AHRQ Grant Final Progress Report

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Title of Project: Targeted Delivery of Multiparametric Telemetry Clinical Messages to Mitigate Alarm Fatigue (Push Electronic Relay for Smart Alerts for End User Situational Awareness [PERSEUS] program)

Principal Investigator and Team Members

PI: Leo Kobayashi, MD
Professor, Department of Emergency Medicine, Alpert Medical School of Brown University, Providence, RI, USA

Team: Derek L. Merck, PhD
Assistant Professor, Department of Diagnostic Imaging, Alpert Medical School of Brown University, Providence, RI, USA

Xiao Hu, PhD
Associate Professor, Department of Physiological Nursing, University of California San Francisco, San Francisco, CA, USA

Kenneth A. Loparo, PhD
Chair, Professor, Department of Electrical Engineering and Computer Science, Case Western Reserve University, Cleveland, OH, USA

Collaborative Research Investigators (Code Development)
Laboratory for Cognitive Neurophysiology & Neuromodulation, Rhode Island Hospital, Providence, RI, USA
Adewole Oyalowo, MSc
Uday Agrawal, MSc
Wael Asaad, MD, PhD (Associate Professor; Laboratory director)

Emergency Department Clinical Research Assistants
Division of Research, Department of Emergency Medicine, Rhode Island Hospital, Providence, RI, USA
Sophia Bonenfant, Mark Brinkman, Darin Chheng, Madeline Cosgriff, Samuel Craft, Rachel Fried, Abbey Haynes, Mark (Daniel) Higgins, Hye In (Sarah) Lee, Evan Meiman, Meredith Mozzone, Christine Ortiz, Alana Oster, Erinn Reilly, Quinneil Simmons, Daniel Strauss, Evaniz Suarez, Jessica Tremblay

Organization (primary site): Emergency Department, Rhode Island Hospital; Department of Emergency Medicine, Alpert Medical School of Brown University

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Federal Program Officer: Kerm Henriksen PhD
kerm.henriksen@ahrq.hhs.gov
(301) 427-1331

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PERSEUS Program Summary Diagram (Proposal and Results)
The figure below indicates the original grant work proposed. Semi-transparent overlays indicate the status of each component: dark grey indicates completion; light grey indicates active work in progress; clear indicates pending work.

PI: LKobayashi

*BDR: Brown Digital Repository

STRUCTURED ABSTRACT

Purpose: The PERSEUS research program sought to develop, implement, and share open innovations to enable the constructive study of alarm fatigue and the scientific advancement of bedside clinical informatics.

Scope: Methods development and applied experimental research in acute care bedside clinical informatics

Methods: Program investigators planned a multiphasic R+D approach with specific tasks for three primary aims: 1) to better understand the alarm fatigue resulting from existing bedside patient monitoring telemetry systems and create a nonproprietary mechanism to augment the analysis and delivery of critical information to clinical providers; 2) to comparatively evaluate the performance and utility of existing and experimental patient monitoring telemetry systems with human factors engineering, simulation, and patient tracer methods; and 3) to prepare and disseminate a nonproprietary medical technology interface toolbox for continued medical device and informatics research at the study institution and beyond.

Results: The research team accomplished the following: 1a) compilation of an expanded study site alarm fatigue knowledgebase and 1b) development of a nonproprietary bedside patient monitor interface [MeTeOR]. These were used with off-the-shelf software solutions to implement a bedside clinical informatics (BCI) research pipeline infrastructure that enabled 2a) acquisition and experimental processing (bedside and offline) of physiologic datastreams from thousands of patients in a live Emergency Department clinical environment, 2b) blinded controlled tracer study of an experimental multiparametric alert [MPA] patient monitoring approach, and 2c) proof-of-concept exploratory applications of innovative analytic approaches for future informatics-/simulation-based live environment studies. The following deliverables were generated for dissemination through traditional and Web-based portals: 3a) peer-reviewed publication of alarm fatigue simulation method with pilot data and lessons learned, 3b) program-developed MeTeOR open code with use instructions and peer-reviewed methods manuscript containing hardware and software specifications along with use-case examples for collaborative research, 3c) de-identified, human-/machine-readable, linearized, and adjudicated/annotated patient physiologic datasets [ATOMICS] for continued investigation, and 3d) active and potential collaborative research initiatives with several clinical institutions, research groups, and industry.

Key Words: alert fatigue health personnel, automatic data processing; clinical alarms; data collection; data curation; data display; data mining; dataset; emergency medicine; environment design; human engineering; information storage and retrieval; information systems; medical informatics; machine learning; medical informatics computing; patient generated health data; supervised machine learning; unsupervised machine learning

PURPOSE (Objectives of Study)

The PERSEUS research program was proposed as a multiphasic, experimental research program with three specific innovations to develop, implement, and share:

Innovation 1: Nonproprietary mechanism for hardware-level access to medical devices (bedside patient monitors) to acquire signals for experimental processing and analyses

Innovation 2: Open, modular framework for exploratory near-/real-time bedside signals processing/analysis

Innovation 3: Targeted, minimally disruptive, need-to-know delivery ("pushing") of high-specificity, designed information through mobile communications platforms to designated clinical providers

SCOPE

Background: Patient monitoring systems are overly sensitive, frequently confused, and easily deceived in live patient care settings while also failing on occasion to effectively advise care providers of true life-threatening events. Building on their clinical experience and previous research, investigators initiated a collaborative biomedical, human factors, and information engineering program to study and mitigate alarm fatigue by developing and implementing nonproprietary monitor interfaces and a bedside experimental research pipeline infrastructure.

Context: A formal, rigorous approach was required to address two critical issues underlying alarm fatigue: 1) improving the accuracy and utility of information generated by bedside patient cardiorespiratory monitors and 2) establishing an effective, efficient mechanism to analyze, process, and convey critical information to providers.

Settings: The primary study site was Rhode Island Hospital, a 719-bed nonprofit tertiary care referral facility and Level-I trauma center. The 91-bed Emergency Department (ED) at RIH manages 100,000 adult patients annually and features 12 critical care spaces, three urgent care areas, behavioral health and fast track sections, an observation unit, two ED-dedicated CT scanners, an ED MRI scanner, and a cardiac catheterization suite.

Baseline System Performance Characteristics: Graham and Cvach[1] have reported a mean of 942 crisis, warning, or system patient monitor warnings per day in a 15-bed ICU at baseline and 536 warnings per day after an alarm fatigue-mitigating intervention (*i.e.,* a 43% reduction) without adverse events. A 2012 study site review of 2 weeks' worth of real-world telemetry alarm logs for 31 monitored RIH ED urgent care spaces revealed positive predictive values (PPV) of 0.53 and 0.02 for severe bradycardia and ventricular tachycardia, respectively --two of the highest-severity red alarms. Without a dedicated infrastructure to study patient monitor datastreams and alarms at program outset, investigators were unable to ascertain *a priori* the study site's prevalence, incidence, nature, severity, and impact of false alarms (as surrogate markers for alarm fatigue).

The Push Electronic Relay for Smart Alerts for End User Situational Awareness (PERSEUS) work was conducted as a multiphasic research program with three primary aims addressed in three phases. Accordingly, the methods and results are presented separately for each aim/phase.

Key: ED = Emergency Dept., RIH = Rhode Island Hospital, CWRU = Case Western Reserve Univ., UCSF = Univ. of California San Francisco

Aim/Phase 1: *To better understand the alarm fatigue resulting from existing bedside patient monitoring telemetry systems and create a nonproprietary mechanism to augment the analysis and delivery of critical information to clinical providers*

Status: Completed

METHODS

Study Design: Investigators started the PERSEUS program by building on their previous work that had demonstrated that focused utility and usability interventions improved an existing ED patient monitor telemetry system's functionality and helped alleviate alarm fatigue. Specific Phase 1 tasks were:

- *Task 0.1 Human factors engineering-based characterization and analysis of study site alarm fatigue*
- *Task 1.1 Development of nonproprietary bedside patient monitor interface as the hardware foundation for experimental intervention*
- *Task 1.2 Development of nonproprietary software for experimental intervention*
- *Task 1.3 Offsite function testing of experimental intervention with simulation*
- *Task 1.4 Pilot installation and function testing of experimental intervention in live ED setting*
- *Task 1.5 Full installation, deployment, and function testing of experimental intervention in live ED setting with simulation and live patient data*
- *Task 1.6 Ongoing monitoring and troubleshooting of experimental intervention installation*

Data Sources/Collection: Phase 1 data sources were:

- *Task 0.1*: Study site alarm fatigue knowledgebase (previously compiled during the initial simulation-enhanced ARGUS study and site assessment,[2] combined with HFE expert (JGosbee) input incorporating expanded literature review[§], U-FMEA, and HFES 2015 conference participation/proceedings; onsite research team meeting participation/proceedings (Providence, RI; 10/2015)
- *Tasks 1.1-1.2*: Bedside patient monitor hardware (Philips Intellivue MPx0 series) interface configuration and access instructions; Medical Interface Bus communications protocols and cable specifications; serial-to-USB adapter specifications; PC requirements and configuration descriptions; CWRU RS232DataExport.exe and pars-27.exe software (C); RIH Laboratory for Cognitive Neurophysiology & Neuromodulation PyMind/NeuroLOGIC code (Python 2.7); and “Data Export Interface Programming Guide; IntelliVue Patient Monitor X2, MP Series, MX Series” (Philips, 2011; available online); onsite research team meeting participation/proceedings (Providence, RI; 10/2015)–these elements were used to develop the necessary PERSEUS research program software and systems
- *Task 1.3*: Clinical performance metrics, survey responses, and interview materials from active duty RIH ED registered nurses (RNs) participating in alarm fatigue research simulation sessions offsite to compare an existing patient monitoring system and an experimental multiparametric alert system
- *Tasks 1.4-1.6*: ED clinical systems and network infrastructure specifications, configurations; live ED patient physiologic datastreams and clinical correlates, and experimental system performance metrics

[§] The literature review and background update covered AAMI-HE-75 [human factors design specification guidance]; FDA MAUDE publications and workshops conducted in conjunction with ECRI and other policy groups; IEC-62366 updates [human factors design process guidance]; and The Joint Commission publications and hospital requirements.

