Design and implementation of a portable physiologic data acquisition system*

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Objective: To describe and report the reliability of a portable, laptop-based, real-time, continuous physiologic data acquisition system (PDAS) that allows for synchronous recording of physiologic data, clinical events, and event markers at the bedside for physiologic research studies in the intensive care unit.

Design: Descriptive report of new research technology.

Setting: Adult and pediatric intensive care units in three tertiary care academic hospitals.

Patients: Sixty-four critically ill and injured patients were studied, including 34 adult (22 males and 12 females) and 30 pediatric (19 males and 11 females).

Interventions: None.

Measurements and Main Results: Data transmission errors during bench and field testing were measured. The PDAS was used in three separate research studies, by multiple users, and for repeated recordings of the same set of signals at various intervals for different lengths of time.

Both parametric (1 Hz) and waveform (125–500 Hz) signals were recorded and analyzed. Details of the PDAS components are

explained and examples are given from the three experimental physiology-based protocols. Waveform data include electrocardiogram, respiration, systemic arterial pressure (invasive and noninvasive), oxygen saturation, central venous pressure, pulmonary arterial pressure, left and right atrial pressures, intracranial pressure, and regional cerebral blood flow. Bench and field testing of the PDAS demonstrated excellent reliability with 100% accuracy and no data transmission errors. The key feature of simultaneously capturing physiologic signal data and clinical events (e.g., changes in mechanical ventilation, drug administration, clinical condition) is emphasized.

Conclusions: The PDAS provides a reliable tool to record physiologic signals and associated clinical events on a second-tosecond basis and may serve as an important adjunctive research tool in designing and performing clinical physiologic studies in critical illness and injury. (Pediatr Crit Care Med 2007; 8:563–569)

Key Words: physiologic signals; waveforms; data acquisition; intensive care unit; research

he intensive care unit (ICU) has long been viewed as similar to a physiology laboratory due to the diverse number of pathophysiologic processes that occur and the relative rapidity by which they progress. However, in order to study closely the pathophysiology of critically ill and injured patients, an accurate physiologic data acquisition system needs to be available that is comparable to those used in experimental laboratories to record both physiologic signals and associated important clinical events (1-4).

To date, such a system for the simultaneous collection of long (hours to days) annotated time series has proven

*See also p. 588.

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Drs. Ellenby, Goldstein, McNames, and Phillips and Mr. Vinecore have no financial interest in PDAS and have no plans for commercial development. The remaining authors were not involved in PDAS development.

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difficult (5) due to insufficient computational power, inadequate specialized software, difficulty in accurately annotating clinical events, and incompatibility between data acquisition, data analysis, and commercial monitoring systems. A number of investigators have described their systems for physiologic data acquisition, archive, and analysis (6, 7), but none have been able to record the finely granular signal data and clinical annotations required to accurately perform clinical physiologic studies in the ICU.

We previously reported a real-time, continuous physiologic data acquisition system developed for the study of disease dynamics in the ICU that captured physiologic signal and parameter (i.e., time averaged mean signals) data from multiple patients simultaneously on a continuous basis (6) and was ideal for blinded data analysis. However, this system was not capable of recording time-sensitive information about changes in a patient's clinical condi-

tion, timing of drug administration, occurrence of noxious environmental stimuli (such as noise and light), and a multitude of other important variables.

This article describes the next generation of the physiologic data acquisition system (PDAS) that allows for synchronous recording of physiologic data, clinical events, event markers, and notation at the bedside of experimental clinical protocols designed for studies of critically ill and injured patients. To date, the PDAS described in this manuscript has been used in four ICUs: the adult and pediatric ICUs at Oregon Health and Science University, the pediatric ICU at Great Ormond Street Hospital, London, UK, and the medical/surgical intensive care unit at Children's Hospital, Boston, MA.

