for predicting the need for LSIs in trauma patients was examined by comparing the performances of different multivariate logistic regression models. Previous studies analysed only traditional vital signs [7] or a combination of heart-rate variability metrics and machine learning [13,14] for discriminating between LSI and non-LSI patients. In both cases, neither used DQIs for identifying LSI patients and, therefore, could not address how quality affected results. Recent work reported the development and validation of a real-time LSI prediction system, but also excluded DQIs in its analyses [12].

Importantly, this study demonstrated that multivariate logistic regression models incorporating DQIs could increase the prediction accuracy for this cohort. The hypothesis that a model utilising a combination of vital signs and DQIs to predict LSI needs could outperform models utilising only vital signs was shown through comparisons of ROC curves and AUC results. A strength of this work was that DQIs were calculated based on means, percentages and standard deviations and were, thus, applicable to every patient with data, regardless of the patient's record length.

A side gain of this work was the implicit validation of how well the WVSM system performs in the real world using a quantitative approach. From previous work and experiences as detailed in Liu et al. [11], the WVSM was shown to yield data of comparable quality to state-of-the-art monitoring systems (standard vital signs monitors) and lead to the identification of the need for LSIs in the ED [11]. Thus, the actual quality of the system was relatively good, without periodic losses of signal, distortions or other errors. This quality applied not only to numerical data, but also to waveform data. Although the system performed relatively well in the past, no quantitative analyses had been performed prior to this study. This work showed that, given 104 patients totalling more than 450 hours' worth of vital signs data, the WVSM system could yield at least 75% good data for blood pressures, HR and RR (see Figure 1). Moreover, visual inspection revealed that 79.8% (83/104) of electrocardiogram and 85.6% (89/104) of pleth waveforms provided identifiable morphology in at least half of their sequences, whereas numerical analysis showed that, on average, 99.9% and 99.1% of these waveforms, respectively, contained non-zero samples.

It is important to note here that data quality was measured as seen from a wearable vital signs monitor. Hence, Figure 1 does not indicate that end-tidal carbon dioxide was almost never present during the protocol and that GCS scores were obtained only 82% of the time. Figure 1 only reveals that data was not always captured due to unavailability of equipment, errors in measurement or device failures. In fact, physical exams (GCS scores) were always performed by the Life Flight personnel and providers in the ED. A major implication of this study was that trauma systems should incorporate processes to regulate data quality of captured physiologic data in the prehospital and emergency departments. By doing so, data quality could be improved and lead to better prediction of needs for LSIs in trauma patients.

Although it is reasonable to assume that higher data quality could aid trauma patient care, the results of this study suggested that LSIs are often performed due to incomplete information or significant changes in vital signs (deviation from mean values). This agrees with previous work by Chen et al. [6] exploring use of trends for pre-hospital care as well as Liu et al. [12] investigating the use of artificial intelligence to relate measurement deviations with needs for LSIs. This also supports evidence that continuous physiologic monitoring could help improve LSI accuracy [5,12,15,16].

Advances in vital signs monitors [11] have made the incorporation of electronic physiologic data recording suitable for continuous data analysis [13], but will require both successful data management and data integrity. The graphical interface of a wearable vital signs monitor plays a significant role in the course of patient care. This interface provides two capabilities: (1) the capture of monitored data and other information manually entered by medical personnel and (2) the graphical display of this data [11]. The potential benefit of these interfaces is related to the concentration of physiologic measurements from disperse, often disparate, sources (e.g. devices, sensors, electrocardiogram leads, pulse oximeter, handcuff)—along with waveforms, trends, injury scores and other markers of patient status—onto one screen, thereby making data more easily accessible for comprehension and analysis. In other words, the wearable wireless vital signs monitor may help develop a cognitively shared framework for understanding a patient's severity of illness and treatment plan.

The development of wearable vital signs monitors and interfaces for the pre-hospital and emergency departments may, perhaps, suggest that real-time data processing, information management and aesthetics play a constructive, if not crucial, role in the diagnosis and treatment of trauma patients [13]. Therefore, it is imperative that, when electronic vital sign measurements lose validity, interfaces must alert medical personnel and even hide those measurements in order to mitigate errors in communication and patient assessment. In addition, clinically useful displays must show trends of available data and identify those trauma patients who may be at high risk, thereby providing decision support capability. Lastly, they should assist medical personnel working outside the sheltered environment of the hospital by ensuring validity of the data through appropriate indicators.

A key question is whether more data used during trauma care actually results in better outcomes for the patient. In principle it would seem that more data are better, but, as recent work has shown with bedside alarms [17], that may not necessarily be the case. The medical team can become overwhelmed with information, making it difficult for them to focus on salient parameters and make optimal decisions. This study extends upon previous work [11] which analysed the efficacy of using the WVSM device to predict the need for LSIs in the ED. There multivariate logistic regression analyses were used to show that the WVSM was a better predictor of LSIs in the ED than standard vital signs monitors currently used for patient care [11]. An LSI, rather than mortality, was chosen as an end-point because of its usefulness for pre-hospital triage [18] and the fact that LSIs could help identify more patients requiring attention from providers, treatment and resources of a trauma centre than mortality. Because this study involved a dataset in which only one patient out of 104 patients died, it did not focus or report on mortality. Like previous work [11], this study employed LSIs as patient outcomes and showed that additional descriptions inherent to data (that is, data quality and integrity), not necessarily more data, may improve outcomes. In other words, metadata easily derived from existing data could help facilitate care. By utilising this metadata in the background and not adding it to displays, monitors could be automated to alert providers about data quality and integrity in order to ensure maximal usage of physiologic information such as numeric and waveform data. It is possible that more data can produce ''false-positive'' outcomes and, therefore, must be examined carefully to warrant use of new technologies and approaches in trauma care.

Like previous work [13], this study had several limitations, including the small size of the dataset, lack of injury severity scores and criteria for selecting the data. Thus, the results were preliminary. Furthermore, this study did not consider separate analyses for examining the discriminating power of the models for the outcome of at least one pre-hospital LSI or one ED LSI. A strategy similar to this study could be applied to perform these analyses in the future [13].

Future studies may need to be conducted to further test whether a lack of information is associated with a tendency to perform LSIs more frequently. If so, trauma systems should again incorporate processes to regulate data quality in the pre-hospital and emergency departments for process improvement.

Acknowledgements

The authors acknowledge the expertise, dedication and professionalism of the Emergency Medical Services paramedics, nurses and staff in Houston who performed the patient care and Denise Hinds, Timothy Welch and Jeannette Podbielski (the University of Texas Health Science Center at Houston, TX).

Declaration of interest

MID is CEO/President of Athena GTX, Inc. and Athena Telemedicine Partners, LLC.

This work was supported by the National Trauma Institute, the Combat Casualty Care Research Program and the State of Texas Emerging Technology Fund.

This study was conducted under a protocol reviewed and approved by the University of Texas Health Science Center at Houston and in accordance with the approved protocol. The opinions or assertions contained herein are the private views of the authors and are not to be construed as official or as reflecting the views of the Department of the Army or the Department of Defense.

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Supplementary materials are provided in online