Interventions:

Task 0.1: Compilation of an expanded study site alarm fatigue knowledgebase to enable the development of experimental mitigation approaches and a clinical microsystem simulation-based alarm fatigue research method for objective, comparative assessment of existing patient monitoring systems and experimental monitoring approaches

Tasks 1.1-1.2: Iterative development, testing, and deployment of the nonproprietary Medical Technology Interface–Open/Research [MeTeOR] toolkit–to access and process institutional bedside patient monitors and ED patient datastreams

Task 1.3: Application of developed simulation method to compare a standard patient telemetry monitoring system against an experimental, multiparametric, and provider-specific alerting approach

Tasks 1.4-1.6: Installation, deployment, testing, and monitoring of the nonproprietary monitor interface with off-the-shelf software in a live ED setting for bedside clinical informatics (BCI) research applications

Measures:

Task 0.1: In order to gauge the face validity and construct validity of the program-developed simulation method for alarm fatigue research, investigators employed the following metrics: 1) RN subject engagement with assigned bundled "distractor" tasks across multiple simulated patients, response to telemetry monitor system true alarms and false alarms; 2) System Usability Scale (SUS[3,4]) scores; 3) Likert scale queries on subjects' perceptions of simulation realism; and 4) semi-structured interviews for usability engineering (thematic analysis)

Tasks 1.1-1.2: Timeliness, accuracy, and reliability of MeTeOR toolkit acquisition of time-stamped/device-labeled ED patient monitor signals of interest in laboratory and pilot settings, including EKG/heart rate (HR), respiratory rate (RR), pulse oximetry (SpO2), noninvasive blood pressure (NIBP), alarms

Task 1.3: Comparison of in-simulation performance metrics obtained with existing and experimental monitoring systems

Tasks 1.4-1.6: Timeliness, accuracy, and reliability of simultaneous, continuous MeTeOR acquisition of live ED unit-wide multiple-monitor datastreams; failure rates (hardware [device failure]; network [transmission/communication failure]; software [data loss, data corruption; algorithm failure])

Limitations: The alarm fatigue knowledgebase and derived simulation assessment method were based on the system/performance characteristics of a single, academic, high-census Emergency Department. Due to delays in software development, the experimental alerting system was HFE tested as a "black box" simulator during Phase 1. Developed materials (simulation method and developed code) were tested primarily within the study institution–open dissemination and extramural collaborations are ongoing.

RESULTS

Principal Findings: An expert-guided literature review and an HFE analysis were completed; factors determined to contribute to alarm fatigue at the study site were identified, characterized, and incorporated into a novel simulation-based alarm fatigue research method. The method was applied to assess provider performance (alarm response and timeliness) in simulated settings for existing and experimental patient monitor systems (see FIGURE 1). A nonproprietary set of tools to access and process patient physiologic datastreams from live clinical environments was developed and deployed successfully with off-the-shelf software and grant-funded monitor additions in a 15-bed ED clinical care space of an academic regional referral center (see FIGURE 2).

Outcomes:

Task 0.1: The program team compiled the necessary knowledgebase and applied core findings to generate a microsystem simulation-based method for alarm fatigue HFE assessment and experimentation. A heuristic evaluation and usability test plan were set up for the proposed experimental multiparametric alert system and its user interfaces.

Tasks 1.1-1.2: Using the research team's experience with CWRU software to access patient monitor datastreams and nonproprietary software developed in collaboration with the RIH Laboratory for Cognitive Neurophysiology & Neuromodulation, the program's MeTeOR modular code accurately and reliably acquired, processed, output, stored, and helped visualize all monitor signals of interest without data loss or corruption in laboratory and pilot settings. Additional code forks to acquire multilead EKG, thoracic impedance respiration, and invasive monitor (CVP, A-line) waveforms and to run on low-

powered devices (*e.g.,* Raspberry Pi 3) and secured platforms (*e.g.,* write-protected thin clients) were developed and successfully tested in live clinical settings.

Task 1.3: Two pilot and four study simulation sessions were conducted with a total of six ED RNs. True alarms and false alarms were generated and elicited appropriate and suboptimal subject responses (*i.e.,* nonresponse to true alarms, response to false alarms, distraction away from/noncompletion of tasks).

Tasks 1.4-1.6: In live ED settings, the networked MeTeOR system demonstrated a 0.14% data packet loss rate (losses from MIB serial-USB throughput/network congestion/packet collision issues at times of high ED census and datastreams). Operating system and device-level crashes resulted in 77 lost data files out of 5,415 possible over a 365-day period for an ~98.6% file creation-data acquisition rate. Three of fifteen MeTeOR listener PC devices required replacement or repair over a 2-year deployment period (separate from ongoing routine maintenance and updates).

Discussion/Conclusions:

The PERSEUS program investigators achieved the following Phase 1 objectives:

1A. Successful compilation of an expanded study site alarm fatigue knowledgebase, which enabled the development and application of an alarm fatigue simulation method for human factors engineering assessment of existing system performance and exploration of experimental mitigatory approaches

HERD manuscript[5] excerpt: "Based on a detailed alarm fatigue knowledgebase and expert HFE analysis, a clinical microsystem simulation method for human factors-based assessment of alarm fatigue was developed and successfully elicited both response and nonresponse to true alarms in provider subjects while affording the opportunity to examine their interactions with false alarms. Amenable to flexible implementation in various practice settings with minor adjustments, the materials developed represent a reproducible and objective technique to study alarm fatigue and the devices involved. The study simulations brought out intrinsic limitations in the existing patient monitoring system's ability to effectively inform providers of clinically important events. Derived from site-specific HFE work, the simulation method's scenarios featured adequate and meaningful complexity to convincingly engage and challenge subjects during the course of simulated care delivery, thereby facilitating the emergence of target behaviors of interest. For example, by triggering a less urgent yellow alarm message (with slow, lower-volume alarm tones) based on study site threshold configurations, one scenario effectively replicated some of the problems associated with single-parameter alarms and highlighted the importance of adaptive, context-sensitive signals processing and response protocols. On the other hand, simulated red alarms appeared to mostly elicit appropriate responses albeit for both true events, such as malignant arrhythmias, and false events (*e.g.,* patient movement and lead disconnections). Moreover, investigators confirmed provider distraction and task disruption by false alarms without timely resumption of interrupted activities. Additional costs to optimal healthcare delivery were partially quantified in the form of provider subject time consumed by false alarm responses. As for evaluating the experimental alerting system, the alarm fatigue simulation method provided the opportunity to assess its potential improved performance relative to standard systems with respect to the selective, successful, and effective notification of providers."

1B. Successful development of the Medical Technology Interface–Open/Research [MeTeOR] toolbox with hardware specifications and modular conduit software components to access patient monitor data-streams; successful deployment of MeTeOR toolkit with additional off-the-shelf solutions to implement a fully functional bedside clinical informatics (BCI) research pipeline infrastructure in a live ED

IEEE Sensors Letters manuscript[6] excerpt: "Investigators created an open, modular, near-real-time conduit toolkit to access and liberate data from patient monitors into an open, portable, standard data format. Interfacing the toolkit and data output with off-the-shelf software established a BCI research pipeline infrastructure and test environment enabling the safe study of experimental patient datastream analytic methods. The materials developed and approach described will hopefully be used at the study site and beyond to contribute to ongoing efforts to improve patient monitor utility and alarm performance. Specifically, the research team is hopeful for intra-/extra-mural adoption of the materials for single-subject monitoring (*e.g.,* laboratory patho-/physiology studies), departmental or institutional adoption (*e.g.,* automated subject screening for research or clinical trial enrollment), or use in biomedical engineering/industry settings (*e.g.,* algorithm derivation and device development)."

Significance: A use-tested method to re-create alarm fatigue in controlled (simulated) settings and a set of research tools to access and process patient datastreams in real-world clinical settings were successfully developed and deployed.

Implications: The program's simulation-based method of eliciting and studying alarm fatigue and its nonproprietary software and hardware toolbox to experimentally study patient physiologic datastreams will facilitate and advance collaborative bedside clinical informatics research.

FIGURE 1: Diagrams illustrating the scenario scripting, programming, manikin descriptions, and programming for the research program's clinical microsystem simulation method for human factors-based assessment of alarm fatigue (excerpted from Kobayashi et al. 2017[5]).