METHODS

Institutional Review Board and Research Ethics Committee Approvals. Three study protocols have been used to date. The Pulse Pressure Variation and Fluid Responsiveness Protocol was approved by the Institutional Review Board of Oregon Health and Science University; the Physiologic Challenge Protocol in Pediatric Traumatic Brain Injury (TBI) Protocol was approved by both the Institutional Review Board of Oregon Health and Science University and the Institute of Child Health/Great Ormond Street Hospital Research Ethics Committee; and the Characterization of Regional Cerebral Blood Flow in Patients with Moyamoya Disease Undergoing Pial Synangiosis Protocol was approved by Children's Hospital Boston Committee on Clinical Investigation.

Study Protocol Summaries. Table 1 briefly summarizes the study protocols referred to in the manuscript. Table 2 lists the subject demographics, diagnoses, and waveforms recorded using the PDAS for each study protocol.

PDAS Hardware and Software. The PDAS consists of a laptop computer, a standard PC-MCIA serial card (Socket Communications, Newark, CA), RS232 serial interface cables

(Oregon Electronics, Portland, OR), and custom software that continuously acquires and stores physiologic signals from the ICU monitoring devices. The laptop is a Gateway M675 with a 3.0-GHz P4 processor (Gateway, Irvine, CA) running Microsoft Windows XP (Microsoft Corporation, Redmond, WA) although any similarly equipped laptop computer will perform adequately. Serial ports were added to the laptop with a dual high-speed serial I/O PCMCIA card. The serial card is connected to RS232 communication ports on the medical devices with custom-built T25-pin serial interface cables. Data are exported from a Philips Component Monitoring System or Intellivue (Philips Medical Systems, N.A. Bothell, WA) patient monitor through the RS232 serial port card. The PCMCIA serial adapter card provides access to up to four physical serial ports for data from secondary monitoring devices, such as continuous cardiac output monitors (PiCCO, Pulsion Medical Systems AG, Munich, Germany), transonic flow meters, and nearinfrared spectroscopy perfusion monitors (Hutchinson Technology, Hutchinson, MN).

The PDAS software, developed at Oregon Health and Science University in collaboration with Portland State University, is the heart of the data collection system. The PDAS software manages the communications with the monitoring devices and coordinates the incoming data flow from each of the physiologic signals while presenting an intuitive graphical user interface to the PDAS operator. The PDAS graphical user interface is customizable to add clinical annotation pages for existing or new studies. All recorded data are transferred to text files that can be easily imported into any off-line analysis tool, such as MATLAB (The MathWorks, Natick, MA), for post hoc signal processing, waveform analysis, and statistical analysis.

Physiologic data from the Philips patient monitors are downloaded at sampling rates of 500 Hz for electrocardiogram (ECG) waveforms and 125 Hz for pressures and most other waveforms. Both waveform signals and parametric data are displayed on the PDAS screen. Since the data transmission rate of the Component Monitoring System patient monitor is 38,400 bps, a maximum of one 500-Hz ECG signal and four additional 125-Hz signals can be recorded and displayed for each RS232 connection. The Intellivue has a throughput of 115,200 bps, which permits up to two ECG waveforms sampled at 500 Hz and five other waveforms sampled at 125 Hz to be acquired for each RS232 connection.

Collected data are stored in an organized, logical, protected, and accessible manner for analysis or presentation by other software applications. The data acquisition software handles file organization with an automatic file name generation scheme that allows for multiple research studies, multiple users, and repeated recording of the same set of signals at arbitrary intervals for arbitrary lengths of time. Data are stored on the laptop's hard drive in a hierarchical structure based on the specific research study, the study-specific patient identification number, the recording session number, and the source of the signal being recorded. Data are stored in ASCII text format files with one data point per line. This permits data to be easily imported into common statistical analysis and digital signal processing packages as well as desktop publishing programs. Signal-specific information, such as scaling values, units, and study start and stop times, for each of the signals recorded is collected into a single information file. Disk space consumption varies depending on the number and type of signals being recorded, but simultaneous acquisition of five waveform signals with associated parametric values requires <45 MB/hr.