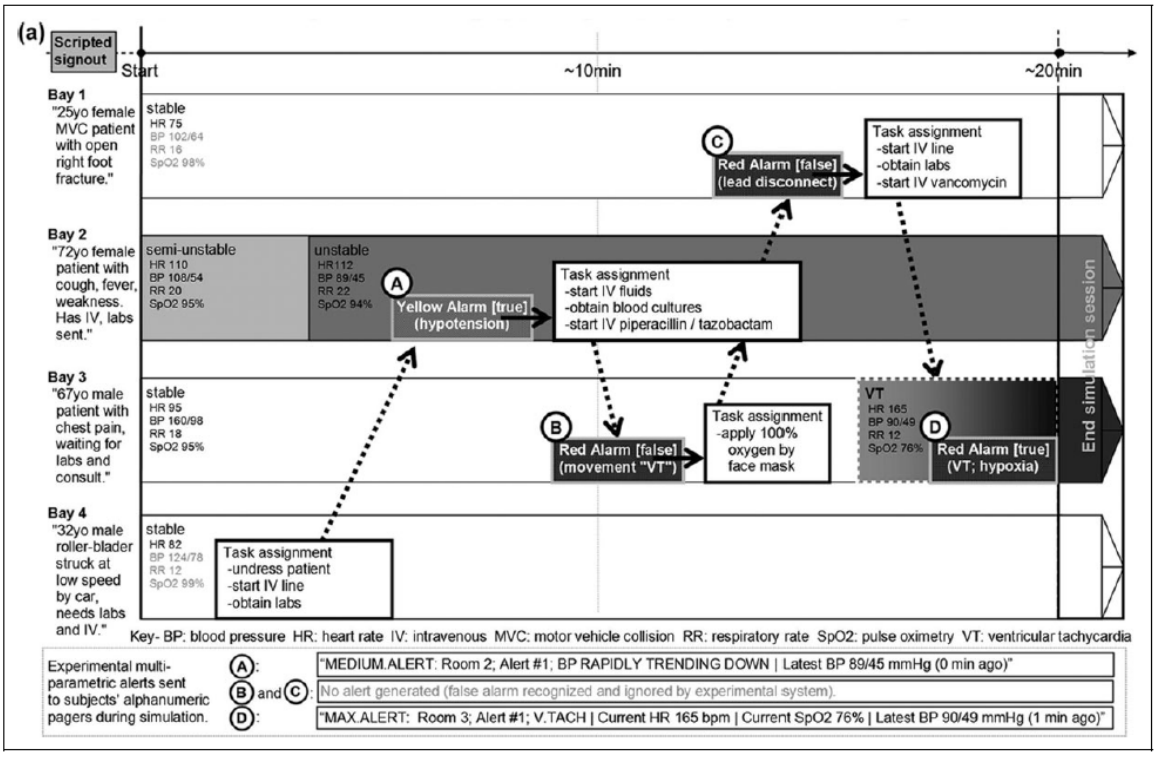


Figure 1. (a) Alarm fatigue research simulation timeline and flow diagram of multiple concurrent patient scenarios. The horizontal axis represents simulation time, starting at the left and moving rightward with scenario progressions; the vertical axis displays the four simulated ED bays with patient descriptors, vital signs, and interval changes (with gray scale representation of illness/injury severity). At the start of the simulation, the RN subject received a brief, scripted nursing sign-out on the simulated patients occupying the ED bays. Patient care (distractor) tasks were assigned for completion, starting in Bay 4. During subject performance of assigned tasks, investigators set off specific critical (red) and urgent (yellow) alarms on the telemetry monitor system, see labeled events A through D. The sequence of triggered alarms and the expected movements of subjects across patient care bays in response to alarm detection are indicated with dashed lines. Multiparametric alert messages generated by the experimental systems for events A through D are included at the bottom. (b) Configuration and equipment setup for concurrent simulated patients in four ED patient care bays as used for alarm fatigue research simulation study sessions.

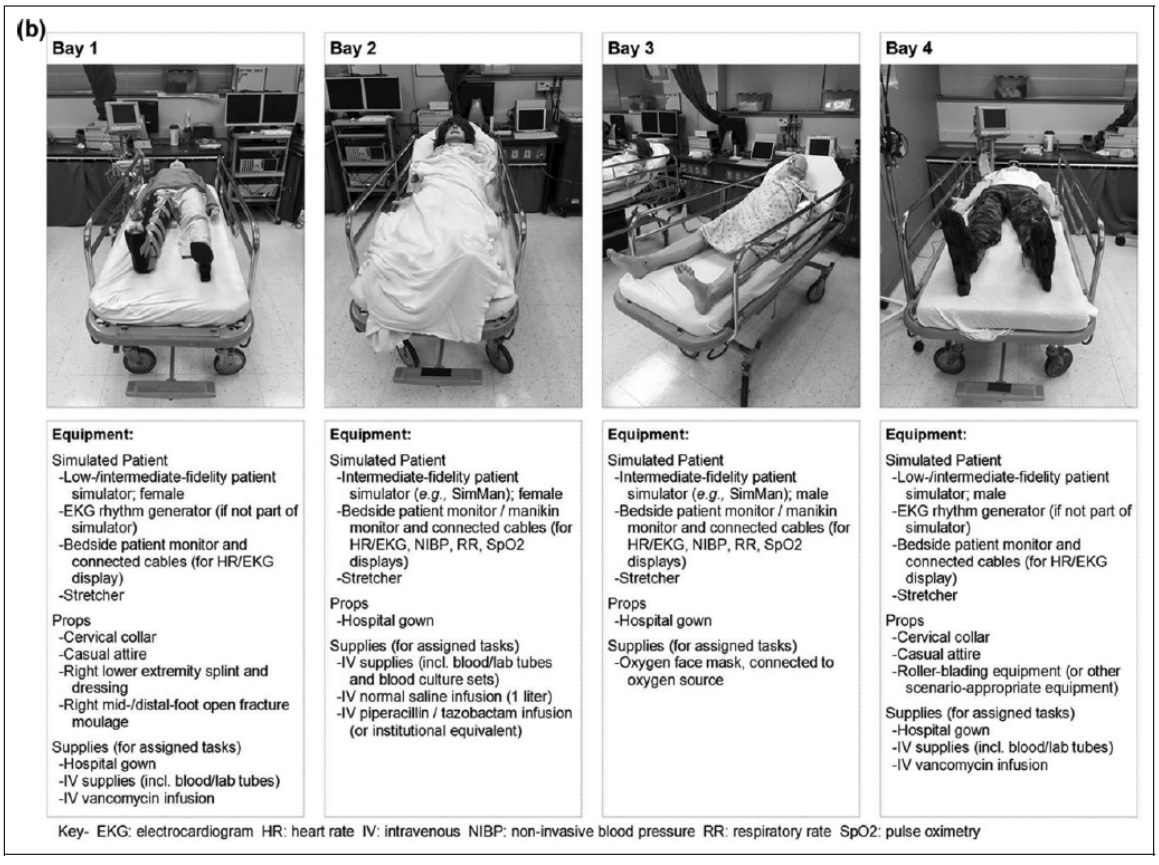
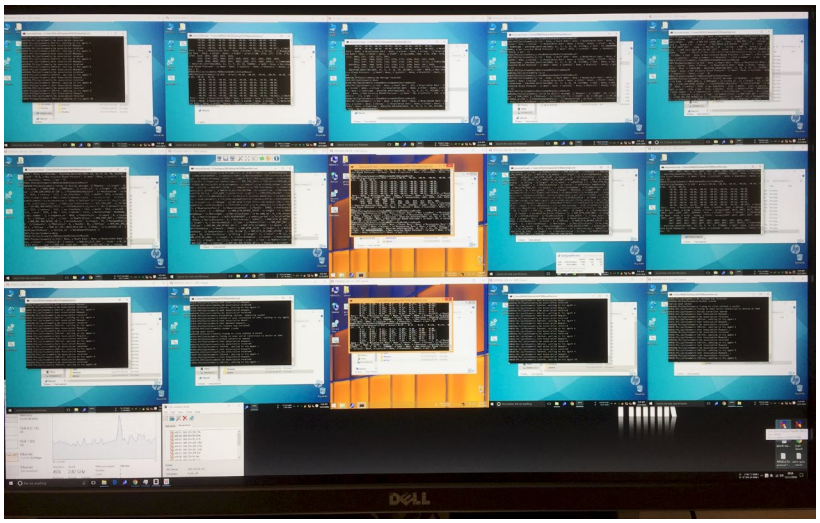
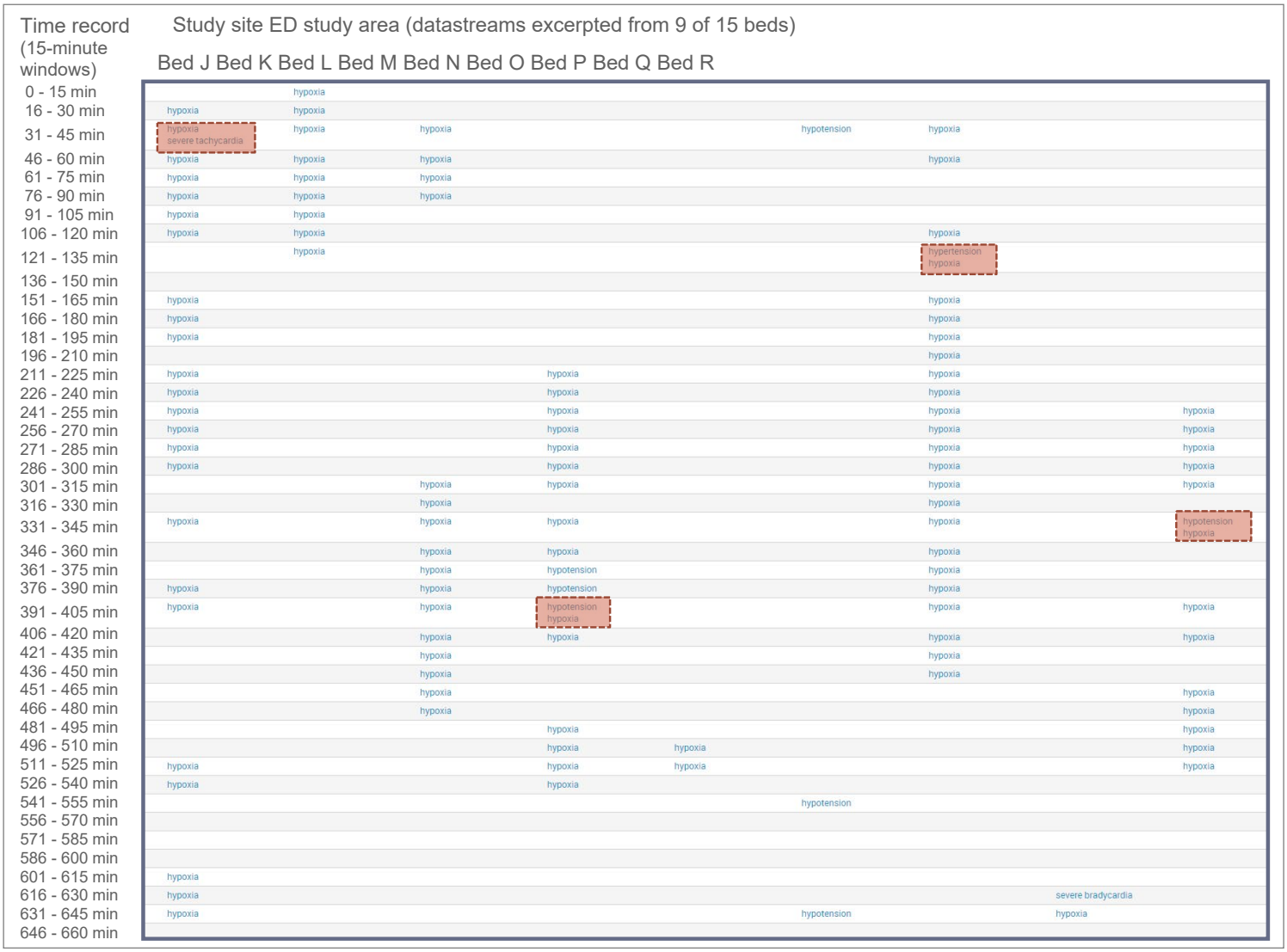