Clinical or study annotations and text comments are entered as free-form text or specifically designed data sets for a particular research study protocol and are stored in a separate ACSII text file with all of the fields for a particular annotation separated by commas and stored on a single line. The file is structured to indicate when the annotation was made and is indexed to both the 125-Hz and 500-Hz data files. Indices into data files recorded at other sampling rates are calculated using the annotation time stamp, the sample rate, and the start time of the recorded data file.

RESULTS

We have successfully recorded physiologic signals with synchronous clinical annotations from 44 subjects under three different research protocols using the PDAS.

Figure 1 is a screen shot of the PDAS main data acquisition screen with the acquired physiologic signal waveforms and parametric values displayed in real time. Figure 2 is an example of a clinical annotation screen designed specifically for the pulse pressure variation study protocol. Figure 3 is an example of the clinical annotation entry page that is used for the pediatric TBI study protocol. Figure 4 shows PDAS fields for free-form text

Table 1. Subject demographics, diagnoses, and waveforms recorded using the physiologic data acquisition system

Study	No. of Subjects	Mean Age, yrs	Gender, Male/Female	Waveforms
Pulse pressure variation	34	45	22/12	ECG, RESP, ABP, Spo ₂ , CVP
Pediatric TBI	11	8	8/3	ECG, RESP, Pairway, ABP, ICP
Pial synangiosis for moyamoya disease	19	9	11/8	ECG, ABP, ETCO2, Spo ₂ , CBF

TBI, traumatic brain injury; ECG, electrocardiogram; RESP, respiration; ABP, arterial blood pressure; Spo₂, pulse oximetry; CVP, central venous pressure; P_{airway}, airway pressure; ICP, intracranial pressure; CBF, cerebral blood flow; ETCO2, end-tidal carbon dioxide.

Table 2. Three experimental clinical protocols using the physiologic data acquisition system

Protocol Title	Background	Main Objective
PPV responsiveness in adult patients with shock	The effects of positive pressure mechanical ventilation on cardiac filling (preload) can be used to determine fluid responsiveness (27). If the patient has low venous return and is thus preload dependent, cardiac output and thus arterial pulse pressure will significantly user with recruiting (i.e., PPV)	1. To record cardiorespiratory signals with clinical annotations to determine PPV as a predictor of intravenous fluid responsiveness.
Physiologic challenge in	Therapy for TBL is largely unsupported by clinical evidence. This	2. To determine if the pulse oximetry signal can be substituted for arterial pressure in calculation of PPV.
pediatric TBI	study uses a randomized protocol that records physiologic signals and clinical events during changes in three standard	and characterize the dynamic physiologic responses.
Physiologic challenge in pediatric TBI Characterization of regional cerebral blood flow in patients with moyamoya disease undergoing pial synangiosis	 Elevating the head of bed between 0° and 40° in 10° random increments Inducing mild hypo- and hyperventilation (decreasing or increasing the end-tidal CO₂ by 4 mm Hg from baseline) Changing the resistance to cerebral spinal fluid drainage (altering the height of the drainage bag between -8 and +8 cm in 4-cm increments from baseline) 	2. To develop an <i>in silico</i> computer model that allows for virtual testing of therapeutic options for elevated ICP before actual treatment is administered.
Characterization of regional cerebral blood flow in patients with moyamoya disease undergoing pial synangiosis	Moyamoya disease is characterized by progressive stenosis of the intracranial internal carotid arteries and compensatory proliferation of dilated collateral arteries at the base of the brain. Pial synangiosis is a surgical procedure that augments surface collateral blood flow to the brain by using the external exact discussion (28, 20) and suturing the superficiel	 To detect episodes of regional cerebral oligemia and ischemia in the postoperative period from various physiologic signals and clinical annotations.
	temporal artery to the pial surface. As a consequence of compromised rCBF, measured by the Bowman Perfusion Monitor (Hemedex, Cambridge, MA), and abnormal cerebral autoregulation, patients are at risk for stroke in the perioperative period (30–32).	2. To test the ability of two noninvasive modalities (near-infrared spectroscopy and electroencephalogram) to detect cerebral ischemia, and to correlate rCBF with mean arterial pressure and end- tidal carbon dioxide values.