FIGURE 2: Images of study site BCI research pipeline infrastructure implementation. Top left: Research hardware and "listener" device housing MeTeOR toolkit components that acquire and process bedside monitor datastreams. Top right: Research server display demonstrating remote administration of 15 bedside patient listener devices and near-real-time querying of their datastreams. Bottom: sample display of database query screen visualization of multiparametric alerts [MPA; highlighted] (*e.g.,* hypoxia and severe tachycardia 31-45 min ago in ED bed J, etc.; other singular entries indicate single parameter alarms [SPA]). Please see text for details.





Aim/Phase 2: *To comparatively evaluate the performance and utility of existing and experimental patient monitoring telemetry systems with human factors engineering, simulation, and patient tracer methods.*

Status: Ongoing (completion anticipated 2019). The live ED environment was successfully instrumented with a fully functional bedside clinical informatics (BCI) research pipeline infrastructure for near-real-time patient monitor datastream acquisition, processing, storage, and forwarding. This enabled sophisticated online and offline analyses of patient physiologic signals and evaluation of existing telemetry systems and experimental approaches–the research team is actively studying the accessed patient monitor datastreams (waveforms, alarms); experimental quality-of-signal analyses and multiparametric alerts; and clinical outcome correlates (from tracer study patient subjects). As the performance and utility of the existing and experimental monitor systems are still being determined, the simulation component of Phase 2 is awaiting analysis results prior to bedside research implementation.

METHODS

Study Design: Using the BCI infrastructure developed and deployed in Phase 1, investigators applied experimental approaches to online (bedside) and offline patient monitor datastream analytics. Specific Phase 2 tasks were:

Task 2.1 Configure and schedule the live ED environment and research resources for controlled experimentation

Task 2.2 Conduct in situ *arrhythmia-on-telemetry medical simulations to assess the effectiveness and utility of the existing system and the experimental intervention*

Task 2.3 Simulation session data analysis

Task 2.4 Conduct a controlled, live patient tracer chart review study to assess the real-life performance characteristics and utility of the existing system and the experimental intervention

Task 2.5 Tracer data analysis

Data Sources/Collection: Phase 2 data sources were:

Task 2.1: Splunk v6.3 (San Francisco, CA) installation and use instructions; study site live ED patient monitor datastreams as acquired by the MeTeOR system into the BCI research pipeline infrastructure–these data were accessed and processed to generate experimental BCI outputs at the bedside in near-real-time conditions; meeting participation/proceedings of PI visits to co-investigator sites (UCSF, 9/2018; CWRU, 10/2018)

Task 2.2-2.3: These tasks are on hold pending analysis results from Tasks 2.1, 2.4, and 2.5. Anticipated data sources are provider subjects' responses to existing and experimental telemetry monitor systems' true alarms/alerts and false alarms/alerts; 2) System Usability Scale (SUS) scores; 3) Likert scale queries on subjects' perceptions of simulation realism; 4) semi-structured interviews for usability engineering (thematic analysis); meeting participation/proceedings of PI visit to co-investigator site (Red Forest, 9/2018)

Task 2.4-2.5: Monitor datastreams and 3-month tracer chart review data from subjects selected/enrolled based on their live ED patient monitor datastreams (as acquired by the MeTeOR system into the BCI research pipeline infrastructure with processing) to generate three study groups:

1) Any patient who triggered an experimental multiparametric alert [MPA] (*i.e.,* two or more red alarms within a 15-minute window; *e.g.,* concurrent hypoxia and hypotension red alarms)
2) Any patient who triggered only single parameter alarms [SPA] during his/her ED stay
3) Any patient who did not trigger any (red) alarms [NA] during his/her ED stay

Interventions:

Task 2.1: The core BCI infrastructure was brought online in early 2017–investigators scheduled full system operation for research purposes starting winter 2017 and formal continuous data acquisition starting spring 2017. Investigators planned to use the BCI research pipeline infrastructure to access ED study area monitor datastreams with 24/7 continuous recording over 12+ months for primary data acquisition for baseline system and experimental system assessments.

Task 2.2-2.3: These tasks are on hold pending analysis results from Tasks 2.1, 2.4, and 2.5. Planned interventions include controlled experimentation with simulated arrhythmias in live ED settings to compare a) targeted delivery of MPAs for smart notification of consented clinical providers against b) the existing monitor system's broadcasted SPA alarms.

Task 2.4-2.5: Investigators ran continuous, near-real-time experimental queries on monitor datastreams to assess for MPAs over an 18-month study period. Monitor datastreams were acquired for all 15 MeTeOR-instrumented ED beds; MPA, SPA, and NA subjects were recruited by research assistants.

Measures:

Task 2.1: In order to gauge the applied research functionality of the BCI research pipeline infrastructure, investigators followed specific outcomes: 1) modular code installation to enable access, acquisition, experimental processing, storage, and export of monitor datastreams with a portable, standardized, human-/machine-readable format; 2) establishment of a safe, parallel test/research environment in a live clinical setting with proof-of-concept implementation(s) of experimental datastream processing code; 3) implementation of a databasing mechanism to manipulate acquired datasets for sophisticated queries and analyses; 4) implementation of a visualization, adjudication, and annotation mechanism to review datasets for clinically significant characteristics

Task 2.2-2.3: Investigators anticipate comparison of live ED study setting performances of existing and experimental monitoring systems through the following metrics: 1) RN subject response to existing and experimental monitor systems' true alarms and false alarms; 2) System Usability Scale (SUS); 3) semi-structured interviews for usability engineering (for thematic analysis)

Task 2.4-2.5: Descriptive statistics of MPA, SPA, and NA subject cohorts enrolled into study; expert adjudication of subjects' MPA and SPA datastreams for human interpretability (interpretable; not interpretable), clinical significance (significant; not significant; indeterminate) and severity (emergent; urgent; nonurgent; indeterminate); pre-specified endpoints for blinded chart review include death, severe cardiopulmonary events (cardiac arrest, respiratory failure, etc.), emergent life-saving procedures (CPR, percutaneous coronary intervention, etc.) amongst others, as set forth by Utstein style and similar standardized reporting guidelines;[7] comparative statistics to test for between-group differences in alarm/alert performance characteristics and clinical outcomes

Limitations: The program's BCI infrastructure was developed, installed, configured, and used in a single, academic, high-census Emergency Department–open dissemination and extramural collaborations are ongoing through web repository hosting and discussions with extramural investigators. The simulation-based comparison of existing and experimental monitoring approaches in the live ED clinical setting has been delayed while awaiting analyses of acquired datasets to drive the derivation/selection of algorithms to be experimentally implemented at the bedside.

RESULTS

Principal Findings: A bedside clinical informatics research pipeline infrastructure was successfully activated, configured, applied, and use tested to conduct online (bedside) and offline patient monitor datastream analytics. A safe, onsite research, development, and test environment for patient monitor signals analysis and experimentation was established in a 15-bed ED clinical care space and enabled successful acquisition, processing, and analysis of large datasets (see FIGURE 3). Experimental monitoring approaches were installed as modular code into the clinical research framework–ED patients' physiologic signals and the standard alarms and experimental alerts/outputs they triggered are now being analyzed along with corresponding clinical correlates (*i.e.,* chart review-based outcome metrics; see FIGURE 4) to drive next-phase ED *in situ* arrhythmia monitoring simulation studies.