PPV, pulse pressure variation; TBI, traumatic brain injury; ICP, intracranial pressure; rCBF, regional cerebral blood flow.

annotations displayed in a spreadsheet format.

Bench and field testing of the PDAS demonstrated excellent reliability. If a data transmission error is detected by the PDAS software, a warning is displayed for the operator and the event is timestamped, tagged with a subject, and then logged along with the clinical annotations. During analysis, error-free data collection can then be confirmed with either a visual inspection of the log file or a simple automated search for the subject tag. Validation of PDAS error detection was performed by replacing live input with specially crafted data packets containing errors. V1.2 of the software has performed >100 recording sessions of between 2 to 24 hrs each without any data transmission errors entered into the event log.

DISCUSSION

The PDAS is a sophisticated, userfriendly, physiologic data acquisition system specifically developed for clinical research in the ICU environment. Data

acquisition systems intended for research purposes must meet several important specifications. The system must be able to interface with many commercial physiologic monitoring devices from different manufacturers and be capable of continuously acquiring and storing every type of physiologic signal with 100% accuracy. The system also needs to include a mechanism for researchers to make timestamped clinical annotations that are precisely synchronized with the collected signals. Protocol-specific pull-down menus for rapid clinical data entry are also needed. And finally, the system must be reliable, versatile, easy to use, costeffective, and compliant with the Health Insurance Portability and Accountability Act (8-10).

We have shown that the PDAS meets the preceding requirements. It is userfriendly, portable, accurate, and adaptable to multiple ICU clinical trial designs. Operators, including bedside ICU nursing staff without prior research or specific computer expertise, have used the system and were easily able to acquire up to four continuous physiologic signals (125–500 Hz) simultaneously with parametric data while detailing important clinical events through the time-stamped PDAS annotation software. With the addition of a second dual high-speed serial I/O PCMCIA card, eight physiologic signals and associated parametric data are possible.

The accuracy of the transmitted data to the PDAS is equal to the accuracy of the patient monitor itself. In other words, the transcription and recording error is zero so the only source of error in *post* hoc physiologic analysis would come from nonstationary sources related to the patient or the external ICU environment (e.g., movement artifact, 60-Hz interference). Because the patient monitor digitizes data as they come in from the various data collection modules and transmits the data in a very precise format with extensive header and trailer information, any corruption of data or loss of signal is immediately recognized and reported by the PDAS software.

To date, no errors have been detected. Although it is theoretically possible that a



Figure 1. The physiologic data acquisition system main data acquisition screen with acquired physiologic signals displayed on the screen in real time.

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Figure 2. An example of a clinical data entry annotation screen designed for use in a specific study protocol evaluating pulse pressure variation and fluid responsiveness. This clinical data entry screen is customized for the particular study that is easily accessible from spreadsheet software and engineering analysis tools.

random bit corruption could occur during electronic data transmission such that the format of received data still conforms to the expected format, the probability of this is extremely low. In addition, the Intellivue patient monitors from Philips use an improved data format that includes a 16-bit cyclic redundancy check over the transmitted packets.

There are few commercial off-the-shelf products that support physiologic data acquisition in intensive care settings that are



Figure 3. An example of a clinical data entry annotation screen designed for use in a pediatric traumatic brain injury (*TBI*) study protocol. Data entry is completed as each screen variable undergoes a change, noting the time of the change and the particular details of each variable and its value.

suitable for clinical studies. This is due in part to the lack of accepted communications protocols or standards, although this has improved since the introduction of the medical information bus (11-13). Many medical devices used for monitoring patients, administering therapy, or both do not permit access to real-time data through external ports, such as the RS232 interface. Those that do often use proprietary serial interface protocols that make it difficult or impossible to develop a portable data acquisition system that can be used with a wide variety of devices. Therefore, products such as BioBench (http://sine.ni.com/nips/cds/ view/p/lang/en/nid/10435, National Instruments, Austin, TX) are largely unsuitable for this type of research.

Relatively few systems have been reported that record physiologic signals for research purposes (6, 7, 14-19). Most researchers have used portable monitoring equipment connected via an analog-todigital board in a personal computer (20). Kropyvnytskyy et al. (7) developed and used a system for continuous recording and processing of physiologic data from brain-injured patients in a neurosurgical ICU. This system was based on the WFDB software package developed for the MIT-BIH arrhythmia database (1) and collected ECG data, arterial blood pressure, intracranial pressure, and calculated cerebral perfusion pressure. All data were sampled at 500 Hz and stored in 10-min ASCII files (~ 2 MB each). Tsui et al. (19) used a system for acquiring, modeling,

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Figure 4. Example of a tabular annotation file of free-form text entries (Microsoft Excel, Microsoft, Redmond, WA).

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Copyright © Society of Critical Care Medicine and World Federation of Pediatric Intensive and Critical Care Societies. Unauthorized reproduction of this article is prohibited. and predicting intracranial pressure in the ICU. The IBIS data library (15) contains continuous electroencephalography signals, multimodal evoked potential recordings, and diagnostic ECG recorded in the ICU and operating room. The data acquisition system also allows for trend data (i.e., parametric data) from patient monitors, laboratory data, and clinical annotations. Each of these systems was more limited than the PDAS in terms of either number of waveforms recorded, length of the recording, number and type of compatible monitoring devices, proscribed clinical research data entry screens, and/or ability for time-stamped clinical and study annotations.

Recent advances in medical informatics and data information protocols have led to electronic medical records and real-time decision support systems that permit access to virtually all of the disparate patient data (21, 22). These systems often are capable of automatic reports and analysis to help clinicians integrate all of the available information (23). These systems are able to collect data from a wide variety of intensive care devices but typically do so automatically for analysis that is not at the bedside. These are insufficient for many clinical studies because they do not permit event annotation through an interface that is suitable for clinical research. There appears to be insufficient market demand to develop this type of system commercially.

Limitations. Signal artifact remains a substantial but not insurmountable problem for any data acquisition system. We previously presented a discussion of the types and character of signal artifact in the ICU setting (6). Although there is no perfect technique for isolating artifact, clinical annotations by an observer stationed in the patient's room, as incorporated with the PDAS, is probably the most accurate. The IMPROVE database used a similar technique with detailed timed annotations regarding patient state, nursing actions, and other patient disturbances by a team of physicians who remained at the bedside throughout the \sim 24-hr recording (15, 24). Annotation of the recording during data collection provided for comparison of any changes in the recorded waveforms or measurements against physician observations. The PDAS works in essentially the same manner. Although PDAS was developed to record data from Philips monitors and stand-alone devices via a PCMCIA serial adapter card, it could be easily be adapted to interface with ICU monitors from other manufacturers, such as SpaceLabs (OSI Systems, Hawthorne, CA) and WelchAllynProtocol (Beaverton, OR).

CONCLUSION

The PDAS may significantly contribute to critical care research in three ways. First, the PDAS may provide a tool to improve our understanding of the pathophysiology of critical illness by closely examining physiologic changes in relation to clinical events on a second-tosecond time frame, including detailed pharmacodynamic studies heretofore not practical. Second, patterns of physiologic variability or organ system interactions may be identified that may yield physiologic markers of impending clinical deterioration (25). And third, the PDAS may aid the development of patient-specific mathematical models representing critical illness that can be shared across different computer formats or via a database such as Physionet (www.physionet.org) (2, 3). In fact, physiologic data from the current pediatric traumatic brain injury project have led to development of a novel dynamic model of intracranial pressure (26).

The PDAS offers a gateway to synthesis of clinical research and the complexities of ICU patient care. There are significant opportunities to perform detailed pharmacodynamic studies not possible with earlier technology and to delineate on a secondto-second basis the natural course and complications from critical illness and injury. Measuring the signals that patients emit continuously and translating them to meaningful physiologic information give us a powerful tool to understand, predict, and eventually influence the course of critical illness (27–32).

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