Outcomes:

Task 2.1: The team successfully implemented a modular, scalable, and flexible BCI research pipeline infrastructure that provided the following capabilities:

1) Access to select bedside monitor physiologic signals in real-world clinical settings for near-real-time acquisition, online processing, storage, and export of high-resolution patient datastreams in a portable format (.json)
2) Safe, institution-approved, bedside testing of experimental datastream analyses in a parallel test environment with research framework
3) Indexing, search/query, and retrieval of datastreams for sophisticated analyses, experimental offline processing, and algorithm development
4) Dataset visualization for expert adjudication of datastream interpretability, alarm clinical significance and severity, and experimental algorithm performance

Specific proof-of-concept experimental outputs from the system as implemented included:

1) Pulse oximetry quality-of-signal (QoS; +1 = good signal, 0 = indeterminate signal, -1 = poor signal) determinations as generated by experimental (UCSF) svd-based code processing of photoplethysmographic signal
2) Multiparametric alerts [MPAs] as generated with an off-the-shelf software solution (Splunk).

Task 2.2-2.3: These tasks are on hold pending analysis results from Tasks 2.1, 2.4, and 2.5.

Task 2.4-2.5: Subject enrollment was terminated after 18 months: 264 total subjects were enrolled; three were excluded for protocol violation, and 171 subjects were matched into 57 [MPA-SPA-NA] triads out of a revised target of 300 patients in 100 triads. Chart review is ongoing and will be completed in spring 2019 (the last subjects' tracer periods end in spring 2019); blinded adjudication of enrolled subjects' MPA and SPA datastreams is being completed in parallel. The results will be combined to test the following hypotheses:

1) Human (clinician) interpretability of the physiologic waveform datastreams that trigger a cardiorespiratory monitor's high-acuity alarms correlates positively with the alarm's *clinical significance* (with respect to morbidity and mortality).
2) The concurrency of high-acuity alarms from different physiologic cardiorespiratory monitoring modalities correlates positively with the *clinical severity* of the condition(s) triggering the alarms (with respect to morbidity and mortality).

Discussion/Conclusions: The PERSEUS program investigators achieved the following Phase 2 objectives:

2A. Successful acquisition and processing (bedside and offline) of physiologic datastreams from a live clinical environment for the objective assessment of existing patient monitoring systems and the development of experimental patient monitoring approaches

Investigators used the BCI research pipeline infrastructure to access ED patient bedside monitor datastreams with 24/7/365 continuous recording. Modular code was added on to enable experimental data processing and patient monitoring approaches at the clinical bedside in a safe, controlled, and institutionally approved manner. The 1.7Tb of primary study data acquired over 12 months were databased and indexed by timestamp for characterization, querying, and visualization. The database is being actively examined to establish performance characteristics of the different patient monitoring approaches.

2B. Live patient datastream and clinical correlate tracer study for experimental investigation of a multiparametric alert approach to patient monitoring

A multiparametric alerting approach was implemented in "shadow mode" (*i.e.,* research purposes only; no clinical provider notification) for the ED study area through the BCI infrastructure's modular software architecture. Cohorts of patients who triggered no alarms, standard single-parameter alarms, or experimental multiparametric alerts were recruited with matching for age, gender, Emergency Severity Index (ESI), and chief complaint category. These subjects' data are actively being compiled and analyzed to determine the performance characteristics of standard and experimental patient monitoring approaches.

2C. Proof-of-concept exploratory applications of multiparametric alert (and other) approaches for future informatics-/simulation-based live environment studies

If completion of Tasks 2.4 and 2.5 results in the successful demonstration of superior performance of the experimental multiparametric alerting approach, the research program's next steps will involve ED *in situ* bedside arrhythmia simulations with consented provider participation. If multiparametric alerts exhibit similar or inferior performance relative to standard single-parameter alarms, the research team will pursue alternative experimental alerting approaches that are expected to be derived from the ongoing "big data" efforts described above. Furthermore, predictive analytics using accepted statistical methods have been applied to small subsets of the research data and have shown promise in potentially prognosticating impending changes in oxygen saturation; ongoing research into waveform near-/real-time quality-of-signal determination is also being pursued.

Significance: Implementation of a fully functional end-to-end research pipeline and network that connected <patients/bedside monitors> to <data access/processing devices running nonproprietary experimental software> to <near-real-time databasing system featuring query, visualization, and statistical functions> in real-world clinical settings has been shown to be feasible, sustainable, and valuable for bedside clinical informatics.

Implications: The PERSEUS program has established an overall framework, core hardware component and connectivity specifications, and nonproprietary modular conduit software toolkit for a use-tested bedside clinical informatics research system that can be flexibly installed and used in live clinical environments.

FIGURE 3: Diagram illustrating the research program's bedside clinical informatics (BCI) research pipeline infrastructure with sample data flow from 15 patient monitors (including algorithmically processed data) to server/storage for adjudication/annotation and experimental applications (excerpted from Kobayashi et al. 2018[6]). Please see text for details.

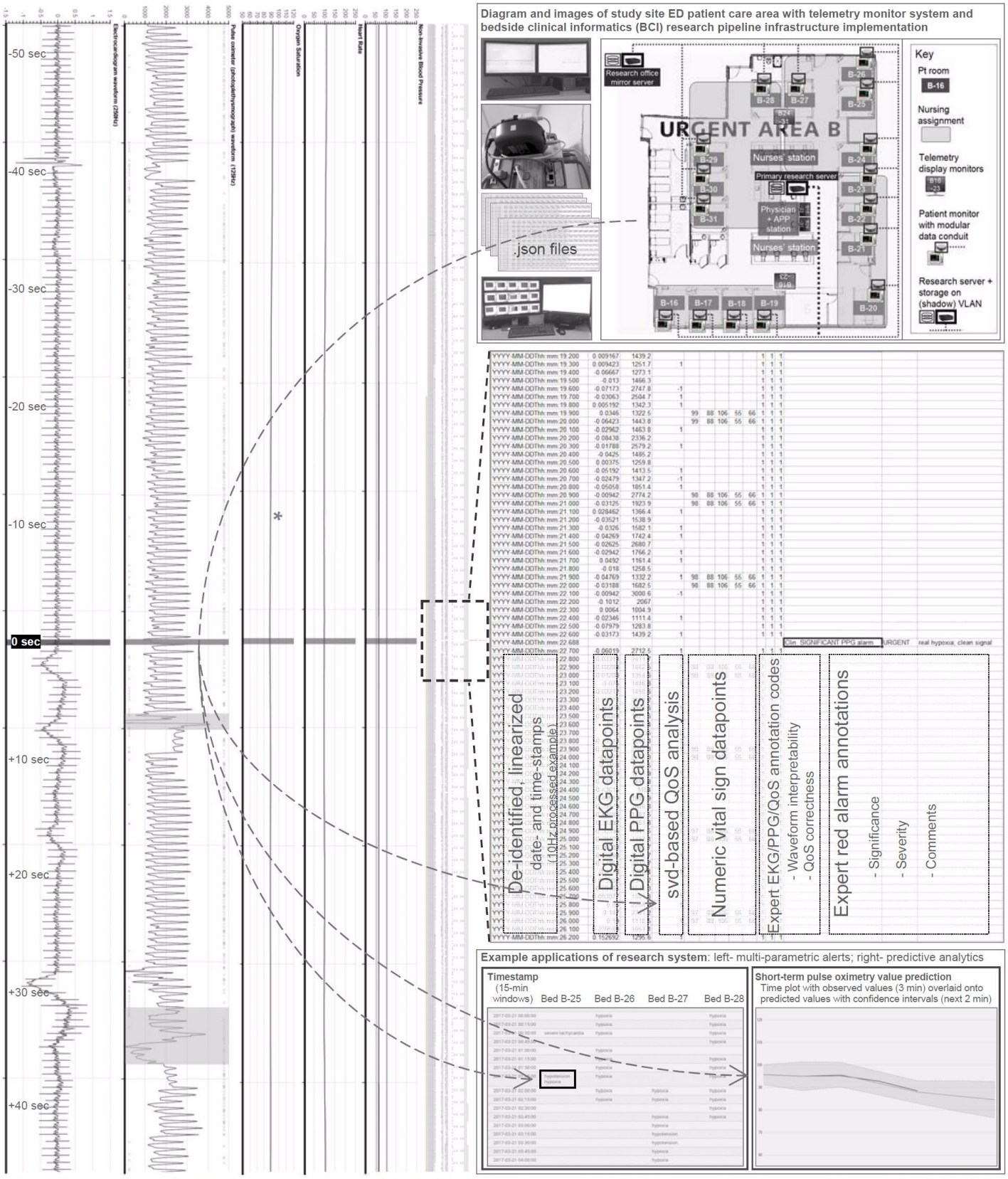
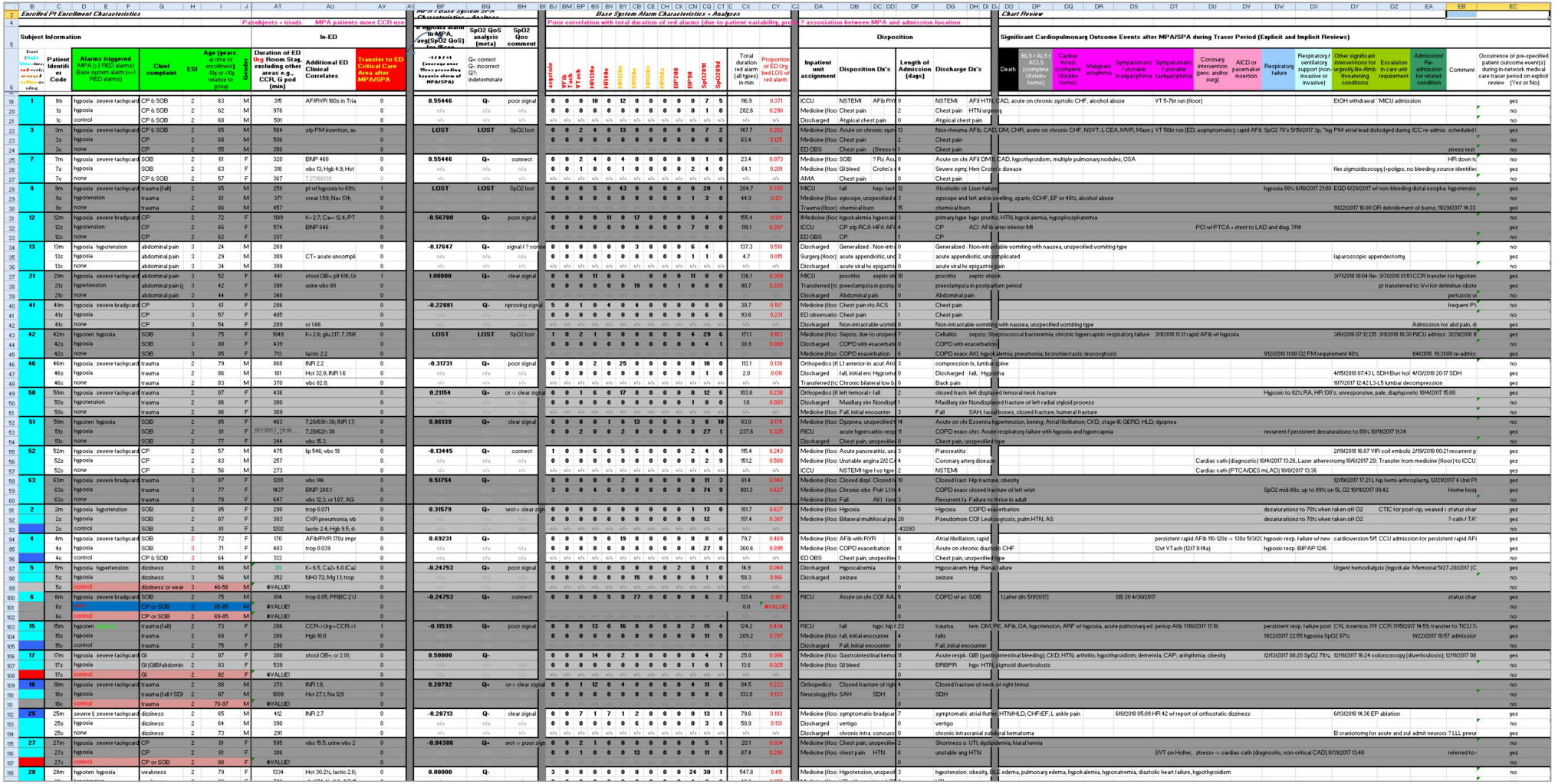


Figure 1. Diagram showing data flow from patient monitor into bedside clinical informatics research pipeline infrastructure through open modular conduit toolkit, with de-identified 100-second sample of an acquired, visualized, and annotated 10-minute data window centered at a true positive hypoxia red alarm (*asterisk indicates patient event with clear pulse oximetry photoplethysmographic signal dropping below 89% oxygen saturation; grey highlight waveform segments indicate expert-annotated non-interpretable signal). The linearized, date-/time-stamped 250Hz single-lead EKG (additional leads optional) and 125Hz pulse oximetry waveform datapoints; svd-based quality of signal (QoS) analysis results; 1Hz numeric vital signs values; alarm information; and expert annotations are stored and exported in human-/machine-readable .json files for experimental development of new monitoring approaches, *e.g.,* multi-parametric alerts and predictive analytics (bottom right insets) for safe and iterative testing in live clinical environments.

FIGURE 4: Screenshot of tracer study dataset (excerpt of 66 patients' de-identified preliminary partial data out of 264 total subjects enrolled), with patient characteristics, experimental alert metrics, existing telemetry system metrics, and clinical outcome metrics. Subject tracer chart review is ongoing until spring 2019; analyses are expected to be completed in summer 2019. Please see text for details.



Aim/Phase 3: *To prepare and disseminate a nonproprietary medical technology interface toolbox for continued medical device and informatics research at the study institution and beyond.*

Status: Ongoing (completion anticipated 2019-2020). The research team has successfully developed a nonproprietary medical technology interface [MeTeOR] toolkit that enabled the compilation of large research datasets–these materials are being disseminated to specific intramural and extramural research teams and are in the final stages of being hosted on Web repositories for open dissemination. Given the significant challenges and delays associated with completing Aims/Phases 1 and 2, the test deployment of the nonproprietary system at a clinical sister site has been delayed; discussions are ongoing with several research groups/sites for this task.

METHODS

Study Design: Specific Phase 3 tasks were:

Task 3.1 Preparation and packaging of medical technology interface toolbox
Task 3.2 Test deployment of medical technology interface toolbox at affiliated ED site
Task 3.3 Ongoing investigative use of deployed experimental toolboxes and systems at study sites
Task 3.4 Positioning of medical technology interface toolbox for dissemination

Data Sources/Collection: Phase 3 data sources were:

Task 3.1: MeTeOR toolkit source and compiled code; development, installation, configuration, and use instruction notes
Task 3.2: This task is on hold pending ongoing discussions with several intramural and extramural research groups. Anticipated data sources are sister site (ED or other acute care environment) patient physiologic datastreams and clinical correlates, and experimental system performance metrics as monitored by program investigators and collaborative investigators.
Task 3.3: Datastreams acquired from the live ED clinical environment–this large collection of patient physiologic data has been sorted, de-identified/obfuscated of any protected health information (PHI) identifiers, post-processed, and packaged as the Adjudicated/Annotated Telemetry Signals for Medically Important and Clinically Significant Events [ATOMICS] datasets for open dissemination
Task 3.4: MeTeOR toolkit, acquired physiologic datastreams, ATOMICS datasets, use instructions, and research-only (nonclinical) end-user license agreement (EULA)

Interventions:

Task 3.1: The nonproprietary MeTeOR toolkit materials and supporting materials will be compiled into a portable, organized, self-contained online dissemination package.
Task 3.2: The research team has been preparing for and discussing internal (ICU) and extramural (ED/ICU) deployments of the developed toolkit and BCI infrastructure with several research groups.
Task 3.3: The BCI infrastructure implemented at the study site ED has been used extensively for PERSEUS program alarm fatigue research as well as exploratory investigations. Numerous live demonstrations and presentations of the system and its capabilities have been completed to facilitate dissemination of similar systems at additional sites.
Task 3.4: The MeTeOR toolkit, acquired physiologic datastreams, and the ATOMICS datasets will be openly shared and disseminated for collaborative research opportunities.

Measures:

Task 3.1: Portable, organized, self-contained online dissemination packages for Web hosting and sharing.
Task 3.2: Timeliness, accuracy, and reliability of simultaneous, continuous MeTeOR acquisition of monitor datastreams at sister/dissemination study sites (internal and extramural); failure rates (hardware [device failure]; network [transmission/communication failure]; software [data loss, data corruption; algorithm failure])
Task 3.3: Deliverables from continuing research conducted with the MeTeOR toolkit and BCI research pipeline infrastructure (*e.g.,* source code and datasets) for dissemination and collaborative use; peer-reviewed manuscripts, abstracts, and presentations on research using the program's systems and materials; intramural and extramural inquiries regarding application of the MeTeOR toolkit and BCI research pipeline infrastructure at the study site and beyond
Task 3.4: Brown Digital Repository (BDR; https://repository.library.brown.edu) and additional repository sites' statistics on numbers of views and downloads of the dissemination packages; intramural and extramural inquiries regarding access and transfer of developed materials

Limitations: At this time, program materials have been disseminated primarily to researchers who are working in nonclinical laboratory settings (see active collaborations in Aim/Phase 3 Outcomes below)–installation and application of program materials in additional live clinical settings and sites are expected to be challenging even with local biomedical engineering, clinical informatics, and institutional support.

RESULTS

Principal Findings: The research team generated multiple research deliverables for dissemination over the course of the program as originally planned (see TABLE 1 and FIGURES 5-7). These materials were able to be uploaded to established Web portals for open dissemination for continued investigative efforts in bedside clinical informatics. A clinical sister site for installation of the developed interface is actively being pursued; its securement will help build and expand on completed work. Collaborations with onsite and offsite research teams are ongoing; these are expected to lead to additional insights and areas of inquiry that will advance patient monitoring and alarm fatigue mitigation.

Outcomes:

Task 3.1: Core MeTeOR source and compiled code with installation and use instructions are currently hosted on GitHub. Full open dissemination of the latest code through the BDR is anticipated in early 2019.

Task 3.2: While the program investigators work to identify and secure a primary collaborative sister site for system deployment, the following research investigators/sites have been using the developed MeTeOR toolkit, acquired datastreams, and ATOMICS datasets in laboratory settings:

- *Active collaborative research investigators (MeTeOR toolkit deployment and use)*
  - -Philips Research, Cambridge, MA (medical device/systems integration)
    Reza Sharifi, PhD (Senior research staff)
  - -Philips Research, Eindhoven, Netherlands (noncontact vital signs acquisition)
    Ihor Kirenko, PhD (Innovation lead; Principal scientist)
    Geoffrey Capraro, MD, MPH (Assistant professor, Brown University; Philips-supported)
    Marek Bartula, MSc (Senior scientist)
    Mukul Rocque, MSc (Research scientist)
- *Potential internal collaborations (MeTeOR toolkit deployment and use)*
  - -Division of Emergency Neurosciences and Critical Care Research (SIREN hub), Rhode Island Hospital, Providence, RI
    Lisa Merck, MD (Associate Professor)
    Derek Merck, PhD (Assistant Professor)
  - -Lifespan Medical Simulation Center, Providence, RI
- *-Potential extramural collaborations (MeTeOR toolkit deployment and use)*
  - -Clinical and Translational Science Institute (CTSI; SIREN hub), Tufts Medical Center, Boston, MA
    Manlik Kwong, BS (Senior IT Program Advisor; Engineer/Scientist/Investigator)

Task 3.3: The primary study site BCI research pipeline infrastructure implementation is offline as of December 2018 due to an impending institution-wide change-over/transition from Philips Intellivue patient monitors to GE CareScape patient monitors in early 2019 (the MeTeOR toolkit is not currently compatible with GE monitors). The study team has secured the acquisition and installation of a GE-Bernouilli research platform for resumption of BCI research using the expertise, protocols, source code, results, and insights from the PERSEUS program.

The program's .json files and ATOMICS datasets are being actively used at the following sites:

- *Active collaborative research investigators (Dataset analysis and application)*
  - -Department of Computer Science, Brown University, Providence, RI
    Abhishek Dutta, MSc (Laboratory researcher)
    Yu (Sherry) Xiang, MSc (Laboratory researcher)
    Ugur Cetintemel, PhD (Departmental chair; Professor)

The following investigators/sites have expressed an active interest in accessing program materials:

- *Potential extramural collaborations (Dataset analysis and application)*
  - -Department of Electrical, Computer, and Systems Engineering, Case Western Reserve University, Cleveland, OH
    Farhad Kaffashi, PhD (Research assistant professor)

-Department of Physiological Nursing, Univ. of California San Francisco, San Francisco, CA
Xiao Hu, PhD (Professor)

Task 3.4: The MeTeOR toolkit software is currently being hosted on a program investigator's GitHub Web repository (https://github.com/)–the repository will be updated then linked to a BDR placeholder. The 5,337 original source .json files (1.7Tb), 2,462 adjudicated/annotated datastream [ATOMICS-0/-1/-2/-3] files (133Gb), and clinical correlate [ATOMICS-CC] dataset (in preparation) are fully de-identified and will be hosted openly by the BDR at https://doi.org/10.26300/h83e-jh51 with possible mirroring through additional sites (*e.g.,* AHRQ Office of Communications) for sharing with the scientific community.

Discussion/Conclusions: The PERSEUS program investigators achieved the following Phase 3 objectives:

3A. Peer-reviewed publication of alarm fatigue simulation method with pilot data and lessons learned

Investigators have presented and published an alarm fatigue simulation method manuscript and a methods manuscript on the development and implementation of the bedside clinical informatics research pipeline infrastructure (see List of Publications and Products below).

3B. Preparation and packaging of program-developed MeTeOR open code (Python) with use instructions and peer-reviewed methods manuscript containing hardware and software specifications along with use-case examples for dissemination through Web portals (GitHub; others pending)

The research team created a functional, scalable, modular system specifically designed to access patient physiologic monitor datastreams for experimental research. This has enabled the RIH investigators to conduct research on noncontact vital signs in the ED setting; several internal and external research groups are using or have expressed interested in the system and approach developed. The research team is working with the BDR and additional online repositories to further disseminate these materials to the scientific community as an accessible, user-modifiable alternative to existing commercial alternatives.

3C. Successful acquisition, processing, de-identification, and packaging of large human-/machine-readable datasets for experimental patient monitoring algorithm development through Web portals (Brown Digital Repository; others pending)–Adjudicated/Annotated Telemetry signals for Medically Important and Clinically Significant events [ATOMICS] datasets

The original .json files and ATOMICS datasets are being post-processed and packaged with expert adjudications/annotations for open dissemination and collaborative investigations. Several research teams are currently using data-mining and deep-learning techniques on these packaged datasets to derive novel algorithms that differentiate clinically significant (true positive) datastream elements from nonsignificant (false positive) datastream elements.

3D. Ongoing dissemination of program-developed materials to collaborative clinical study sites (discussions in progress), research groups (Brown University, CWRU, UCSF), and industry (Philips Research)

The program's next steps include 1) derivation of patient monitoring algorithms from study datasets for testing and validation in laboratory and bedside settings and 2) the identification of additional partner clinical sites to share the toolkit and coordinate site-specific implementations of the BCI infrastructure. Preliminary examples of exploratory multimodal data fusion (MMDF) applications employing the research system and study data include multiparametric alerting and predictive analytics as potential mechanisms for alarm fatigue mitigation and earlier detection of impending clinical instability.

Significance: A nonproprietary bedside patient monitor interface system was applied with off-the-shelf software to acquire large datasets of live ED patient physiologic datastreams over 12 months. The processed, adjudicated/annotated, de-identified, packaged, and openly disseminated datasets will enable collaborative research of experimental patient monitoring and data analytic approaches.

Implications: The bedside clinical informatics (BCI) approach developed by the research team enables access to a significant proportion of patient monitors (Philips Intellivue, estimated at 30% market share globally[‡]) in current use–applying the toolkit and techniques described will liberate datastreams from closed, black-boxed architectures that have presented significant challenges to open research initiatives. The large datasets acquired by the research team represent a voluminous collection of (de-identified) physiologic datastreams from thousands of live patients with varying illnesses, injuries, comorbidities, and outcomes; these data are hoped to serve as a primer and testbed for next-generation patient monitoring research.

[‡] China Medical Monitor Industry Report, 2014-2017. http://www.researchinchina.com/Htmls/Report/2014/8033.html

TABLE 1A. ATOMICS Data Subset Descriptions (1 of 2)

Data Subset	Intended Application	Data Subset De-identified?	Datastream Source Pool	Datastream Window	Peri-alarm Monitor Datastreams Included			
					1-lead EKG (250Hz) and pulse oximetry PPG (125Hz) waveforms	Numeric vital signs (1Hz)	Alarms extracted (select red alarms only)	UCSF svd-based Quality of Signal (QoS) (variable frequency)
ATOMICS-0	Training (control data subset)	yes	15 ED beds * 7 days	-5min <- alarm -> +5min	yes	yes	no	yes
ATOMICS-1	Training (derivation data subset)	yes	15 ED beds * 7 days	-5min <- alarm -> +5min	yes	yes	yes	yes
ATOMICS-2	Training (derivation data subset)	yes	15 ED beds * 7 days	-5min <- alarm -> +5min	yes	yes	yes	yes
ATOMICS-3	Training (exploratory data subset)	yes	15 ED beds * 7 days	-5min <- alarm -> +5min	yes	yes	no	yes
ATOMICS-CC	Testing (clinical correlate data subset)	yes	15 ED beds * 640 days	-15sec <- alarm	yes	yes	yes	yes
Source .json	Testing (original full dataset)	yes	15 ED beds * 365 days	n/a	all	all	no	all

TABLE 1B. ATOMICS Data Subset Descriptions (2 of 2)

Data Subset	Adjudications/Annotations Included				Total red alarms^	Red alarms by monitor modality			Clinically *significant* red alarms			Clinically *nonsignificant* red alarms			Clinically *indeterminate* red alarms		
	EKG waveform annotation	PPG waveform annotation	QoS correctness adjudication	Alarm adjudications		EKG	PPG	BP	EKG	PPG	BP	EKG	PPG	BP	EKG	PPG	BP
ATOMICS-0	no	no	no	yes (true negative controls[#])	**300**	n/a	n/a	n/a	n/a	n/a	n/a	n/a	n/a	n/a	n/a	n/a	n/a
ATOMICS-1	no	no	no	yes (true positives; true negatives; indeterminates)	**853**	365	388	100	263	83	93	93	117	4	9	188	3
ATOMICS-2	yes	yes	3 of 7 days	yes (true positives; true negatives; indeterminates)	**1,234**	671	430	133	550	84	126	92	190	2	29	156	5
ATOMICS-3	no	no	no	no	n/a	n/a	n/a	n/a	n/a	n/a	n/a	n/a	n/a	n/a	n/a	n/a	n/a
ATOMICS-CC	no	no	yes	yes (true positives; true negatives; indeterminates)	**~300**	TBD	TBD	TBD	TBD	TBD	TBD	TBD	TBD	TBD	TBD	TBD	TBD
Source .json	no	no	no	no	n/a	n/a	n/a	n/a	n/a	n/a	n/a	n/a	n/a	n/a	n/a	n/a	n/a

[#] no alarm-generating waveform or vital signs

^ Red alarms included:
VTach/VFib
Severe tachycardia (HR > 130bpm); Tachycardia (HR > 120bpm)
Severe bradycardia (HR < 50bpm); Bradycardia (HR < 40bpm)
Hypoxia (SpO2 < 89%)
Hypertension (SBP > 200mmHg)
Hypotension (SBP < 90mmHg)

FIGURE 5: Raw sample excerpt of bedside patient monitor datastream output exported as .json files for open dissemination and collaborative research.

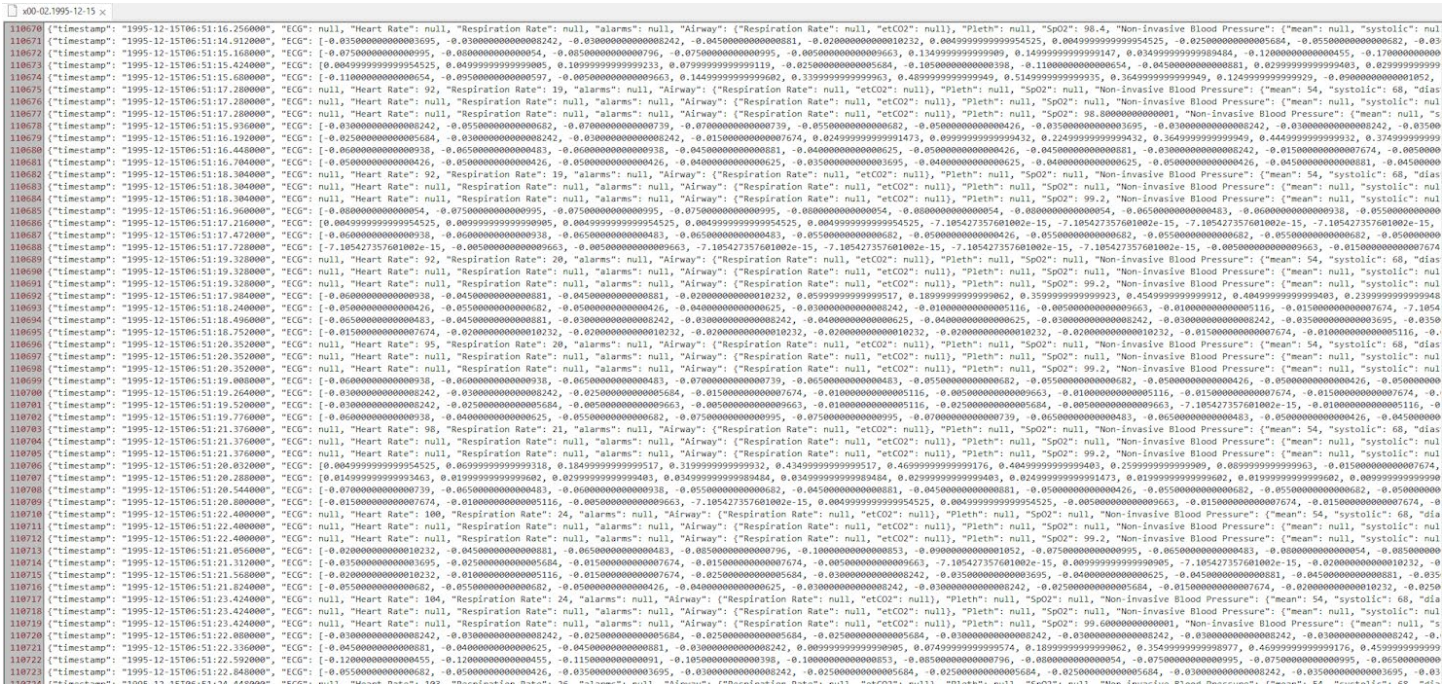
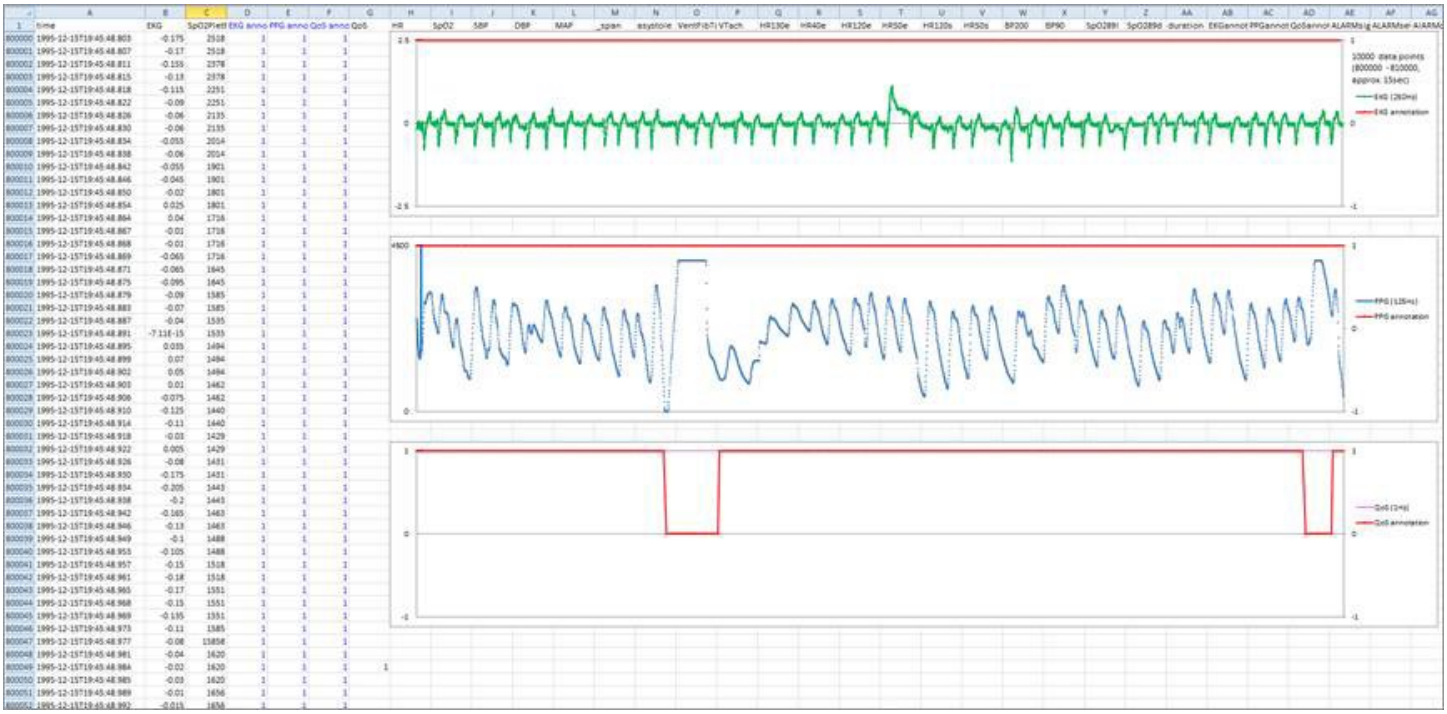


FIGURE 6: Sample adjudicator/annotator view of ppgAnnotator visualization code (de-identified) for expert review of EKG and PPG waveforms for human interpretability (interpretable; not interpretable) and standard monitor system's red alarms for clinical significance (significant; not significant; indeterminate) and severity (emergent; urgent; nonurgent; indeterminate). Please see text and Kobayashi et al. 2018[6] for details.

FIGURE 7: Sample excerpt of post-processed, linearized, adjudicated/annotated ATOMICS data (de-identified) as imported into Excel for demonstration purposes. The human-/machine-readable data in the research program's open dissemination packages can be readily accessed and studied with available analytics software. The left columns contain post-processed data; the right top, middle, and bottom panels display original single-lead EKG waveform (250Hz), pulse oximetry waveform (125Hz), and UCSF svd-based bedside pulse oximetry quality-of-signal (QoS) analysis output (+1 = good QoS; 0 = indeterminate QoS; -1 = poor QoS), respectively. The solid lines in the top two panels indicate investigator expert annotation of waveform quality (+1 = interpretable signal; 0 = no signal; -1 = noninterpretable signal); several days worth of the ATOMICS-2 dataset additionally contain annotations of QoS correctness (not shown).



LIST OF PUBLICATIONS AND PRODUCTS

Bibliography of Published Works

Peer-reviewed publications

- Kobayashi L, Gosbee JW, Merck DL. Development and application of a clinical microsystem simulation methodology for human factors-based research of alarm fatigue. *HERD* 2017 Jul;10(4):91-104 PMID:27815527 DOI: 10.1177/1937586716673829
- Kobayashi L, Oyalowo AC, Agrawal U, Chen S, Asaad W, Hu X, Loparo K, Jay G, Merck DL. Development and deployment of an open, modular, near-real-time patient monitor datastream conduit toolkit to enable healthcare multimodal data fusion in a live Emergency Department setting for experimental bedside clinical informatics research. Accepted for publication, *IEEE Sens Lett, October 2018.*

Peer-reviewed Publication in preparation

- Kobayashi L, Oyalowo AC, Agrawal U, Hu X, Loparo K, Jay G, Merck DL. Comparison of experimental multiparametric alert and standard single-parameter alarm patient monitoring approaches in a live emergency department patient cohort. In preparation for *Ann Emerg Med*.

Bibliography of Electronic Resources

Adjudicated/Annotated datasets for open dissemination

- Kobayashi L, Oyalowo A, Agrawal U, Hu X, Loparo KA, Leary OP, Jay GD, Merck DL. Push Electronic Relay for Smart Alarms for End User Situational Awareness (PERSEUS) research program full original .json files dataset. Brown Digital Repository, 2018. Available at: https://doi.org/10.26300/1t2a-qm27

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- Kobayashi L, Oyalowo A, Agrawal U, Hu X, Loparo KA, Leary OP, Jay GD, Merck DL. Adjudicated/Annotated Telemetry signals for Medically Important and Clinically Significant events-CC (ATOMICS-CC) dataset. Brown Digital Repository, 2019. Available at: https://doi.org/10.26300/m9pp-4m49

Programming source code/compiled code for open dissemination in preparation

- Kobayashi L, Oyalowo A, Agrawal U, Asaad W, Hu X, Loparo KA, Jay GD, Merck DL. Medical Technology interface- Open/Research (MeTeOR) toolkit. Brown Digital Repository, 2019. Available at: https://doi.org/10.26300/8rvh-eq12

Invited Presentations

International/National conferences

- Kobayashi L. Systems testing using simulation. Academic Emergency Medicine Consensus Conference. Catalyzing system change through healthcare simulation: systems, competency, and outcomes. May 16, 2017, Orlando, FL.
- Kobayashi L, Merck DL. Acute care patient bedside telemetry monitor datastream processing, visualization, and querying with Splunk. Splunk .conf2017, September 26, 2017, Washington, DC.

Regional/Local conferences

- Kobayashi L. Topics in clinical engineering: alarm fatigue. Department of Biomedical Engineering, University of Connecticut. March 27, 2017, Providence, RI.
- Kobayashi L. Topics in translational research and technology- alarm fatigue. Department of Engineering, Brown University, April 21, 2017 and March 9, 2018, Providence, RI.
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